

Electronic Supplementary Material

Contents

ESM 1. Assessment tools for diabetes distress	2
ESM 2. Plain Language Summary: 2026 EASD guideline on assessing and managing diabetes distress	10
ESM 3. Methods used to develop the guideline	13
ESM 4. Evidence Synthesis Technical Report	28
ESM 5. Concept evidence to Good Practice Statements for the assessment clinical questions	136
ESM 6. GRADE Evidence Profiles for the management clinical questions	147
ESM 7. GRADE evidence-to-decision (EtD) frameworks for the management clinical questions	162
ESM 8. Guideline Development Panel members	382

Electronic Supplementary Material 1: Assessment tools for diabetes distress

The following list is not exhaustive; other measures have been established and validated in specific populations or settings [1]. However, those summarised here are the most frequently used in research and clinical practice and their selection was reinforced by the scoping reviews completed by the Guideline Development Panel when determining the clinical questions for the guideline. The measures represent the evolution of assessment from its historical foundations through to contemporary measures. They are summarised here to provide options for practical, valid and reliable assessment:

- The **Problem Areas in Diabetes (PAID or PAID-20) scale** includes 20 items assessing negative emotions related to diabetes, difficulties with the treatment regimen, social challenges, concerns about complications, and problems in interactions with healthcare professionals. Items are rated from 0 (no problem) to 4 (serious problem), summed, and converted to a 0–100 scale. Scores of 40 or higher have been interpreted widely as indicating high diabetes distress, though additional evidence-based classifications have been published [2, 3]. The PAID scale was designed as a unidimensional scale, and later attempts to establish subscale structures have not resulted in a validated or widely accepted solution. Consequently, the recommended scoring for the PAID is as a total score only [4]. In addition to using the PAID total score, healthcare professionals are encouraged to review individual item responses to identify specific problem areas that may guide conversations or interventions.
- The **PAID-11** is a shorter version of the PAID, including 11 items (#3, 6, 7, 8, 9, 11, 12, 13, 16, 19, 20 of the original PAID-20), and is validated specifically for adults with type 1 diabetes. The PAID-11 demonstrates strong internal consistency reliability (Cronbach's $\alpha=0.93$) and concurrent validity (95% sensitivity and 96% specificity) for detecting severe diabetes distress [5]. Like the PAID-20, the PAID-11 is scored as a unidimensional measure with a single total score. As a relatively recent development, the responsiveness of the PAID-11 has yet to be determined.
- The **PAID-5** is a brief version including 5 items (#3, 6, 12, 16, 19 of the PAID-20). The PAID-5 demonstrates strong psychometric properties, including high correlation with the full PAID-20 ($r>0.90$), strong internal consistency reliability (Cronbach's $\alpha>0.85$), and concurrent validity for detecting diabetes distress (94% sensitivity and 89% specificity) [6, 7]. However, as a relatively brief tool, it cannot guide targeted support or intervention.
- The **PAID-1** is a single-item tool, based on item #12 of the PAID-20: "Worrying about the future and the possibility of serious complications". It has concurrent validity for detecting diabetes distress (sensitivity and specificity around 80%) [7]. While brief and seemingly pragmatic, the PAID-1 provides only a reductionist screening approach and does not capture the complexity of the nature of diabetes distress [1, 8]. Further, it has been criticised for the high risk of false positives for diabetes distress, as many people worry about the future and the possibility of serious complications without necessarily experiencing elevated diabetes distress [9].

- The **Diabetes Distress Scale (DDS or DDS-17)** includes 17 items, combined to form a composite scale score: the mean of all item scores (rated from 1 to 6). The DDS was validated for adults with type 1 diabetes and type 2 diabetes but is referred to most recently as the DDS-T2 or T2-DDS, suggesting it is now recommended only for adults with type 2 diabetes. It provides four subscale scores, which are calculated using the same scoring method [10, 11]. These subscales demonstrate consistent internal reliability and validity across multiple clinical settings and can help identify specific sources of diabetes distress to guide targeted support and intervention.
- The **DDS-2** is a 2-item screening version of the DDS, comprising items 6 and 14 of the DDS [12]. While brief and seemingly pragmatic, the DDS-2 provides only a reductionist screening approach and does not capture the complex nature of diabetes distress.
- The **Diabetes Distress Scale for Type 1 Diabetes (T1-DDS)** includes 28 items combined to form a composite scale score: the mean of all item scores (rated from 1 to 6) [13]. The T1-DDS also provides seven subscale scores, each calculated using the same scoring method [14]. This was the first diabetes distress measure to be developed and validated specifically for the unique experiences of adults living with type 1 diabetes [1, 8].
- The **Type 1 Diabetes Distress Assessment System (T1-DDAS)** is a relatively recent measure, designed and validated specifically to assess diabetes distress among adults with type 1 diabetes [15]. It includes two components (scales), which may be used independently. The Core scale contains eight items that assess the central emotional experience of diabetes distress, rated from 1 to 5, with higher scores indicating greater distress. The Sources scale includes 22 items assessing 10 common sources of diabetes distress. Each of the 10 subscale scores reflects the average of the items within that source and helps identify specific drivers of distress that may warrant clinical attention. Combining these subscales into a single total score is not recommended. Together, the Core scale provides an overall estimate of diabetes distress, while the Sources scale assists in identifying the specific areas of living with type 1 diabetes that contribute most to an individual's distress. As the T1-DDAS is a recent development and offers a flexible structure, it is a contemporary option for assessing diabetes distress among adults with type 1 diabetes.
- The **Type 2 Diabetes Distress Assessment System (T2-DDAS)** is a relatively recent measure, designed and validated specifically to assess diabetes distress among adults with type 2 diabetes [16]. Similar to the T1-DDAS, it includes two scales that can be used independently of each other. The Core scale includes eight items assessing the central emotional experience of diabetes distress, rated from 1 to 5, with higher values indicating greater distress. The Sources scale contains 21 items covering seven common sources of distress, with seven separate subscale scores calculated by averaging the items within each source. Combining the Sources subscales into a single composite score is not recommended. The Core scale provides an overall estimate of diabetes distress, while the Sources scale helps identify specific contributors that may warrant clinical attention [17]. As a recent development, the T2-DDAS offers a flexible

structure, it is a contemporary option for assessing diabetes distress among adults with type 1 diabetes.

The key characteristics of each measure is summarised in Supplementary Table 1. Several published reviews and commentaries provide further insights [1, 18].

Supplementary Table 1: Commonly used validated tools for assessing diabetes distress among adults with type 1 diabetes and type 2 diabetes

Instrument [reference]	T1D or T2D	Number of items and scale structure	Scoring: range* and cut-points	Key strengths	Key limitations	Languages other than English
PAID (aka PAID-20) [2, 3]	Both	20 items summed to form a total scale only	Range: 0–100 ≥40 high; 17–39 moderate; <17 low or no DD	Extensive validation and use in RCTs; well-established cut points; 20 items capture large range of issues known to contribute to DD; responses to individual items may guide targeted clinical support or intervention	Lacks validated subscale structure; older tool, which may not reflect modern challenges; not specific to type 1 diabetes or type 2 diabetes, so may not reflect specific challenges for either condition	Yes: >60 languages ^a
PAID-11 [5]	T1D	11 items summed to form a total scale only	Range: 0–44 ≥18 elevated	High sensitivity/specificity (95–96%); may be an appropriate length for clinical use	Despite being validated specifically for T1D, as it was derived from the PAID-20, it may not reflect challenges specific to T1D; no evidence of use in RCTs (due to recent development)	Yes: derived from PAID ^a
PAID-5 [6, 7]	Both	5 items summed to form a total scale only	Range: 0–20 ≥8 elevated	Brief, strong correlation with full PAID ($r>0.90$); high internal consistency; easy to administer	No subscales; limited T1D-specific validation; limited use in RCTs	Yes: derived from PAID ^a

Instrument [reference]	T1D or T2D	Number of items and scale structure	Scoring: range* and cut-points	Key strengths	Key limitations	Languages other than English
PAID-1 [7]	Both	1 item	Range: 0–4 ≥3 elevated	Ultra-brief, single-item screener	Reductionist; high risk of false positives due to reliance on a single item known to be a concern to many; cannot capture the complexity of DD nor guide targeted clinical support or intervention; no use in RCTs	Yes: derived from PAID ^a
DDS (aka DDS-17) [10, 11]	T2D or Both	17 items: scores can be averaged to form a single composite score and 4 subscales: Emotional burden; Regimen-related distress; Interpersonal distress; Physician-related distress	Range: 1–6 ≥3 high; 2.0–2.9 moderate; <2 little or no DD	17 items capture large range of issues known to contribute to DD; responses to individual items may guide targeted clinical support or intervention; greater use in RCTs than many other DD tools	Limited RCT use compared to PAID-20; not specific to the challenges of T1D	Yes: >40 languages ^b
DDS-2 [12]	Both	2 items can be combined to form a single composite score	Range: 1–6 ≥3 high; 2.0–2.9 moderate; <2 little or no DD	Ultra-brief, two-item screener	Reductionist; cannot capture the complexity of DD nor guide targeted clinical support or intervention; no use in RCTs	No

Instrument [reference]	T1D or T2D	Number of items and scale structure	Scoring: range* and cut-points	Key strengths	Key limitations	Languages other than English
T1-DDS [13]	T1D-specific	28 items: scores can be averaged to form a single composite score and 7 subscales: Powerlessness; Negative social perceptions; Physician-related distress; Friend/family-related distress; Hypoglycaemia - related distress; Management distress; and Eating distress	Range: 1–6 ≥3 high; 2.0–2.9 moderate; <2 little or no DD	First T1D-specific measure of DD; 28 items capture large range of issues known to contribute to DD among adults with T1D (e.g. hypoglycaemia); responses to individual items may guide targeted clinical support or intervention	Longer to administer / complete than some other DD tools; limited contemporary validation	Yes: Dutch, French (Canada & France), German, Lithuanian, Portuguese, Russian, Spanish ^b
T1-DDAS Core + Sources [15]	T1D-specific	8 items form the Core distress scale; and 22 additional items (forming 10 scales) assessing 10 common sources of DD	Range: 1–5 No cut points established	Contemporary measure; designed specifically for adults with T1D to capture their concerns; flexible administration; actionable sources of DD	Brevity of Source subscales may limit identification of relevant sources of DD; due to recent development, limited evidence of concurrent validity, and no evidence of use in RCTs (though included in planned/ongoing trials)	Yes: French (Canada), Spanish ^b

Instrument [reference]	T1D or T2D	Number of items and scale structure	Scoring: range* and cut-points	Key strengths	Key limitations	Languages other than English
T2-DDAS Core + Sources [16]	T2D	8 items form the Core distress scale; and 21 additional items (forming 7 scales) assessing 7 common sources of DD	Range: 1–5 ≥3 high; 2.0–2.9 moderate; <2 little or no DD	Contemporary measure; designed specifically for adults with T2D to capture their concerns; flexible administration; actionable sources of DD	Brevity of Source subscales may limit identification of relevant sources of DD; due to recent development, limited evidence of concurrent validity, and no evidence of use in RCTs (though included in planned/ongoing trials)	Yes: French (Canada), Spanish, Welsh ^b

*Higher scores indicate greater diabetes distress

aka: also known as; DD: Diabetes distress; DDAS: Diabetes Distress Assessment Scale; DDS: Diabetes Distress Scale; PAID: Problem Areas In Diabetes; RCTs: randomised controlled trials; T1D: type 1 diabetes; T2D: type 2 diabetes

a. All information correct as of December 2025. For updates, see: <https://eprovide.mapi-trust.org/instruments/problem-areas-in-diabetes-scale>

All information correct as of December 2025. For updates, see: <https://behavioraldiabetes.org/scales-and-measures/>

Electronic Supplementary Material 1 References

1. Dennick, K., J. Sturt, and J. Speight, *What is diabetes distress and how can we measure it? A narrative review and conceptual model*. J Diabetes Complications, 2017. **31**(5): p. 898–911.
2. Polonsky, W.H., et al., *Assessment of diabetes-related distress*. Diabetes Care, 1995. **18**(6): p. 754–60.
3. Welch, G.W., A.M. Jacobson, and W.H. Polonsky, *The Problem Areas in Diabetes Scale. An evaluation of its clinical utility*. Diabetes Care, 1997. **20**(5): p. 760–6.
4. Fenwick, E.K., et al., *What is the best measure for assessing diabetes distress? A comparison of the Problem Areas in Diabetes and Diabetes Distress Scale: results from Diabetes MILES-Australia*. J Health Psychol, 2018. **23**(5): p. 667–680.
5. Stanulewicz, N., et al., *PAID-11: A brief measure of diabetes distress validated in adults with type 1 diabetes*. Diabetes Res Clin Pract, 2019. **149**: p. 27–38.
6. Vislapuu, M., et al., *Psychometric properties of the Norwegian version of the short form of The Problem Areas in Diabetes scale (PAID-5): a validation study*. BMJ Open, 2019. **9**(2): p. e022903.
7. McGuire, B.E., et al., *Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1*. Diabetologia, 2010. **53**(1): p. 66–9.
8. Fisher, L., et al., *Bringing the assessment and treatment of diabetes distress into the real world of clinical care: Time for a shift in perspective*. Diabet Med, 2024. **41**(12): p. e15446.
9. de Wit, M., F. Pouwer, and F.J. Snoek, *How to identify clinically significant diabetes distress using the Problem Areas in Diabetes (PAID) scale in adults with diabetes treated in primary or secondary care? Evidence for new cut points based on latent class analyses*. BMJ Open, 2022. **12**(3): p. e056304.
10. Fisher, L., W.H. Polonsky, and D. Hessler, *Addressing diabetes distress in clinical care: a practical guide*. Diabet Med, 2019. **36**(7): p. 803–812.
11. Fisher, L., et al., *When is diabetes distress clinically meaningful?: establishing cut points for the Diabetes Distress Scale*. Diabetes Care, 2012. **35**(2): p. 259–64.
12. Fisher, L., et al., *A longitudinal study of affective and anxiety disorders, depressive affect and diabetes distress in adults with Type 2 diabetes*. Diabet Med, 2008. **25**(9): p. 1096–101.
13. Fisher, L., et al., *Understanding the sources of diabetes distress in adults with type 1 diabetes*. J Diabetes Complications, 2015. **29**(4): p. 572–7.
14. Fisher, L., R.E. Glasgow, and L.A. Strycker, *The relationship between diabetes distress and clinical depression with glycemic control among patients with type 2 diabetes*. Diabetes Care, 2010. **33**(5): p. 1034–6.
15. Fisher, L., et al., *A novel approach to understanding and assessing the emotional side of type 1 diabetes: The Type 1-Diabetes Distress Assessment System*. Diabet Med, 2024. **41**(7): p. e15282.
16. Polonsky, W.H., et al., *Toward a more comprehensive understanding of the emotional side of type 2 diabetes: A re-envisioning of the assessment of diabetes distress*. J Diabetes Complications, 2022. **36**(1): p. 108103.
17. Fisher, L., et al., *A new perspective on diabetes distress using the type 2 diabetes distress assessment system (T2-DDAS): Prevalence and change over time*. J Diabetes Complications, 2022. **36**(8): p. 108256.
18. Schmitt, A., et al., *How to assess diabetes distress: comparison of the Problem Areas in Diabetes Scale (PAID) and the Diabetes Distress Scale (DDS)*. Diabet Med, 2016. **33**(6): p. 835–43.

Electronic Supplementary Material 2: Plain Language Summary: 2026 EASD guideline on assessing and managing diabetes distress

Why focus on diabetes distress?

Living with diabetes means thinking every day about glucose levels, insulin, other medicines, food, physical activity and symptoms. For many people, diabetes brings a heavy emotional load. This is called diabetes distress. It includes the worries, frustrations, fears, guilt, tiredness, and overwhelm caused by the constant work of living with diabetes.

Diabetes distress is common. At least one in three adults with diabetes have high levels of diabetes distress. Many more report at least some emotional problems related to their diabetes.

Diabetes distress is not the same as depression or anxiety. It is not a mental illness. It is a natural response to living with a long-term condition. But if diabetes distress is intense or lasts a long time, it can harm emotional health. It can make self-care harder. It affects both physical health and quality of life.

Even though it matters, diabetes distress is often missed in routine care. Clinic visits usually focus on glucose levels and screening results. There is often little space for people to talk about how they are coping. Healthcare professionals say they are unsure about how to ask about diabetes distress and what to do when they see it.

This guideline was created to address these gaps and to support care that focuses on the whole person, not just numbers.

What is the aim of this Guideline?

This guideline is designed to help healthcare professionals support adults with type 1 diabetes or type 2 diabetes. The aim is to help healthcare professionals know how to assess and manage diabetes distress. This will make talking about the emotional side of diabetes a normal and expected part of routine care. It will also improve both the emotional and the physical health of adults living with diabetes.

What is it based on?

The guideline is based on evidence. It was written by a team of experts, including people living with diabetes, medical doctors, nurses, psychologists, and researchers. People with diabetes shared their lived experiences to make sure that the guideline meets real-world needs and priorities. The guideline is based on reviews of scientific studies about how to check for diabetes distress and about what helps to reduce it.

Key Messages:

Checking for Diabetes Distress

Talking about emotions should be routine in diabetes care. Healthcare professionals need to:

- **talk about the emotional side of diabetes at every clinic visit**, not only when problems are obvious.
- **ask open, supportive questions** about what it is like to live with diabetes and what feels most challenging.
- **use valid tools** to check for diabetes distress. These help to spot distress and track changes over time.
- **check in regularly about diabetes distress**. For example, during annual reviews or when changes in health, treatment or life circumstances may affect distress.
- **discuss the findings**, whether diabetes distress appears low, moderate, or high.
- **make decisions together**. This means the healthcare professional and the person living with diabetes agree on next steps, based on the person's preferences and needs.

Not everyone with diabetes distress needs to see a mental health specialist. All healthcare professionals should have the basic skills to listen with empathy, offer emotional support, and help people to solve day-to-day diabetes problems. They should also know when and how to involve specialist care if distress is severe, ongoing or complex.

Managing Diabetes Distress

For adults with type 1 diabetes or type 2 diabetes, talking with a trained psychologist or counsellor can help.

For adults with type 1 diabetes, some technologies also help. These include continuous glucose monitors and automated insulin delivery (AID) systems.

For adults with type 2 diabetes, diabetes education can help. Diabetes education that includes emotional and coping support can also reduce diabetes distress.

Peer support (i.e. connecting with other people who have diabetes) does not generally reduce diabetes distress on its own, though it can have other benefits.

Across both types of diabetes, there is no single approach that works for everyone. Not all types of support are equally effective. The evidence is stronger for some approaches than others. This means we need more high-quality research. Support should be matched to each person's needs, including their main sources of distress, their situation and culture, and the healthcare resources available.

Why This Guideline Matters

This is the first guideline to focus only on diabetes distress. It sends a clear message: emotional wellbeing is central to good diabetes care. It is not an extra add-on.

This guideline aims to make talking about the emotional side of diabetes a routine part of every diabetes clinic visit. It aims to reduce stigma and improve support for people living with diabetes, by helping their healthcare professionals to listen, understand, and respond to their needs.

In the end, assessing and managing diabetes distress is about recognising that emotional health is just as important as physical health.

Electronic Supplementary Material 3: Methods used to develop the guideline

The development of this guideline adhered to the standards established by the National Academy of Medicine (NAM) [1] and the Guidelines International Network (GIN) [2], ensuring transparency, methodological rigour, and stakeholder inclusivity. The process followed the EASD standard operating procedure for clinical practice guidelines [3]. Key components included the structured selection and roles of the Guideline Development Panel (GDP) members comprising multidisciplinary experts and individuals with lived experience of diabetes, the transparent management of conflicts of interest, adherence to the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) methodology for guideline development [4, 5], and a transparent development and review process. The details underpinning each of these processes have been previously published [3].

Guideline Development Panel

The GDP comprised ten members: two co-chairs (JSp, RH), two members with lived experience of diabetes (WJ, ML), four clinical experts (NH, KK, AM, JSt), and two methodologists (TK, FZ). The GDP included members of both sexes and as multinational (Australia, Denmark, Germany, Greece, Italy, the Netherlands, Romania, Slovenia, and the UK). Clinical members represented a range of professional backgrounds, including medicine, nursing, clinical psychology, statistics, and methodology. The two individuals with lived experience acted as representatives, using their judgment on behalf of a group, rather than as delegates following explicit instructions. The GDP acknowledges a lack of ethnic and racial diversity.

The EASD Guidelines Oversight Committee (GOC) oversaw the appointment and operation of the GDP, as they do for all EASD guidelines [3]. For the present guideline, which is the first to be commissioned under the new EASD guideline development process [3], the GOC appointed the two GDP co-chairs and selected two in-house EASD GOC methodologists. The GDP co-chairs then proposed additional GDP members, who were subsequently approved by the GOC.

The two GDP co-chairs played a central leadership role in coordinating the work of the GDP, facilitating discussions during meetings, ensuring adherence to timelines, and guiding the GDP in reaching consensus at key decisions. The two GDP methodologists provided essential support throughout the process, by ensuring consistent application of the GRADE methodology and EASD standard operating procedure [3]. They guided the GDP in formulating the clinical questions in structured PICOT formats, drafted the GRADE evidence profiles [6] and Evidence-to-Decision (EtD) frameworks [7] for the clinical questions on the management of diabetes distress, and ensured alignment between the evidence and the final recommendations.

The inclusion of two GDP members with lived experience of diabetes was integral to the development of the guideline, ensuring that lived experience was considered in every aspect of the process. They informed the GDP about how diabetes distress can affect daily life, ensuring that the guideline's clinical questions addressed issues that matter to people living with diabetes. They actively participated in all GDP discussions and

contributed to the GDP's interpretation of the evidence, particularly in relation to the diversity of values and preferences of people living with diabetes and the acceptability and feasibility of assessing and managing diabetes distress in clinical practice.

All GDP members held equal voting rights and actively contributed to all stages of the guideline development process, including the formulation and refinement of the clinical questions, review and interpretation of the evidence, and drafting and finalisation of the clinical practice recommendations.

All GDP members completed the INGUIDE Level 1 training, which provides a foundational understanding of evidence-based guideline development and GRADE methodology [8]. In addition, the two GDP methodologists (TK, FZ) completed the INGUIDE Level 2 training, which is required for methodological leads and provides advanced instruction on applying the GRADE approach in guideline development [8].

Administrative support

The EASD Office team provided crucial support throughout the development of this guideline. Although not formal members of the Guideline Oversight Committee, the GDP, or the EST, the EASD Office team ensured the smooth operation of the process by coordinating meetings, distributing materials, facilitating communication between parties involved, and record-keeping. Their efficiency and responsiveness contributed greatly to the effective collaboration across all parties involved.

Management of conflicts of interest

The management of conflicts of interest followed the EASD standard operating procedure [3], in alignment with the Reporting Items for practice Guidelines in Healthcare (RIGHT) statement [9]. Conflicts of interest disclosures from all GDP members were collected and categorised as either 'significant' or 'non-significant', based on their financial magnitude and relevance to the guideline topic [3]. The disclosures of GDP co-chairs and GDP methodologists were reviewed by the GOC, while those of the remaining GDP members were reviewed jointly by the GDP co-chairs and GOC. All GDP members were required to update their disclosures annually or if new relevant interests emerged. Disclosures are provided at the end of this document, covering the duration of the guideline development and the year preceding its commencement.

Formulation of clinical questions

The development of the guideline began with initial scoping of GDP members' expertise and knowledge of the field. The methodologists conducted PubMed literature searches for previously published systematic reviews of diabetes distress. Through this process, and further scoping of published evidence, the introduction section was developed and evidence gaps explored. This led to the identification, and prioritisation, of potentially important clinical questions [3]. The methodologists prepared and circulated a template to all GDP members, inviting additions and revisions of the potential clinical questions, using a format adapted from GRADE guidance [10]. The responses were collected, grouped, and used to guide GDP discussions focused on reviewing, selecting and refining the most clinically relevant questions. The findings were summarised in tabular form and shared with the GDP to inform decisions. The final clinical questions

were selected based on their relevance to clinical practice, and aligned to the priorities of people living with diabetes, and feasibility of addressing them within the available timeframe and resources. These steps led to agreement within the GDP to organise the questions into two broad domains: assessment and management of diabetes distress.

The final set of clinical questions included two broad questions related to the assessment of diabetes distress, one for adults with type 1 diabetes and one for adults with type 2 diabetes, and six overarching questions related to its management (Supplementary Box 1). For the management questions, the GDP applied the PICOT (Participants, Intervention, Comparator, Outcomes, and Type of studies) framework [10]. The management questions were developed separately for adults with type 1 diabetes and type 2 diabetes and were further distinguished by the type of comparison. The aetiology, management, treatment and experiences of those living with diabetes and associated distress can differ by diabetes type and may, therefore, require different types of support [11].

Supplementary Box 1: Clinical questions for the assessment and management of diabetes distress

Assessment of diabetes distress

Should healthcare professionals discuss the emotional side of diabetes during routine consultations?

How should healthcare professionals ask about diabetes distress in routine consultations?

How should healthcare professionals assess for the presence of diabetes distress?

How often should healthcare professionals assess for diabetes distress?

When diabetes distress is assessed, how should healthcare professionals respond?

How should healthcare professionals communicate the findings of the assessment?

When diabetes distress is identified, how should healthcare professionals respond?

When diabetes distress is identified, should healthcare professionals deliver psychological support or refer to a mental health professional?

Management of diabetes distress in adults with type 1 diabetes

Should psychological interventions be used, rather than usual care, to reduce diabetes distress among adults living with type 1 diabetes?

Should psychoeducational interventions be used, rather than usual care, to reduce diabetes distress among adults living with type 1 diabetes?

Should educational interventions be used, rather than usual care, to reduce diabetes distress among adults living with type 1 diabetes?

Should peer support interventions be used, rather than usual care, to reduce diabetes distress among adults living with type 1 diabetes?

Should psychological interventions be used, rather than psychoeducational interventions, to reduce diabetes distress among adults living with type 1 diabetes?

Should psychological interventions be used, rather than educational interventions, to reduce diabetes distress among adults with type 1 diabetes?

Should psychoeducational interventions be used, rather than educational interventions, to reduce diabetes distress among adults with type 1 diabetes?

Should continuous glucose monitoring (CGM) be used, rather than capillary glucose monitoring (finger prick), to reduce diabetes distress among adults with type 1 diabetes?

Should automated insulin delivery (AID) systems be used, rather than no use of AID, to reduce diabetes distress among adults with type 1 diabetes?

Management of diabetes distress in adults with type 2 diabetes

Should psychological interventions be used, rather than usual care, to reduce diabetes distress among adults with type 2 diabetes?

Should psychoeducational interventions be used, rather than usual care, to reduce diabetes distress among adults with type 2 diabetes?

Should educational interventions be used, rather than usual care, to reduce diabetes distress among adults with type 2 diabetes?

Should peer support interventions be used, rather than usual care, to reduce diabetes distress among adults with type 2 diabetes?

Should psychological interventions be used, rather than psychoeducational interventions, to reduce diabetes distress among adults with type 2 diabetes?

Should psychological interventions be used, rather than educational interventions, to reduce diabetes distress among adults with type 2 diabetes?

Should psychoeducational interventions be used, rather than educational interventions, to reduce diabetes distress among adults with type 2 diabetes?

Should educational interventions be used, rather than peer support interventions, to reduce diabetes distress among adults with type 2 diabetes?

Should continuous glucose monitoring (CGM) be used, rather than capillary glucose monitoring (finger prick), to reduce diabetes distress among adults with type 2 diabetes?

Eligible interventions were classified into three broad categories: (1) psychological interventions, based on psychotherapeutic approaches such as cognitive behavioural therapy, (2) psychoeducational interventions, which combined psychological components with educational content, and (3) miscellaneous interventions, encompassing approaches that did not fall into the previous categories, including education-only interventions, peer support interventions without a psychological component, or device-based interventions (e.g., continuous glucose monitoring systems) (Supplementary Box 2). Comparators included either no active intervention (e.g., usual care alone) or an active intervention from a different category. The GDP also reviewed available validated scales for assessing diabetes distress, and also a minimal clinically important difference (MCID) for the outcome of diabetes distress was defined to support interpretation of the magnitude and clinical relevance of intervention effects. The only study design considered eligible for addressing the management questions was RCTs.

Supplementary Box 2: Definitions of interventions included in the guideline

Psychological interventions in diabetes: interventions that are collaborative psychological treatments grounded in psychotherapeutic research and approaches, including:

- Cognitive-behavioural therapy (CBT)
- Acceptance and commitment therapy (ACT)
- Motivational interviewing (MI)
- Mindfulness
- Problem-solving strategies and more.

In these interventions, the individual actively engages with the therapist to reduce the emotional burden of diabetes and to have better management of the illness. The most researched and effective psychotherapies in diabetes are those grounded in CBT.

Educational interventions in diabetes: interventions that imply a more passive role of the recipient and primarily comprise didactic education in diabetes (e.g. lectures, classes on understanding diabetes distress, its consequences, and treatment options such as classes on nutrition, diabetes treatment plan, how to use diabetes devices) [12].

Psychoeducational interventions in diabetes: interventions that combine psychological intervention components with educational content (e.g. understanding what diabetes distress is combined with CBT strategies or diabetes self-management education underpinned by behavioural/psychological frameworks)

Peer support in diabetes: connections established between people with diabetes to enable them to support each other (one-to-one or group-based) and to build relationships of self-understanding, non-judgmental acceptance, and empowerment in diabetes self-management and coping with emotional burden.

For the assessment questions, the GDP opted to issue Good Practice Statements, as described in the next sections of the present document, due to the lack of RCTs to inform the clinical questions. For the management questions, the GDP commissioned a *de novo* systematic review, which was conducted by an independent Evidence Synthesis Team (EST). The EST collaborated closely with the GDP to finalise the review protocol and to operationalise the PICOT elements for each question. Further details on the characteristics of the questions and the methodology of the evidence synthesis are available in Supplementary Material A: Evidence Synthesis Technical Report.

Categories of clinical practice recommendations

EASD clinical practice guidelines include three categories of recommendations: GRADE recommendations, Good Practice Statements, and Recommendations based on

Ungraded Evidence (Supplementary Table 2). These categories reflect the methodological principles described in the EASD standard operating procedure for guideline development [3].

Supplementary Table 2: Categories of EASD clinical practice recommendations

Category	Description
GRADE Recommendation	Evidence-based recommendation based on GRADE certainty of evidence assessment and GRADE EtD framework, following a commissioned systematic review and meta-analysis results.
Good Practice Statement	Issued when necessary for safe and effective care, when the expected benefit is substantial and clear. Not based on a commissioned systematic review and meta-analysis, but supported by summaries of existing evidence.
Recommendation based on Ungraded evidence	Developed when insufficient evidence is found to permit a meta-analysis and GRADE certainty assessment. Based on other GRADE EtD parameters and the judgement of the GDP.

EtD: Evidence-to-Decision; GDP: Guideline Development Panel; GRADE: Grading of Recommendations, Assessment, Development and Evaluation

GRADE Recommendations

GRADE recommendations are developed based on a structured assessment of the evidence, starting with the structured formulation of clinical questions (i.e., in PICOT format for management questions), and followed by a formal systematic review and meta-analyses by an EST and commissioned by the EASD. For each clinical question, the certainty of evidence is assessed (Supplementary Table 3), and GRADE evidence profiles are developed based on the following domains: risk of bias, inconsistency, indirectness, imprecision, and additional domains (e.g., publication bias) [13].

Supplementary Table 3: Levels of certainty of evidence according to GRADE methodology

Certainty	Explanation
High ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate ⊕⊕⊕○	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low ⊕⊕○○	We have limited confidence in the effect estimate: the true effect may be substantially different from the estimate of the effect
Very low ⊕○○○	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

GRADE: Grading of Recommendations, Assessment, Development and Evaluation

In addition to the GRADE evidence profiles, additional considerations are incorporated in the development of a recommendation using the GRADE EtD framework [14]. These include parameters such as balance between desirable and undesirable effects, values

and preferences, resource use and cost-effectiveness, equity, acceptability, and feasibility [7]. GRADE recommendations are labelled according to both strength of evidence and direction (e.g., in favour of or against an intervention) [15] (Supplementary Table 4).

Supplementary Table 4: Strength and direction of recommendations based on the GRADE ‘Evidence to Decision’ framework

Strength and direction	Explanation ^a
Strong in favour of the intervention	Desirable effects of the intervention clearly outweigh undesirable effects
Conditional (weak) in favour of the intervention	Desirable effects of the intervention probably outweigh undesirable effects but uncertainty exists (e.g. because of low certainty of evidence or because desirable and undesirable effects are closely balanced)
Conditional (weak) for either the intervention or the comparator	The balance of desirable and undesirable effects does not clearly favour either the intervention or the comparator.
Strong against the intervention	Undesirable effects of the intervention clearly outweigh desirable effects
Conditional (weak) against the intervention	Undesirable effects of the intervention probably outweigh desirable effects but uncertainty exists (e.g. because of low certainty of evidence or because desirable and undesirable effects are closely balanced)

^a Desirable and undesirable effects include both the evidence on clinical outcomes (GRADE evidence profiles) and consideration of additional GRADE EtD parameters. GRADE: Grading of Recommendations, Assessment, Development and Evaluation; EtD: Evidence-to-Decision; GRADE: Grading of Recommendations, Assessment, Development and Evaluation

Good Practice Statements

Good Practice Statements are issued when a recommendation is considered ethically imperative, clearly beneficial, and unlikely to change in light of new evidence. A Good Practice Statement is appropriate when the following criteria are met: the action is necessary for safe, effective healthcare; the expected net benefit is substantial and clear; and conducting a formal evidence synthesis would be an inefficient use of the GDP’s resources due to high opportunity cost [3, 16, 17]. Although a formal systematic review was not commissioned by the EASD for these recommendations, they are supported by existing evidence, such as prior systematic reviews or other types of pertinent research. Each Good Practice Statement is labelled as such [3].

Recommendations based on Ungraded Evidence

The GRADE methodology allows for recommendations based on ungraded evidence to be formulated when there is lack of primary studies and so no meta-analysis can be conducted [3]. However, the GDP decided against producing recommendations based on Ungraded Evidence and instead opted to produce research recommendations to address these questions.

Assessment of diabetes distress

The clinical questions on the comprehensive assessment of diabetes distress were addressed using Good Practice Statements in accordance with the EASD guidelines standard operating procedure [3]. Good Practice Statements were considered appropriate because the GDP judged that key aspects of comprehensively assessing diabetes distress could not be primarily informed by RCTs, but rather by a broader body of conceptual, theoretical, observational and experiential evidence. In particular, the GDP recognised a clinical imperative to make recommendations that reflect real-world practice, professional consensus, and the practical needs of people living with diabetes. The aim was to provide clear and actionable guidance on core components of good clinical practice for identifying and comprehensively assessing diabetes distress, without the use of a formal evidence synthesis and meta-analysis commissioned by the EASD, which would have entailed a high opportunity cost.

To inform the Good Practice Statements, the GDP used the findings of two opportunistic *de novo* realist reviews, which were conducted by the D-Stress project, an independent team of researchers within a separate research programme supported by the UK National Institute for Health Research Programme Grants for Applied Research and Diabetes UK (NIHR PGfAR reference number NIHR205441). Recognising the relevance and rigour of the realist reviews, the GDP sought and obtained approval from the D-Stress project to use their findings as the foundation for formulating the Good Practice Statements on the assessment of diabetes distress. The EASD had no role in commissioning or funding these reviews.

To support this process, the lead investigator of D-Stress project (JSt), also a member of the GDP, shared a report with the GDP describing the realist reviews' methodology, key concepts and findings [18, 19]. This report provided both the conceptual framework and evidentiary foundation for the development of the Good Practice Statements. In brief, the realist reviews used a theory-driven approach to synthesise data from diverse sources and settings, with the goal of understanding how, for whom, and in what contexts various approaches to the complex and comprehensive assessment of diabetes distress are effective [18, 19]. Separate realist syntheses were undertaken for type 1 diabetes and type 2 diabetes, and the findings were integrated into a set of coherent theoretical and practical insights relevant to clinical practice. Based on this information, two GDP members (JSt and JSp) prepared an initial draft of clinical questions, Good Practice Statements and rationales. These drafts were reviewed and discussed by the full GDP, and the Good Practice Statements were finalised by expert consensus (Electronic Supplementary Material 4).

Management of diabetes distress

The recommendations on the management of diabetes distress were based on a *de novo* evidence synthesis commissioned by the EASD and were formulated using the GRADE EtD framework.

Evidence synthesis

For the clinical questions on the management of diabetes distress, a systematic review of RCTs was conducted by the EST. The selection of the EST followed the procedures

outlined in the EASD standard operating procedure, including an EASD open call and evaluation of tender applications both by the EASD GOC and external reviewers. In particular, the selection of the EST was based on the team's track record and experience in conducting high-quality systematic reviews and meta-analyses in topics relevant to the guideline, their professionalism, motivation and readiness to undertake the required tasks, and presence of minimal conflicts of interest[3].

The EST developed the protocol in collaboration with the GDP, and applied standardised methods for literature searching, screening, data extraction, risk of bias assessment, and meta-analyses. A detailed presentation of the evidence synthesis methodology including the protocol, data analyses, and findings is available in Supplementary material A: Evidence Synthesis Report. The EST Lead (FR) participated in regular meetings, approximately twice per month, with the GDP to provide updates and ensure alignment between the evidence synthesis and the clinical questions. In parallel, the GDP methodologists maintained close communication with the EST Lead, acting as the main liaison between the EST and the GDP to ensure methodological consistency and clarity throughout the process. All RCTs included in the meta-analyses assessed diabetes distress using either the DDS or the PAID scale, including validated variations of these instruments. To support the interpretation of the magnitude and clinical relevance of intervention effects on diabetes distress, the GDP defined a threshold for MCID on the standardised mean difference (SMD) scale. Because diabetes distress outcomes were synthesised across multiple validated patient-reported outcome measures, and no single anchor-based MCID is applicable across instruments, a pragmatic SMD-based threshold informed by the established interpretation of effect sizes for patient-reported outcomes and by panel consensus was adopted [20, 21]. Specifically, an SMD of 0.3 was considered to represent a minimal clinically important difference. Based on this framework, effects were categorised as large ($SMD \leq -0.5$), moderate ($-0.5 < SMD \leq -0.3$), small ($-0.3 < SMD \leq -0.2$), or trivial/no effect ($SMD > -0.2$). More negative values indicated greater benefit (i.e., reduction in diabetes distress).

GRADE certainty of evidence assessments

For each management clinical question where meta-analysis was feasible, the certainty of evidence was assessed using the GRADE approach [6]. Independent assessments were conducted by the two GDP methodologists using the GRADEpro web application (available at <https://www.gradepro.org/>), based on five GRADE domains: risk of bias, inconsistency, indirectness, imprecision, and other domains (i.e., publication bias). The certainty of evidence for each meta-analysis estimate was categorised as high, moderate, low, or very low (Supplementary Table 3), and findings were documented in GRADE evidence profiles. The two GDP methodologists then reviewed and compared their independent GRADE certainty assessments and resolved any differences by consensus. These evidence profiles were subsequently presented to the GDP during an in-person meeting, discussed, and finalised by unanimous agreement of all GDP members. The final GRADE evidence profiles (available in Supplementary material C: GRADE Evidence Profiles for the management clinical questions) served as the basis for constructing the GRADE EtD frameworks and formulating clinical practice recommendations.

Formulation of recommendations

The two GDP methodologists drafted the GRADE EtD framework for each management clinical question, integrating both the GRADE evidence profiles and additional EtD parameters, including the balance of desirable and undesirable effects, values and preferences of people living with diabetes, resource use and cost-effectiveness, equity, acceptability, and feasibility [7]. Information for these parameters was drawn from focused PubMed searches conducted by the GDP methodologists, expert judgement of GDP members, inclusion of any additional pertinent evidence, and input from the two GDP members with lived experience of diabetes distress. The draft EtD frameworks and proposed recommendations were discussed and refined during an in-person meeting of the GDP using GRADEpro web application (available at <https://www.grade-pro.org/>). Final recommendations were reached by consensus, with additional feedback incorporated from follow-up review rounds as needed.

The wording of the recommendations was formulated using standardised GRADE terminology, indicating both the strength and direction of each recommendation (Supplementary Table 4).

Writing of the guideline

The writing of the guideline followed the procedures outlined in the EASD standard operating procedure for guideline development [3] and was structured according to the RIGHT statement and checklist [13].

Drafting responsibilities were shared among GDP members according to their roles and areas of expertise. The GDP methodologists (TK, FZ) took responsibility for drafting the methods section, as well as the GRADE evidence profiles and GRADE EtD frameworks that supported the development of the GRADE recommendations related to the management of diabetes distress. Recommendations related to the assessment of diabetes distress, formulated as Good Practice Statements, were primarily drafted by a GDP content expert (JSt), who also served as the chief investigator of the D-stress study whose research team delivered the realist reviews underpinning the Good Practice Statements, and by one of the GDP co-chairs (JSp). The initial draft of the introduction was prepared by NH and JSp and the initial draft of the discussion was prepared by RH. GDP members with lived experience, clinical and content expertise reviewed all sections, ensuring that the recommendations were clinically relevant and appropriately contextualised. All GDP members reviewed the full guideline and provided feedback, suggestions, and additional contributions. Drafts were shared and revised using tracked versions, with successive iterations refined collaboratively until consensus was reached. The GDP co-chairs (JSp and RH) coordinated the writing process and ensured timely progression through each drafting stage.

Each recommendation is presented in a consistent and structured format comprising: (1) the clinical question; (2) the recommendation; and (3) a rationale and explanation, which summarises the key considerations or concepts that informed the recommendation. For management-related clinical questions that were supported by a GRADE certainty of evidence assessment, a concise summary of the corresponding GRADE evidence profile is also presented.

Review of the guideline

The guideline underwent a review process in accordance with the EASD standard operating procedure for guideline development [3]. The process included an initial internal review conducted by the GDP and EST lead. GDP members reviewed the complete draft, and the GDP co-chairs coordinated the integration of feedback ensuring consensus across the GDP and consistency with the EASD standard operating procedure. In addition, the Appraisal of Guidelines, Research and Evaluation (AGREE) II score sheet [14] was completed independently by two methodologists from the EASD GOC who were not members of the GDP.

Following the internal GDP review, the guideline was submitted to the EASD GOC for formal internal review. Where comments were provided, the GDP addressed them and incorporated revisions accordingly. After this stage, the guideline was presented in draft form at the EASD Annual Meeting in Vienna in September 2025 and was then made available for external review through a 6-week period of public consultation, open to people living with type 1 diabetes or type 2 diabetes, healthcare professionals and any other interested parties.

Feedback was received from 25 individuals or groups of individuals. Most individuals submitted multiple comments. The locations of the respondents where indicated were Australia, Brazil, France, Germany, Luxembourg, Mexico, Netherlands, Norway, UK, and USA. The GDP reviewed and considered all comments. The comments were summarised and themed before further changes were made to the guideline.

The final stage of peer review involved an external review by clinicians, researchers, and representatives of working partners and community collaborators directly affected by the recommendations. These reviewers are appointed by the EASD GOC and their role was to assess the clarity, completeness, and relevance of the guidance, without altering the recommendations issued by the GDP.

Following the review, the GDP made further changes before the guideline was finally approved by the GOC and EASD Board.

Dissemination plan and future update

In accordance with the EASD standard operating procedure for guideline development [3], a dissemination plan will be developed to support the accessibility and implementation of this guideline. This includes publication of the full guideline document in a peer-reviewed journal, free availability of this report (open access) on the EASD website and/or through the websites of partner organisations (e.g. the PsychoSocial Aspects of Diabetes (PSAD) Study Group) and communication via social media or other channels. Additionally, accessible plain language formats (e.g., summaries for people living with diabetes) may be developed to support broader awareness and uptake. The dissemination plan may also include the use of the GRADE-ADOLOPMENT approach [22], enabling other groups to adopt, adapt, or selectively implement the recommendations according to their local context. Such adaptations will require approval from the EASD Guideline Oversight Committee and EASD Board.

The EASD standard operating procedure further outlines the potential for future updates to EASD guidelines [3], based on the emergence of new evidence or changes in clinical practice. Any decision to update this guideline will be made by the Guideline Oversight Committee in consultation with the GDP, based on the relevance and magnitude of new evidence or other justifying factors.

Electronic Supplementary Material 3 References

1. Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. Clinical Practice Guidelines We Can Trust. Graham R, Mancher M, Miller Wolman D, Greenfield S, Steinberg E, editors. Washington (DC): National Academies Press (US); 2011.
2. Qaseem, A., et al., *Guidelines International Network: toward international standards for clinical practice guidelines*. Ann Intern Med, 2012. **156**(7): p. 525–31.
3. Karagiannis, T., et al., *European Association for the Study of Diabetes (EASD) Standard Operating Procedure for the development of guidelines*. Diabetologia, 2025. **68**(8): p. 1600–1615.
4. Guyatt, G., et al., *GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables*. J Clin Epidemiol, 2011. **64**(4): p. 383–94.
5. Guyatt, G., et al., *Core GRADE 1: overview of the Core GRADE approach*. BMJ, 2025. **389**: p. e081903.
6. Guyatt, G., et al., *GRADE guidelines: 11. Making an overall rating of confidence in effect estimates for a single outcome and for all outcomes*. J Clin Epidemiol, 2013. **66**(2): p. 151–7.
7. Piggott, T., et al., *Standardized wording to improve efficiency and clarity of GRADE EtD frameworks in health guidelines*. J Clin Epidemiol, 2022. **146**: p. 106–122.
8. Schunemann, H.J., et al., *An international guideline training and certification programme*. Bull World Health Organ, 2025. **103**(4): p. 281–284.
9. Xun, Y., et al., *Reporting Conflicts of Interest and Funding in Health Care Guidelines: The RIGHT-COI&F Checklist*. Ann Intern Med, 2024. **177**(6): p. 782–790.
10. Guyatt, G.H., et al., *GRADE guidelines: 2. Framing the question and deciding on important outcomes*. J Clin Epidemiol, 2011. **64**(4): p. 395–400.
11. Crawford, J., K. Wilhelm, and J. Proudfoot, *Web-Based Benefit-Finding Writing for Adults with Type 1 or Type 2 Diabetes: Preliminary Randomized Controlled Trial*. JMIR Diabetes, 2019. **4**(2): p. e13857.
12. Zu, W., et al., *The effectiveness of psychological interventions on diabetes distress and glycemic level in adults with type 2 diabetes: a systematic review and meta-analysis*. BMC Psychiatry, 2024. **24**(1): p. 660.
13. Chen, Y., et al., *A Reporting Tool for Practice Guidelines in Health Care: The RIGHT Statement*. Ann Intern Med, 2017. **166**(2): p. 128–132.
14. Brouwers, M.C., et al., *AGREE II: advancing guideline development, reporting and evaluation in health care*. J Clin Epidemiol, 2010. **63**(12): p. 1308–11.
15. Andrews, J., et al., *GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations*. J Clin Epidemiol, 2013. **66**(7): p. 719–25.
16. Guyatt, G.H., et al., *Guideline panels should not GRADE good practice statements*. J Clin Epidemiol, 2015. **68**(5): p. 597–600.
17. Guyatt, G.H., et al., *Guideline panels should seldom make good practice statements: guidance from the GRADE Working Group*. J Clin Epidemiol, 2016. **80**: p. 3–7.
18. Harris R, S.S., Due-Christensen M, Stenov V, Abrams R, Fabian-Therond C, Ahuja S, O'Connor S, Papachristou Nadal I, Peck M, Speight J, Holt RIG, Sturt J, *Introducing diabetes emotional wellbeing into routine consultations for adults with Type 1 Diabetes: A rapid realist review*. Metabologia (under review), 2026.
19. Peck M, P.N.I., Stenov V, Due-Christensen M, Sims S, Harris R, Holt RIG, Speight J, Sturt J, *Introducing Diabetes Emotional Wellbeing into Routine Consultations for Adults with Type 2 Diabetes: A Rapid Realist Review of what Works, for Whom, and in what Circumstances*. Metabologia (under review), 2026.

20. Mouelhi, Y., et al., *How is the minimal clinically important difference established in health-related quality of life instruments? Review of anchors and methods*. Health Qual Life Outcomes, 2020. **18**(1): p. 136.
21. Welch, G., et al., *Responsiveness of the Problem Areas In Diabetes (PAID) questionnaire*. Diabet Med, 2003. **20**(1): p. 69–72.
22. Schunemann, H.J., et al., *GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT*. J Clin Epidemiol, 2017. **81**: p. 101–110.

Electronic Supplementary Material 4

Systematic review of interventions to reduce diabetes-related distress among adults with type 1 diabetes and type 2 diabetes

Technical report to the European Association for the Study of Diabetes (EASD) to inform the EASD 2026 guideline on the assessment and management of diabetes distress

On behalf of the Evidence Synthesis Team

Samantha Schipper¹, Sharon Remmelzwaal¹, Marieke Blom², Noa Dagan¹, Linda Schoonmade¹,
Miranda Langendam¹, Petra Elders², Joline W. Beulens¹, Femke Rutters¹

¹Amsterdam UMC, Department of Epidemiology and Data Science, Amsterdam

²Amsterdam UMC, Department of General Practice, Amsterdam

Preface

This is the technical report on the systematic review of interventions to reduce diabetes-related distress among adults with type 1 diabetes and type 2 diabetes performed by the Evidence Synthesis Team. This systematic review was commissioned by the European Association for the Study of Diabetes (EASD) to inform the EASD guideline on the assessment and management of diabetes distress. The work was started in September 2024 and this technical report describes the process followed and the results as of January 2026.

Table of Contents

Abstract	32
Plain language summary	34
Summary of findings for comparisons of interventions for diabetes distress	35
Abbreviations	36
Background	37
Methods	39
Prisma flow chart	46
Results	46
Psychological interventions	48
Psychological interventions compared to psychoeducational interventions for type 1 diabetes	48
Psychological interventions compared to educational (without psychological component) interventions for type 1 diabetes	48
Psychological interventions compared to usual care for type 1 diabetes	49
Psychological interventions compared to psychoeducational interventions for type 2 diabetes	55
Psychological interventions compared to educational interventions for type 2 diabetes	55
Psychological interventions compared to usual care for type 2 diabetes	59
Psychoeducational interventions	64
Psychoeducational interventions compared to educational interventions for type 1 diabetes	64
Psychoeducational interventions compared to usual care for type 1 diabetes	67
Psychoeducational interventions compared to educational interventions in type 2 diabetes	68
Psychoeducational interventions compared to usual care in type 2 diabetes	73
Miscellaneous interventions	78
Devices in T1D	78
Automated insulin delivery compared to no automated insulin delivery	78
Continuous glucose monitoring compared to other types of continuous glucose monitoring or intermittently scanned monitoring	80
Continuous glucose/intermittently scanned glucose monitoring compared to standard blood glucose measurement for type 1 diabetes	81
Devices compared to usual care for T2D	83
Peer Support Interventions compared to usual care for type 1 diabetes	85
Peer Support interventions compared to educational interventions for type 2 diabetes	86

Peer Support Interventions compared usual care for type 2 diabetes	88
Educational interventions compared to other interventions for type 2 diabetes	91
Educational interventions compared to usual care for type 2 diabetes	92
Discussion	93
Declarations	98
Differences between protocol and review	98
Appendix S1 Search strategy	100
Appendix S2 Prospero protocol as downloaded on 30-6-2025	104
Appendix S3 Reasons for exclusion of full text papers	113
Appendix S4 Baseline characteristics	120
Appendix S5 Risk of bias assessment	121
References	124

Abstract

Interventions to reduce diabetes-related distress among adults with type 1 diabetes and type 2 diabetes: a systematic review and meta-analysis

Samantha Schipper¹, Thomas Karagiannis², Francesco Zaccardi³, Sharon Remmelzwaal¹, Noa Dagan¹, Marieke Blom¹, Linda Schoonmade¹, Miranda Langendam¹, Theresa Mohr¹, Maartje de Wit¹, Petra Elders¹, Martin M. Jensen⁴, Walther Jensen⁵, Norbert Hermanns⁶, Karin Kanc⁷, Michelle Law⁵, Andreia Mocan⁸, Jackie Sturt⁹, Joline W. Beulens¹, Jane Speight^{10,11}, Richard I.G. Holt^{12,13} and Femke Rutters¹

1 Amsterdam UMC, the Netherlands

2 Aristotle University of Thessaloniki, Greece

3 University of Leicester, United Kingdom

4 Department of Public health Aarhus University Denmark, Aarhus, Denmark

5 European Association for the Study of Diabetes

6 University of Bamberg and Research Institute of the Diabetes Academy Mergentheim, Germany

7 Jazindiabetes Private Diabetes Centre, Slovenia

8 Emergency Clinical County Hospital, Romania

9 University Hospital Southampton NHS Foundation Trust, United Kingdom

10 Deakin University, Australia

11 The Australian Centre for Behavioural Research in Diabetes, Diabetes Victoria, Australia

12 University of Southampton, Southampton, United Kingdom

13 King's College London, United Kingdom

Background and aims Diabetes distress (DD) refers to the experienced emotional and psychological burden, specifically due to living with and managing diabetes. We aimed to systematically identify, summarize and critically appraise all available evidence from randomized controlled trials (RCTs) assessing the efficacy of interventions for reducing DD (either as primary or secondary outcome) among adults with type 1 diabetes (T1D) or type 2 diabetes (T2D).

Materials and methods We searched PubMed, Cochrane Database of Systematic Reviews, PsycINFO and CINAHL until 23rd September 2024. Eligible studies were RCTs in adults (≥ 18 years) with T1D or T2D in which the efficacy of an active intervention on DD was recorded as primary or secondary outcome. We used GRADE methodology to assess certainty of evidence. When possible (sufficient data were available

from ≥ 2 studies), we performed a random-effects meta-analysis. The effect estimate was a standardized mean difference (SMD) with 95% confidence interval (95%CI) of endpoint DD measurement as assessed with a validated questionnaire. We conducted subgroup analyses based on baseline level of DD, intervention delivery method, risk of bias assessment (ROB2) and study duration.

Results We included 248 studies, with 59 studies reporting on psychological therapeutic interventions, 68 on psychoeducational interventions and 121 on miscellaneous interventions (non-psychological or non-psychoeducational, including devices, education without psychological component, peer support without psychological component, devices, telehealth, health behaviours and an assorted mix). 52 studies included participants with T1D including two during pregnancy, 160 studies included participants with T2D, and 36 had a mixed or undefined population of adults with diabetes. The total sample size was $N = 55,497$, with study sample sizes ranging from 12 to 2,334 participants. The methodological quality of the studies was rated as some concerns for risk in 107 studies and high risk of bias in 81 studies.

Compared to usual care, psychological interventions reduced DD in adults with T1D (SMD -0.22 , 95% CI: -0.35 to -0.08) and T2D (SMD -0.31 , 95% CI: -0.50 to -0.13). Additionally, continuous glucose monitoring or flash glucose monitoring reduced DD in adults with T1D (SMD -0.26 , 95% CI: -0.41 to -0.11), while educational interventions reduced DD in adults with T2D (SMD -0.34 , 95% CI: -0.56 to -0.11). Other comparisons including those of psychological, psychoeducational, peer support, educational, and device-based interventions against various active controls or usual care did not show statistically significant effects. Results did not differ meaningfully across predefined subgroups. For all studies certainty of evidence assessed by GRADE methodology was moderate, low or very low in two, five, and seven comparisons. No meta-analyses could be conducted for telehealth, health behaviours and the assorted mixed interventions, due to heterogeneity or an insufficient number of studies.

Conclusion Psychological interventions consistently reduced DD among adults with T1D and T2D, while devices did in adults with T1D and education in adults with T2D. Most other interventions showed little or no clear effect. Telehealth and health behaviours categories could not be analysed due to heterogeneity and limited data.

Plain language summary

Interventions to reduce diabetes-related distress among adults with type 1 diabetes and type 2 diabetes

Clinical question To investigate which interventions are effective in reducing diabetes distress (DD) among adults with type 1 diabetes (T1D) or type 2 diabetes (T2D).

Background Diabetes-related distress refers to the negative emotional experiences of people living with diabetes, namely their concerns about managing the condition, support, burden and access to health care. About one third of all people with T1D or T2D experience DD. In turn, DD affects diabetes self-care and outcomes. We aimed to identify which interventions are effective for reducing DD among adults with T1D or T2D.

Study characteristics We found 248 randomized controlled trials; these are studies where people are randomly assigned to one of two or more treatment groups. We looked for three types of studies and found: 59 on psychological therapeutic interventions, 68 on psychoeducational interventions and 121 with other miscellaneous types, such as devices. The studies included both adults with T1D and T2D, were individual- or group-based, with diverse durations (ranging from few weeks to years). Many studies included people who had with low levels of DD at the start of the trial.

Key results Compared to usual care, psychological interventions had a positive effect on reducing DD among adults with T1D and T2D. Continuous glucose monitoring (CGM) or flash glucose monitoring also reduced DD among adults with T1D, while education did in adults with T2D. Other types of interventions, such as psychoeducation, peer support, and other devices, showed little or no effect. This evidence is up to date as of September 2024.

Quality of the evidence Overall, the quality of the evidence was low because studies were small, there were missing data, or there were other limitations in the design or conduct of the studies.

Summary of findings for comparisons of interventions for diabetes distress

Type 1 diabetes	Effect estimate, SMD (95% CI)	Number studies	Subgroup differences
Psychological versus psychoeducational interventions	x	x	x
Psychological versus educational interventions	-0.11 (95% CI: -0.44 to 0.23)	2	No
Psychological interventions versus care as usual	-0.22 (95% CI: -0.35 to -0.08)	16	No
Psychoeducational versus educational interventions	-0.02 (95% CI: -0.23 to 0.20)	3	No
Psychoeducational interventions versus care as usual	-0.17 (95% CI: -0.62 to 0.28)	2	x
Educational versus peer support interventions	x	x	x
Peer support interventions versus care as usual	x	x	x
Educational interventions versus care as usual	x	x	x
AID systems versus no AID	-0.15 (95% CI: -0.33 to 0.02)	5	No
CGM/Flash glucose monitoring versus capillary glucose monitoring	-0.26 (95% CI: -0.41 to -0.11)	6	No
Type 2 diabetes			
Psychological versus psychoeducational interventions	x	x	x
Psychological versus educational interventions	-0.29 (95% CI: -0.98 to 0.39)	10	No
Psychological interventions versus care as usual	-0.31 (95% CI: -0.50 to -0.13)	21	No
Psychoeducational versus educational interventions	-0.15 (95% CI: -0.34 to 0.03)	13	No
Psychoeducational interventions versus care as usual	-0.19 (95% CI: -0.40 to 0.02)	23	Study duration
Peer support versus educational interventions	0.10 (95% CI: -0.08 to 0.28)	3	No
Educational versus miscellaneous interventions	x	x	x
Peer support interventions versus care as usual	-0.03, 95% CI: -0.19 to 0.13)	4	Delivery format + Study duration
Educational interventions versus care as usual	-0.34 (95% CI: -0.56 to -0.11)	3	No
CGM versus capillary glucose monitoring	-0.35 (95% CI: -0.98 to 0.28)	3	Baseline distress

Statistically significant results are shown in bold

AID, Automated Insulin Delivery system; CGM, Continuous Glucose Monitoring; SMD, Standardized Mean Difference; X, No meta-analysis was conducted; No, Subgroup analyses revealed no significant subgroup effects based on baseline diabetes distress score, study duration, delivery format or risk of bias score

Abbreviations

AID	Automated Insulin Delivery System
ADA	American Diabetes Association
CAU	Care As Usual
CGM	Continuous Glucose Monitor
DD	Diabetes Distress
DDS	Diabetes Distress Scale
EASD	European Association for the study of Diabetes
HbA1c	Haemoglobin A1c
GRADE	Grading of Recommendations Assessment, Development and Evaluation
MCID	Minimal Clinically Important Difference
NICE	National Institute for Health and Care Excellence
NR	Not reported
PAID	Problem Areas In Diabetes
PRISMA-P	Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols
QSD	Questionnaire on Stress in Diabetic Patients
RCT	Randomized controlled trial
SMD	standardized mean difference
T1D	Type 1 diabetes
T2D	Type 2 Diabetes

Background

Diabetes mellitus is a chronic metabolic disorder affecting hundreds of millions of people worldwide. It is associated with significant morbidity, mortality, and healthcare costs and requires ongoing self-management to prevent complications [1]. Beyond the physical burden associated managing the condition, people living with diabetes frequently experience an emotional or psychological burden. The wide range of negative feelings, including frustration, anxiety, guilt and fear attributed to the challenges of living with and managing diabetes is often referred to as diabetes distress (DD) [2].

Factors that can contribute to DD include worries about long-term complications, frustrations with monitoring and managing glucose levels, burden of self-care, social interactions, financial burden of diabetes and its management, feelings of isolation or overwhelm, stigma and not feeling in control of the condition [3]. Unlike clinical depression and anxiety, which are generic mood disorders, DD is directly related to the living with and managing diabetes [4]. Although the prevalence of DD varies across populations, study settings and by the instrument used, reviews estimate 20-36% [5-7] of the people with diabetes experiences elevated DD.

Evidence suggests a bidirectional association between DD and glycaemic indicators, which suggests greater DD is associated with higher HbA1c, less time in range, higher fasting glucose and vice versa [8]. However, glucose levels being within target range does not necessarily indicate the absence of DD [9]. In addition, DD is associated with less engagement in glucose management and other healthy self-care behaviours. Consequently, people with DD have higher risk of diabetes-related complications [8]. Therefore, addressing DD is not only beneficial for a person's emotional and mental health, but also for enabling optimal diabetes management and outcomes [8].

Although DD is a significant concern for people with diabetes, healthcare professionals lack detailed guidance for how to assess and manage it in clinical practice. In 2016, the American Diabetes Association (ADA) published a position statement on psychosocial assessment and care in people with diabetes [10]. It focused on the most common psychological factors affecting people with diabetes, including DD. However, these recommendations, including frequent monitoring for DD, were based on commonly used clinical models, expert consensus and tested interventions, not on a systematic review of the evidence [10]. The National Institute for Health and Care Excellence (NICE) guideline for the management of diabetes in adults in England and Wales [11] makes similar recommendations, also not based on a systematic evidence synthesis.

The European Association for the Study of Diabetes (EASD) has recognized the importance of DD and has commissioned an evidence-based clinical guideline to enable healthcare professionals to optimise their support of people living with diabetes and DD[12]. The purpose of this systematic review and meta-analysis is to update and expand the evidence base on the clinical management of DD by including randomized controlled trials (RCTs) that assess the efficacy of a wide range of interventions on DD as a primary or secondary outcome. To date, previous systematic reviews have only focused on specific types of interventions such as psychological interventions or digitally enabled peer support, or only included studies primarily designed to reduce DD [13-20], while interventions not specifically targeting DD may reduce DD as a by-product.

For instance, an RCT assessing the effect of a proactive and psychoeducational telehealth intervention to improve medication taking in 400 people with diabetes and depression, also showed a reduction in DD [21]. Additionally, an RCT in people with T2D that compared flash glucose monitoring to self-monitoring of glucose levels showed a non-significant reduction in DD [22], suggesting that interventions not specifically targeting DD can reduce DD as a by-product. Therefore, our aim was to systematically identify, summarize and critically appraise all available evidence from RCTs that assess the efficacy of psychological and other interventions on DD reduction (either as primary or secondary outcome) among adults with T1D or T2D.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed [17]. The protocol of this review was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database under number: CRD42024598512, see Appendix S2 and the protocol was submitted to the journal Trials (under review).

Data sources and search strategy

A search of the literature was conducted in PubMed, Cochrane Database of Systematic Reviews, PsycINFO and CINAHL, all from inception to 23 September 2024, in collaboration with a medical librarian (LS) and the EASD Guideline Development Panel (TK, FZ, WJ, NH, KK, ML, AM, JS, JS, RH). Search terms included controlled terms (MeSH in PubMed) as well as free-text terms. Reference lists of included studies and relevant systematic reviews were searched manually for additional eligible publications. The search strategy focused on three domains: (1) diabetes, (2) distress, and (3) RCT. The three domains were included in a three-step search combining relevant search words and MeSH terms with Boolean logic operators (OR and AND). A search filter was applied to limit the results to humans. The search was performed without date or language restrictions. Duplicate articles were excluded. The full search strategy is provided in Appendix S1.

Selection of studies

Publications were included if the following criteria were satisfied: 1) The study focused on adults (≥ 18 years) with T1D or T2D, 2) the study reported results on DD as a primary or secondary outcome, using data collected with the use of a validated measure such as the Diabetes Distress Scale (DDS) [23], Problem Areas In Diabetes (PAID) scale [2], the Questionnaire on Stress in Diabetic Patients (QSD)[24] and their subscales or derivatives (including short-form measures and versions developed for specific populations, e.g. for adults with T1D), 3) the study is an RCT, irrespective of its duration or the type of randomization used (e.g. individual, cluster), 4) the study examines the efficacy of an active intervention, which can either be generic or diabetes-specific.

There were no restrictions on delivery mode (e.g. in-person, online, digital applications, delivered by a specialized mental health professionals, specialist diabetes health professionals, general health professionals or expert peers (e.g. people with lived experience of diabetes who are trained to deliver the intervention)), setting (individual versus groups), comparators (e.g. usual care, waiting list or active comparator), design, duration, publication date, language or status of the patient (e.g. hospitalized,

pregnancy). We excluded studies on participants aged <18 years, or with other types of diabetes (e.g., gestational diabetes), or populations with combined groups including these types (e.g. children plus adults), where no separate results were reported for the adults' group.

The following three categories of intervention were defined:

- A) Psychological interventions, which includes cognition-focused, emotion-focused, or emotion-cognition therapeutic interventions facilitated by a health professional trained in psychology. Examples include, but are not limited to, cognitive behavioral therapy, motivational interviewing, supportive counselling, mindfulness, acceptance and commitment therapy;
- B) Psychoeducational interventions, which includes diabetes self-management education, peer support, health coaching or psychological interventions, all combined with a diabetes-related educational component (e.g., carbohydrate counting, insulin dose adjustment) as well as focus on improving self-management (e.g., cognitive reframing, goal setting, planning, problem solving) based on psychological theory or theories. This category typically includes interventions delivered at greater scale, e.g. in groups or via online programs, it includes interventions such as, but not limited to: peer support via an online platform, motivational interviewing through an app, depression treatment via telehealth, conversation maps, psychoeducational, self-management support or nudging;
- C) Miscellaneous types of interventions, which includes interventions that could not be categorized as psychological or psychoeducational. Examples include devices (for the administration of insulin or other glucose-lowering medications, or for glucose monitoring or both); education or peer support without a clearly described psychological component (i.e. interventions with no clear description of the use of frameworks, models or techniques that have psychology or behavioral science at their core); telehealth (e.g., apps, online interventions of diverse nature); health behaviours (e.g. physical activity, sleep, weight loss); medication (e.g. glucose-lowering injectable or oral medication); complex health service interventions (e.g. healthcare pathways, models of care); insulin titration (e.g. different protocols for insulin titration); personalized risk assessment or use of Patient Reported Outcome Measures to assess outcomes in care. The miscellaneous interventions category was further subcategorized and described if ten or more studies reported on the same type of intervention.

Study screening

After deduplication, two independent reviewers screened the titles and abstracts of all studies identified in the literature search in duplicate using Covidence [25]. Subsequently, full-text versions of the potentially eligible publications were retrieved (by contacting corresponding authors if necessary) and assessed by two independent reviewers based on the inclusion and exclusion criteria. In the selection process, we did not mask information about the article, such as the journal that published it, the authors, the institution, or the magnitude and direction of the results. Reasons for exclusion were recorded and are provided in Appendix S3. Discrepancies were resolved through discussion, by consulting a third reviewer and after that, when still in doubt we consulted with the Guideline Development Panel members.

Data extraction

Data extraction was performed by one reviewer and checked by another reviewer, using a standardized, pre-piloted form. In the event of duplicate publications, companion documents or multiple reports of a primary study, we merged those papers in Covidence and we maximized yield of information by collating all available data, and we used the most complete data set aggregated across all related publications. In general, we gave priority to the longest follow-up associated with our primary outcome. Extracted data included: 1) study characteristics (first author, publication DOI, year of publication, setting, trial identifier, trial duration, duration of intervention, description of intervention and control condition (e.g. content, intensity, the professional involved and delivery methods), geographical location, number of participants), 2) participants' baseline characteristics (men/women ratio, mean age, diabetes duration, baseline distress score, type of diabetes), 3) DD data for each trial arm, including measurement method and relevant metrics (baseline and end-of-study mean. For DD at follow-up, the latest available timepoint with complete data was taken. For trials with several intervention groups, we included all the intervention and control groups, resulting in trials sometimes being reported more than once in any one analysis (for example Quinn et al. [26] which compares coach-only vs coach with primary care providers portal vs coach with primary care providers portal with decision making vs control to test whether adding a mobile application coaching and patient/provider portals to usual care reduces HbA1c). Any uncertainties identified during data extraction were resolved by consulting a third reviewer. If resolution of a disagreement was not possible, we contacted the corresponding authors for clarification. Additional or missing information was requested also by email, if needed. When mean data were missing, but median data were present, we imputed the mean from the median data [27]. When standard deviations for outcomes were not reported and we did not receive information from study authors, we imputed

these values by assuming the standard deviation of the missing outcome to be the standard deviation of the baseline value and when this was also not reported (n=1), as suggested in the Cochrane standard we extrapolated the standard deviation from a trial with very similar population and intervention [27].

For each included study, we extracted the description of the intervention and active comparator as described in each study. Based on this extracted information, we categorized the interventions into one of the predefined categories (psychological, psychoeducational, or miscellaneous with subcategories for the latter). This categorization was subsequently reviewed and verified by the content and clinical experts of the Guideline Development Panel to ensure consistency and appropriateness. When consensus could not be reached, the majority opinion was used. We categorized studies to the best of our ability, although in some cases, insufficient detail was provided about the underlying psychological theory or intervention content. Due to the heterogeneous nature of interventions, some studies could have been assigned to more than one category, for example Dale et al. [28], could be considered both a peer support and an educational intervention. In such cases, we followed the authors' own description to guide classification. To facilitate meta-analysis, we aimed to limit subcategorization and combine studies wherever methodologically reasonable. However, in some cases, such as the health behaviours category, which included a wide range of interventions from dietary supplements to food bank support and sleep studies, the heterogeneity was too great to allow meaningful pooling.

Risk of bias assessment

Risk of bias was assessed using the Cochrane RoB2 tool for RCTs [27, 29] for the primary outcome DD. The RoB2 tool has five domains: Domain 1 assesses bias arising from the randomization process, e.g. lower rating if information on randomization was missing or baseline differences in the outcome variables suggest a problem with randomization; Domain 2 assesses bias due to deviations from the intended interventions, e.g. lower ratings were given if deviations arose due to the trial context or if analyses were not conducted based on intention-to-treat analysis; Domain 3 assesses bias due to missing outcome data, e.g. lower ratings were assigned if more than 5% of the primary outcome data were missing and/or no analysis was performed to assess the impact of missing data; Domain 4 assesses bias in measurement of the outcome, e.g. lower ratings where measurement involves self-report. In this review, an inclusion criterion was the use of validated Person Reported Outcome Measures (PROM) to assess DD. This necessitated a lower ROB rating for Domain 4 for all included studies; Domain 5 assesses bias in selection of the reported result, e.g. lower ratings were assigned if analyses were not conducted

in concurrence with a pre-specified analysis plan or if multiple analysis of the outcome were performed. An 'overall risk of bias' judgement was made, summarizing the score of the five bias domains. Overall risk of bias was considered 'low' if the RCT was judged to be at low risk in all domains, and 'high' when the trial was judged to be high risk in at least one domain or the trial is judged to have some concerns for multiple domains. The overall risk of bias was considered as 'some concerns for risk of bias' in all other cases.

Risk of bias was performed by one independent reviewer and checked by a second reviewer (FR, SS). Discrepancies were resolved through discussion or the consultation of a third reviewer. The review team tested the form for the assessments of risk of bias on a pilot sample of five to ten papers that spanned a range from some concerns to high risk of bias to ensure that we were consistently applying criteria and could reach a consensus. Review authors were not blinded to the names of the authors, institutions, journal or results of the study when assessing its methods for risk of bias. We assessed risk of bias in studies from all three categories of interventions. However, for miscellaneous interventions, we only assessed risk of bias in the subcategories with more than ten or more studies that reported on the same subtype of intervention, namely devices, educational interventions without psychological component as well as peer support without psychological component. The latter category was smaller than ten studies (n=7), however, due to the strong overlap with the psychoeducational category, based on content we also assessed those.

Data synthesis

Studies were meta-analyzed using random-effects models, primarily due to clinical heterogeneity (particular in terms of the intervention used in each study) and also due to differences in methodology across studies, when at least two studies reported results for DD. We used R version 4.3.2 for the analyses. For the miscellaneous interventions, due to high clinical heterogeneity even among the same type of subcategory, we were only able to synthesize studies that assessed devices, peer support and educational interventions in a meta-analysis. Additionally, we were only able to do meta-analyses on post-intervention (endpoint) values, since too many studies did not report baseline or change from baseline values and/or respective measures of dispersion for these values. According to the Cochrane Handbook for systematic reviews, 'post-intervention value and change scores should not in principle be combined using standard meta-analysis approaches when the effect measure is a standardized mean difference (SMD) [27]. Since different scales were used to assess DD, SMDs were calculated. The rule of thumb of how to interpret these measures is that an SMD less than 0.40 indicates a small effect, 0.40 to

0.70 a moderate effect, and more than 0.70 a large effect, as described in the Cochrane Handbook for Systematic Reviews of Interventions [27]. To support interpretation of the magnitude and clinical relevance of intervention effects on diabetes distress, the Guideline Development Panel defined a threshold for minimal clinically important difference (MCID) on the SMD scale. Because diabetes distress outcomes were synthesised across multiple validated patient-reported outcome measures using SMDs, and no single anchor-based MCID is applicable across instruments, a pragmatic SMD-based threshold informed by the established interpretation of effect sizes for patient-reported outcomes and by panel consensus was adopted. Specifically, an SMD of 0.3 was considered to represent an MCID. Based on this framework, effects were categorised as large ($SMD \leq -0.5$), moderate ($-0.5 < SMD \leq -0.3$), small ($-0.3 < SMD \leq -0.2$), or trivial/no effect ($SMD > -0.2$). This threshold was used to support GRADE Certainty of Evidence Assessment.

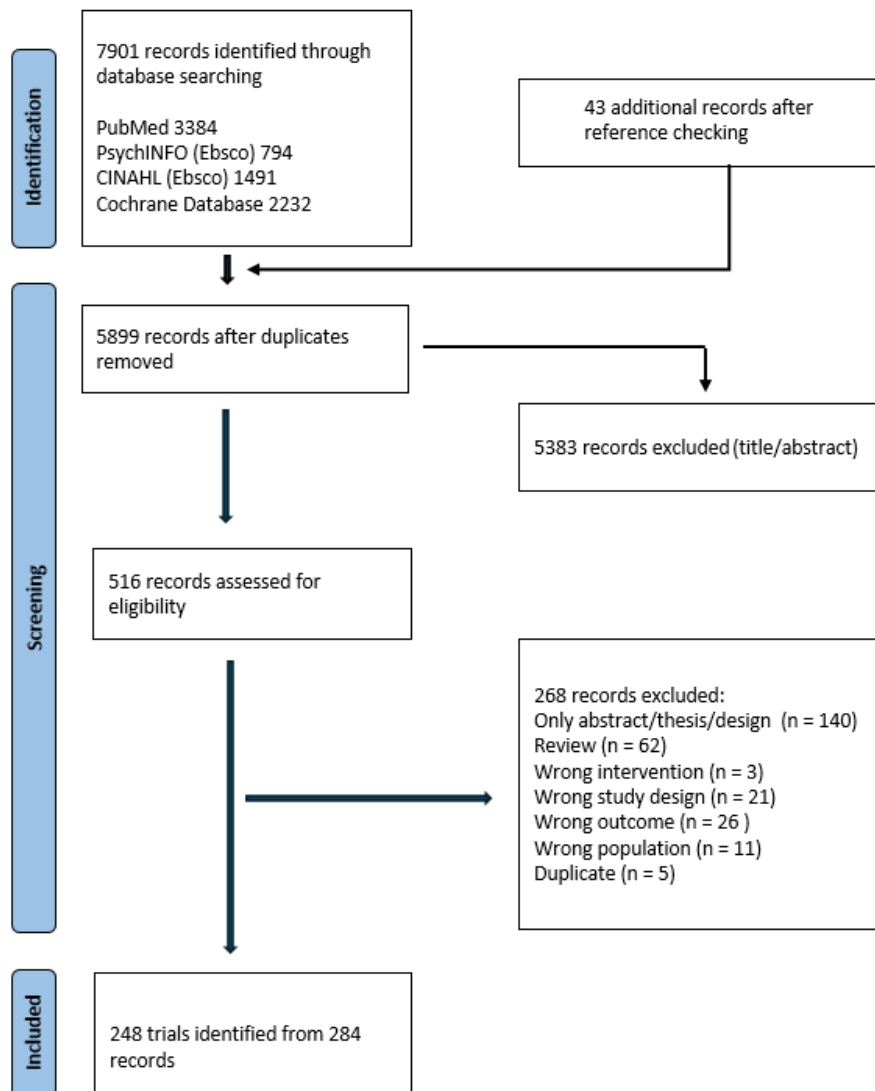
We considered the level at which randomization occurred, such as cross-over trials, cluster-randomized trials and multiple observations for the same outcome. In case of cross-over trials or cluster-randomized trials, when possible we extracted effect estimates that took into account the correlation of the measurements. Where the trials reported two interventions versus a control group, we halved sample size of the control group to avoid double counting. Due to predefined substantial clinical heterogeneity in terms of type of diabetes, we performed separate analyses for T1D and for T2D. If a study recruited a mixed population (both T1D and T2D), as a rule of thumb, we included the study in one group if $\geq 60\%$ of the participants had that type of diabetes. When the proportion was approximately 50/50 or undefined, we included the study in both the T1D and T2D analyses. Additionally, analyses were stratified by type of intervention (psychological/ psychoeducational/subcategories of miscellaneous interventions), comparator (i.e. usual care and waiting list or active comparator) as well as the tool used to measure DD (i.e. DDS, PAID, T1-DDS, PAID-5). In two comparisons originally labelled as having “miscellaneous” comparators (i.e. interventions other than psychological or psychoeducational), we re-analyzed the data to improve clinical relevance, when we observed that $>90\%$ of the comparator belonged to one subcategory. We then conducted a sensitivity analysis by including trials with the heterogeneous comparator types ($n=2$) and retained those in which the comparator clearly belonged to a single, clinically coherent category (e.g. educational interventions). These sensitivity analyses were prioritized in the guideline, while the broader analyses including all miscellaneous comparators are still documented in this review for transparency. Heterogeneity between studies was assessed using the I^2 statistic, which quantifies inconsistency across trials, where an I^2 statistic of 75% or more indicates a considerable level of heterogeneity [27].

Additionally, we performed subgroup analyses based on: 1) risk of bias score, 2) intervention delivery format (i.e., one-to-one vs group-based; in-person vs online), 3) intervention duration (using the median duration of all included studies within each intervention category as the threshold for subgrouping), 4) level of DD at baseline (high DD defined as DDS ≥ 3 , PAID or PAID20 ≥ 40 , PAID11 ≥ 18 , PAID8 ≥ 13 , PAID5 ≥ 8) to assess possible explanations for heterogeneity. When there was an indication of a possible subgroup effect (i.e. p for interaction < 0.05), we planned to assess its credibility using the ICEMAN tool [30]. When we included three trials or more investigating a particular outcome, we used the funnel plots to assess small study effects. There are several possible explanations for an asymmetrical funnel plot, including true heterogeneity of effect with respect to trial size, poor methodological design (and hence bias of small trials) and publication bias. We therefore interpreted results with caution [29]. If meta-analysis was not possible, we presented a narrative summary of eligible studies.

Certainty of evidence assessment

We assessed the overall certainty of the evidence of analysis results according to the GRADE approach [31], which considers issues the domains of risk of bias, inconsistency, imprecision, publication bias, and indirectness. Two Guideline Development Panel methodologists independently rated the certainty of evidence using the GRADEpro online application, and any discrepancies were resolved through consensus with all members of the Guideline Development Panel.

Prisma flow chart



Results

Characteristics of Included Studies

As presented in figure 1 (PRISMA flow chart), 7901 records were identified from the systematic literature search, which resulted in 5898 records after duplicates were removed, and 43 records were added that were identified manually from reference lists of relevant papers. We excluded 5383 records based on title and abstract. 516 records were assessed in full text. Of these, 284 records reporting on 248 trials met the inclusion criteria. The mean Kappa score for full-text screening was 0.87, which suggests perfect

agreement. We categorized 59 trials as psychological interventions, 68 as psychoeducational interventions and 121 as miscellaneous (neither psychological nor psychoeducational) interventions. The other types of interventions included: 27 on devices (for the administration of glucose-lowering medications, glucose monitoring or both); 15 on peer support without psychological component; 10 on education without psychological component; 23 on telehealth (e.g. apps, online consults); 21 on health behaviours (e.g. sleep, weight loss, dietary supplements); and 25 that included a diverse selection of interventions (<10 per group) that encompassed complex health service interventions (e.g., healthcare pathways, models of care), insulin titration, medication, PROMS, surgery and personalized risk assessment.

An overview of the characteristics of the included studies is shown in Table 1 (baseline table, Appendix S4). Of the 248 studies, 52 included participants T1D of which two studies were conducted pregnant women with T1D, 160 included participants with T2D, 36 included a combined population. All studies are RCTs, of which 15 were cross-over RCTs and 22 cluster RCTs. All studies measured DD with either (variations of) the PAID scale (138 studies), (variations of) the DDS scale (107 studies) or both (3 studies). The total sample size was 55,497, with study sample sizes ranging from 12 to 2334. The studies were conducted in 37 countries, including USA (n = 88), Netherlands (n = 20), UK (n = 19), Australia (n = 19), Germany (n = 16), China (n = 10), Canada (n = 7), Denmark (n = 7), Norway (n = 5), Spain (n = 5), Sweden (n = 5), Brazil (n = 4), Iran (n = 3), Korea (n = 3), Mexico (n = 3), Singapore (n = 3), Belgium (n = 2), Hong Kong (n = 2), Iceland (n = 2), India (n = 2), Indonesia (n = 2), New Zealand (n = 2), Taiwan (n = 2), Argentina (n = 1), Croatia (n = 1), France (n = 1), Ghana (n = 1), Greece (n = 1), Ireland (n = 1), Israel (n = 1), Italy (n = 1), Malaysia (n = 1), Nepal (n = 1), Pakistan (n = 1), Saudi Arabia (n = 1), and South Africa (n = 1).

Risk of bias assessment

An overview of the methodological quality assessment of the studies is presented in the ROB2 summary table in Appendix S5. The methodological quality of the studies was rated as some concerns for risk of bias in 107 studies and high risk of bias in 81 studies. Most of the concerns for risk of bias ratings were due to a high risk of selection bias and reporting bias.

Meta-analysis results

As was prespecified in the protocol, we present the results per diabetes type and by type of intervention and comparator (either an active comparator or usual care). In addition, when possible, several subgroup

analyses are presented based on level of baseline DD (low versus high), method of delivery (in group or in person), and overall ROB assessment and study duration.

Psychological interventions

Psychological interventions compared to psychoeducational interventions for type 1 diabetes

One study was found that compared psychological interventions to psychoeducational interventions in adults with T1D [32]. Narrative analysis showed a non-significant reduction of DD in favor of cognitive behavioral therapy when compared to blood glucose awareness training [32].

Psychological interventions compared to educational (without psychological component) interventions for type 1 diabetes

Two studies were found that compared psychological interventions to educational interventions (without psychological component) in T1D [33-35]. Meta-analysis (figure 2a) showed that the difference in DD between psychological and educational interventions was non-significant (−0.11 (95% CI: −0.44 to 0.23)) [33-35]. The respective GRADE evidence profile is shown in figure 2b. No subgroup analyses were conducted due to only two studies being included.

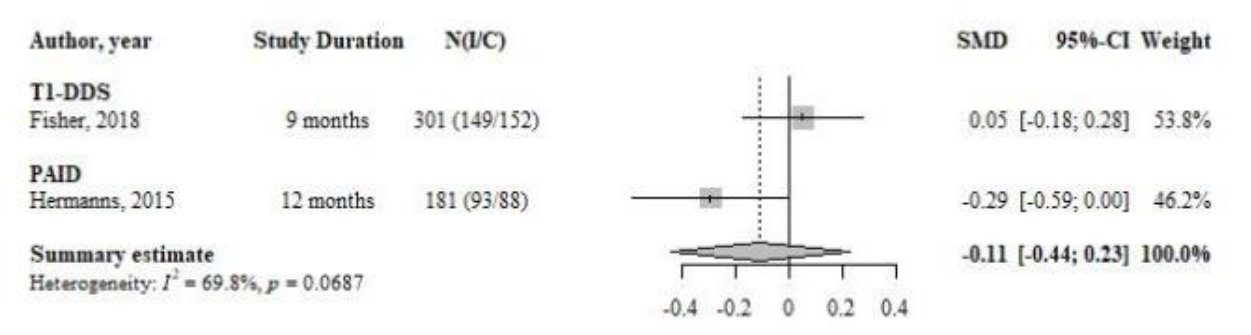


Figure 2a: Standardized mean difference for psychological interventions compared to educational interventions (without psychological component) for T1D

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 9 months to 15 months; assessed with: DDS-PAID)												
2	randomised trials	very serious ^a	very serious ^a	very serious ^c	serious ^d	none	242	240	-	SMD 0.11 SD lower (0.44 lower to 0.23 higher)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. One study at high ROB and one with some concerns. p-interaction for ROB = 0.0687
- b. I² = 69.8% and effect not large (very serious limitations)
- c. Different types of comparators
- d. CI crosses both -0.3 and null but not +0.3

Figure 2b: GRADE evidence profile for psychological interventions compared to educational interventions (without psychological component) for T1D

Psychological interventions compared to usual care for type 1 diabetes

17 studies were found that compared psychological interventions to usual care in adults with T1D [36-53]. Meta-analysis of 16 studies (17 comparisons) showed a significant effect (-0.22 (95% CI: -0.35 to -0.08)) for the reduction of DD favoring psychological interventions (figure 3a) [36, 38-43, 45-53]. The respective GRADE evidence profile is shown in figure 3f. Subgroup analyses revealed no significant subgroup effects by baseline DD, study duration, intervention delivery format or risk of bias score (P>0.05). Narrative analysis of the study that could not be included in the meta-analysis, showed a similar effect with the meta-analysis in the reduction of DD [37].

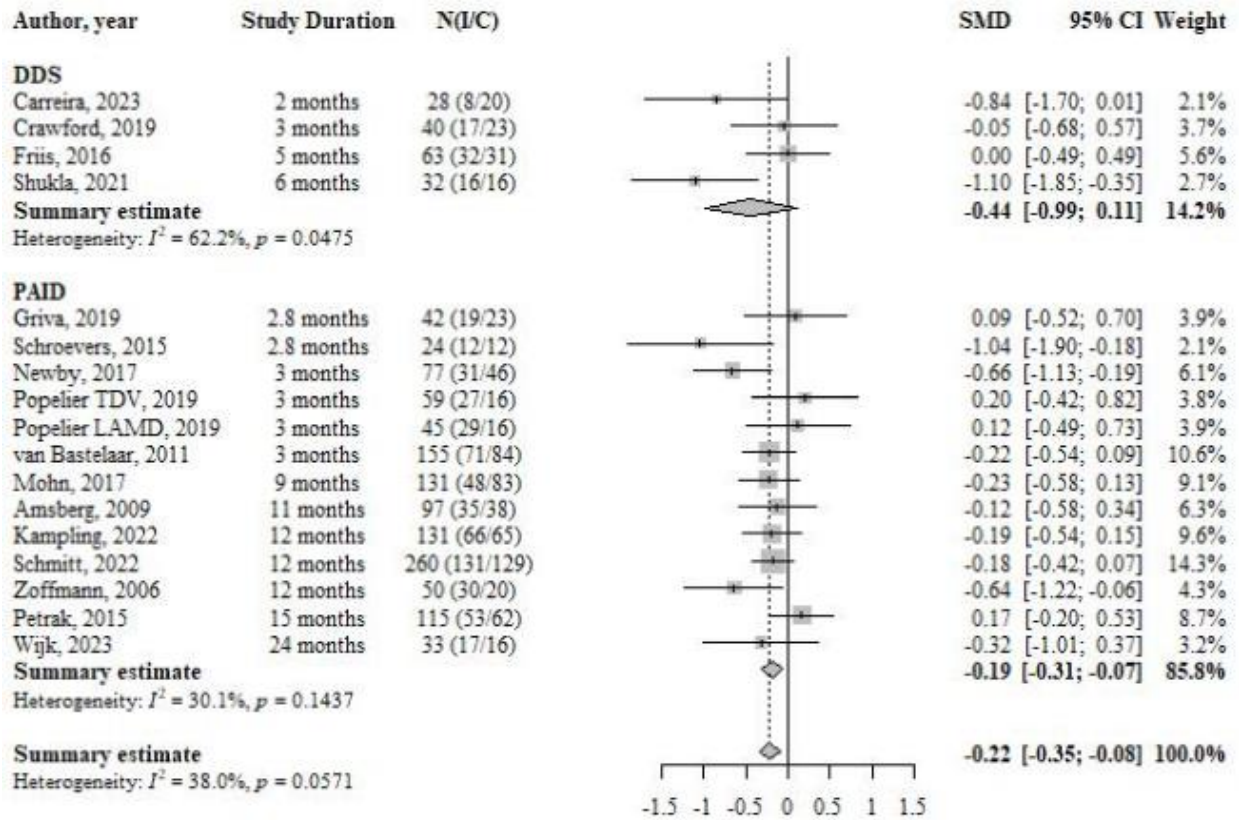


Figure 3a: Standardized mean difference for psychological interventions compared to usual care for T1D

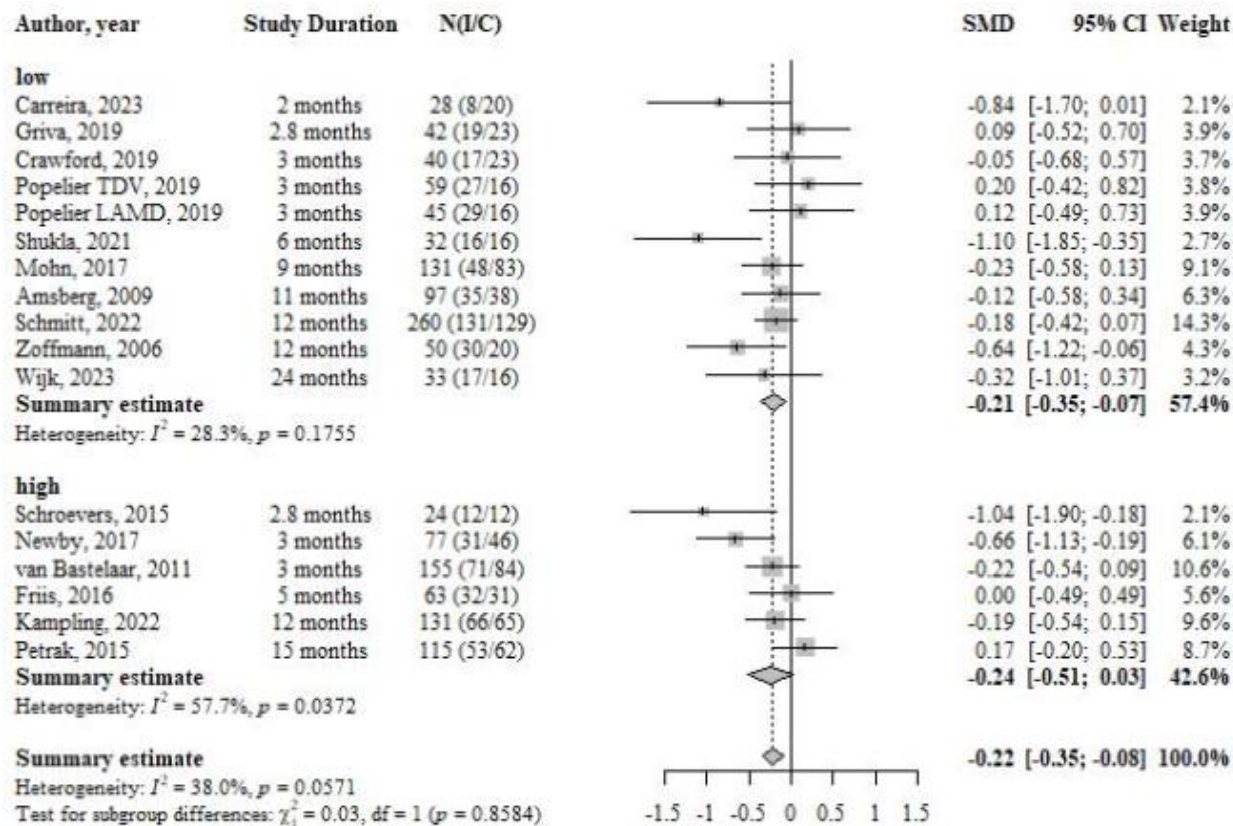


Figure 3b: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T1D stratified by baseline distress level

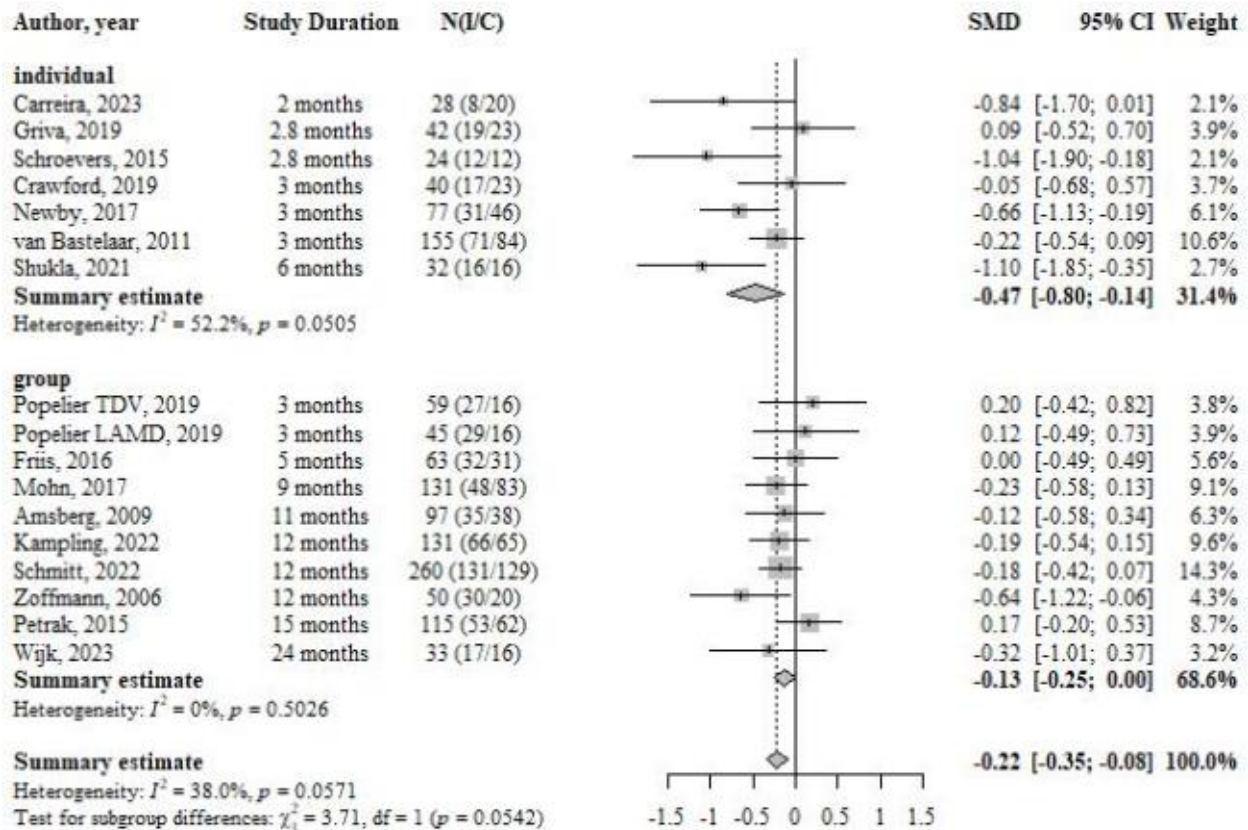


Figure 3c: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T1D stratified by delivery format

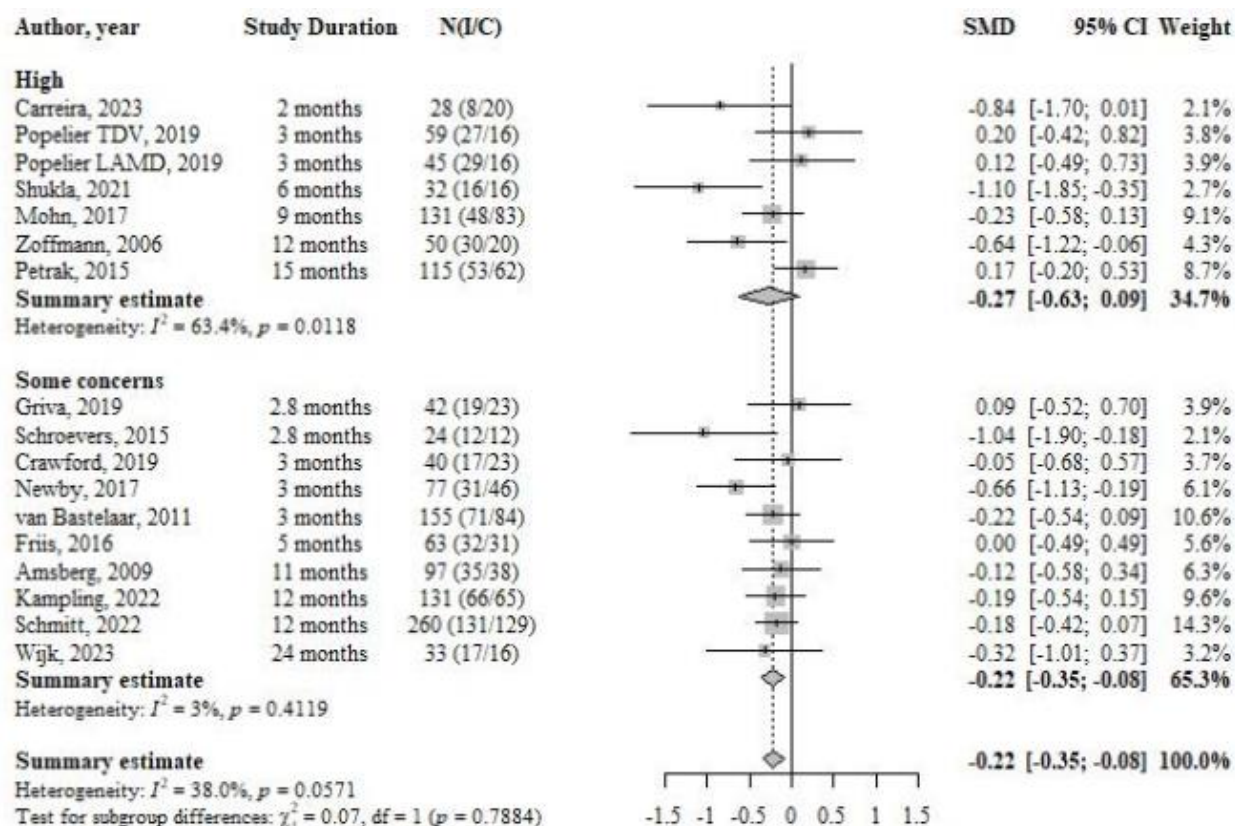


Figure 3d: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T1D stratified by risk of bias assessment

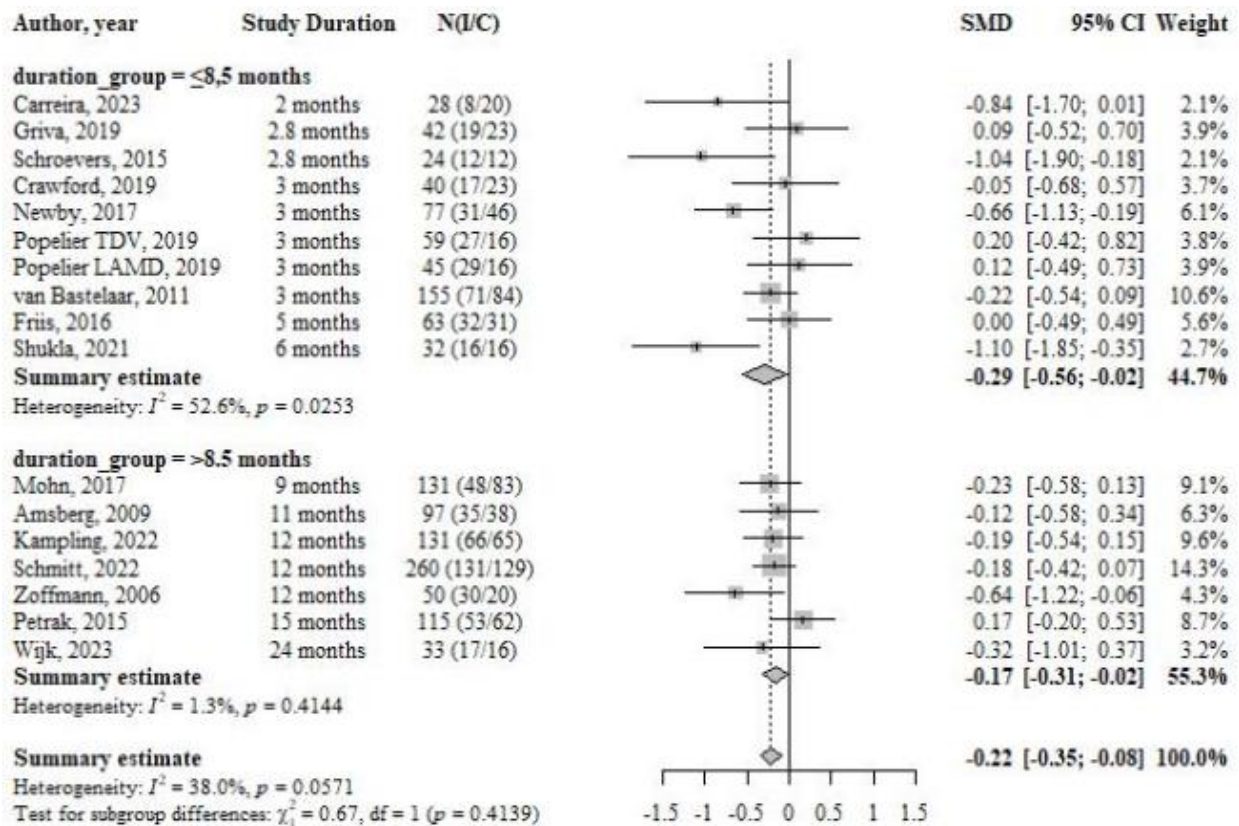


Figure 3e: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T1D stratified by study duration

Certainty assessment							N# of patients		Effect		Certainty	Importance
N# of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 2 months to 24 months; assessed with: DDS-PAID)												
16	randomised trials	serious ^a	not serious ^b	not serious ^c	serious ^d	none	642	700	-	SMD 0.22 SD lower (0.35 lower to 0.08 lower)	⊕⊕○○ Low ^{a,b,c,d}	CRITICAL

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. None at low risk of bias. Most studies with some concerns
- b. $I^2 = 38\%$
- c. Variations in the type of interventions not considered important to downgrade.
- d. CI crosses MCID and does not cross null effect

Figure 3f: GRADE evidence profile for psychological interventions compared to usual care for T1D

Psychological interventions compared to psychoeducational interventions for type 2 diabetes

One study was found that compared a psychological intervention to a psychoeducational intervention in adults with T2D [54]. Narrative analysis showed a non-significant effect in favor of an integrated mindfulness intervention to diabetes self-management education (DSME), compared to DSME alone in the reduction of DD [54].

Psychological interventions compared to educational interventions for type 2 diabetes

Eleven studies were found that compare psychological interventions to a set of miscellaneous interventions in adults with T2D [55-65]. Of these, ten studies compared a psychological intervention to an educational intervention (without psychological component), whereas one study that compared written emotional disclosure to neutral writing was not included in the main analyses due to the control group not being clearly classifiable [64]. Of note, a sensitivity analysis including this study did not show significant differences. Meta-analysis of ten studies (12 comparisons) showed a non-significant effect favoring psychological interventions for the reduction of DD compared to educational interventions (without psychological component) (-0.29 (95% CI: -0.98 to 0.39)) (figure 4a). The respective GRADE evidence profile is shown in figure 4g. Additional subgroup analyses revealed no significant subgroup effects by baseline DD, study duration, intervention delivery format or risk of bias score ($p > 0.05$).

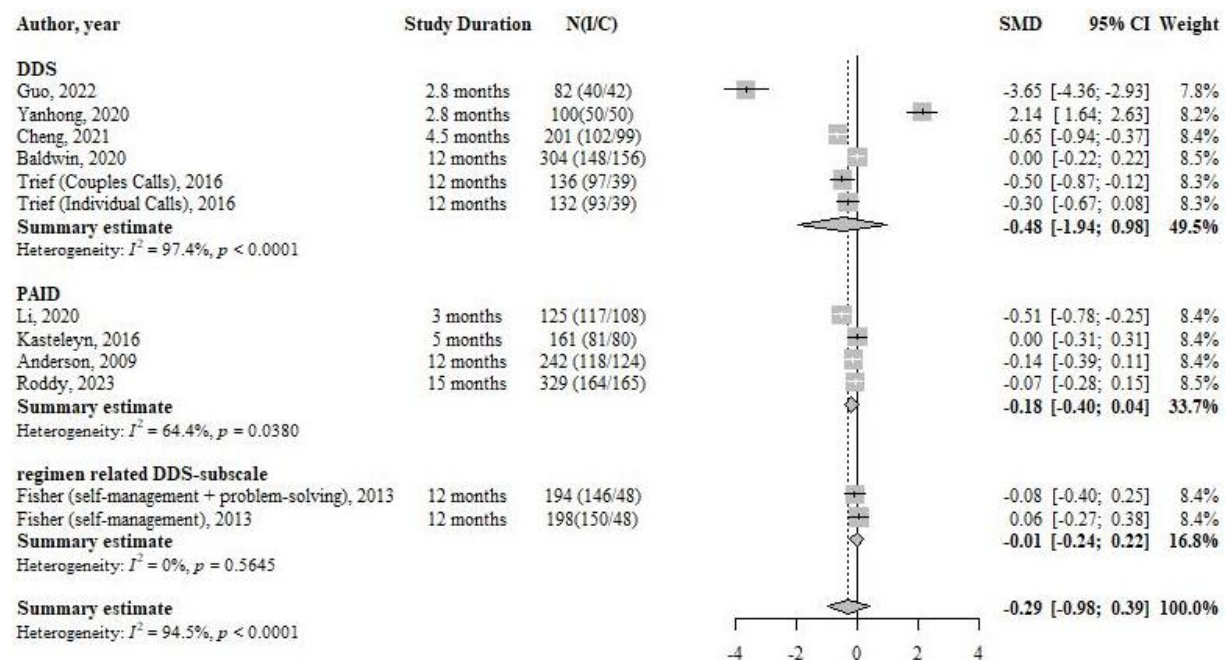


Figure 4a: Standardized mean difference for psychological interventions compared to educational interventions for T2D

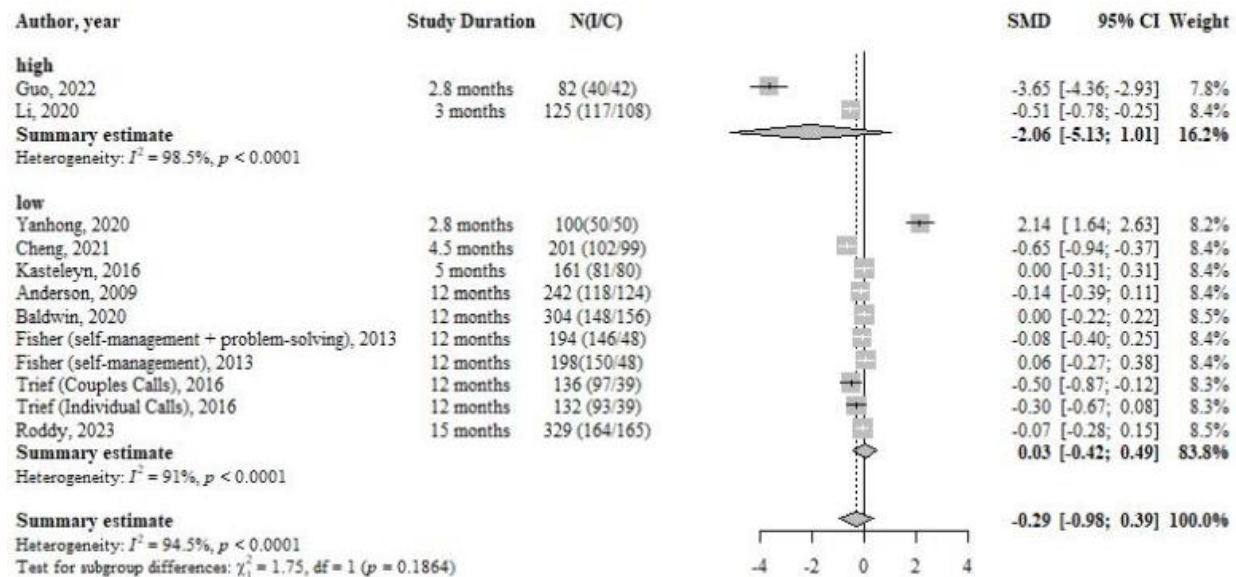


Figure 4b: Standardized mean difference subgroup analysis for psychological interventions compared to educational interventions for T2D stratified by baseline distress level

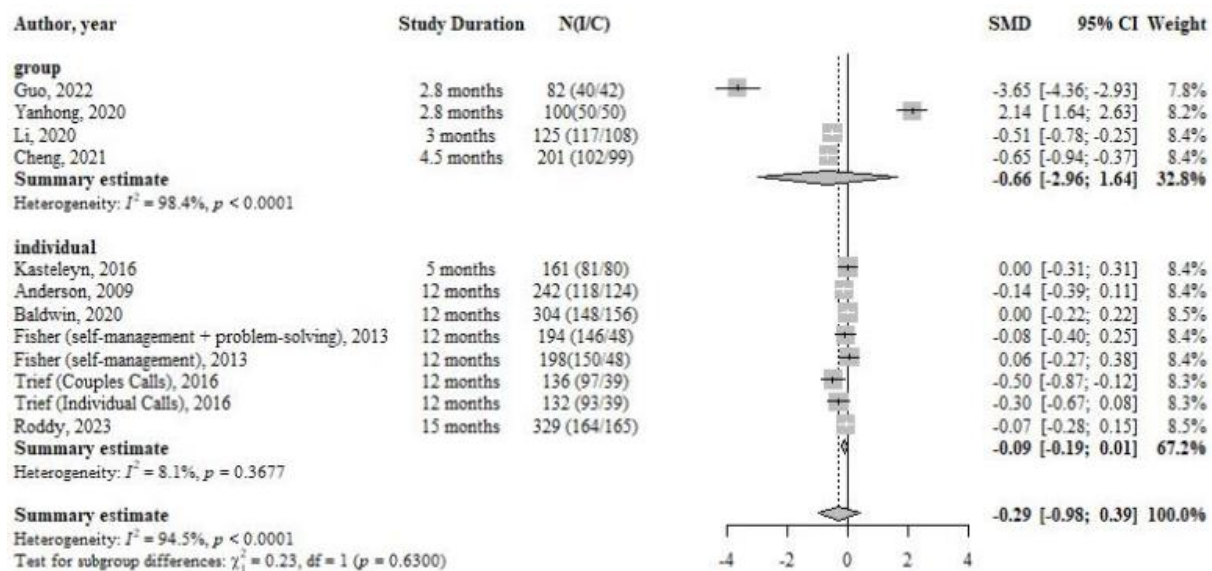


Figure 4c: Standardized mean difference subgroup analysis for psychological interventions compared to educational interventions for T2D stratified by delivery format

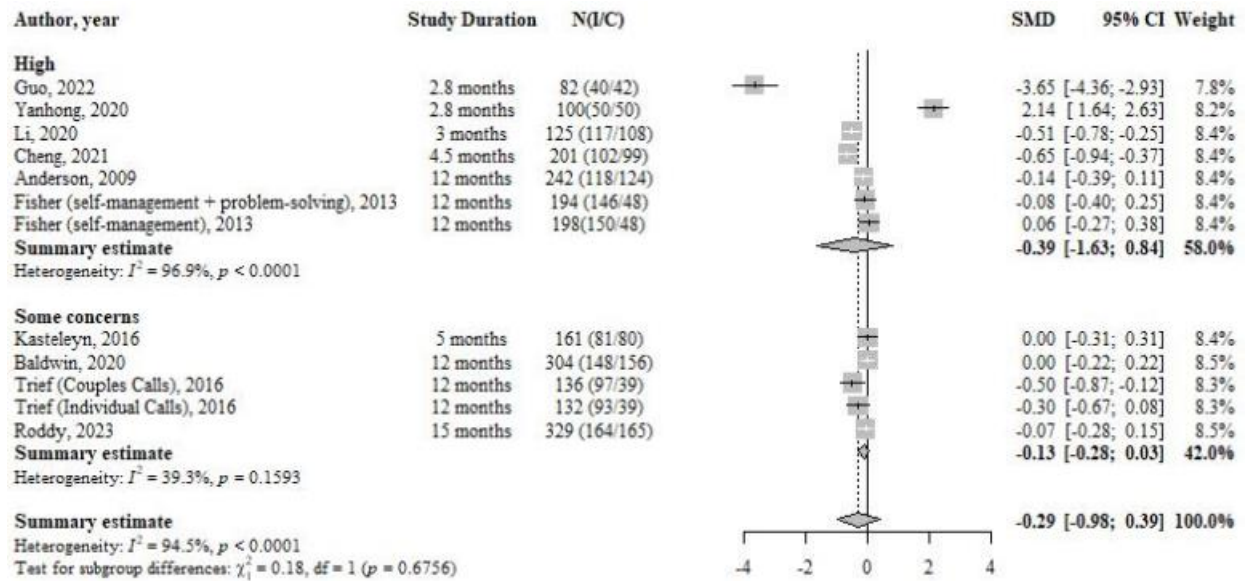


Figure 4d: Standardized mean difference subgroup analysis for psychological interventions compared to educational interventions for T2D stratified by risk of bias assessment

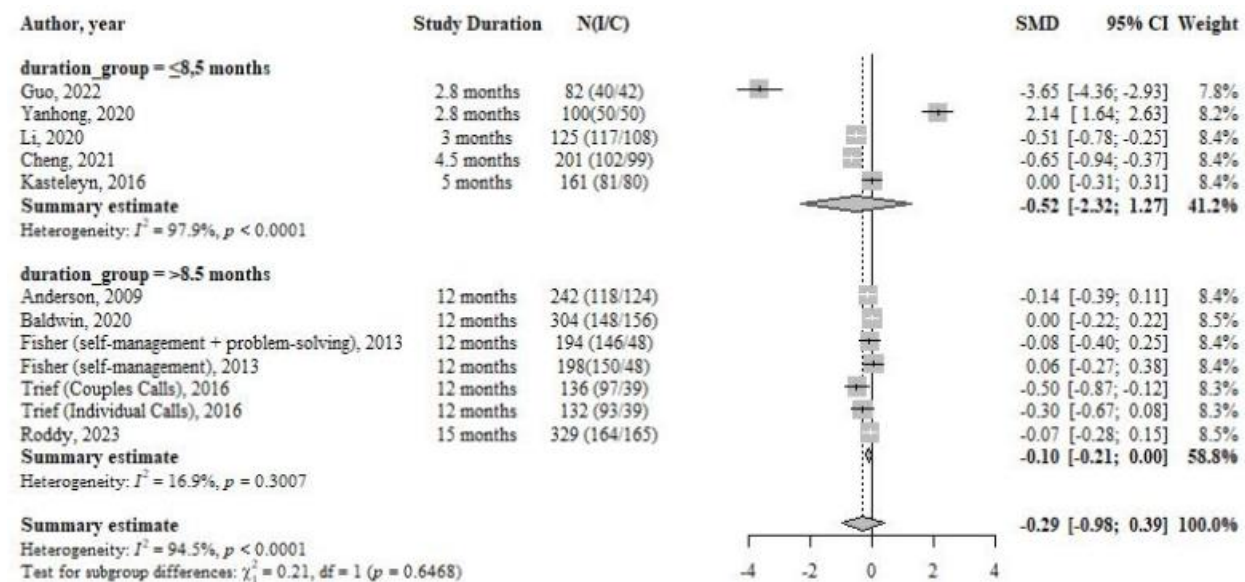


Figure 4e: Standardized mean difference subgroup analysis for psychological interventions compared to educational interventions for T2D stratified by study duration

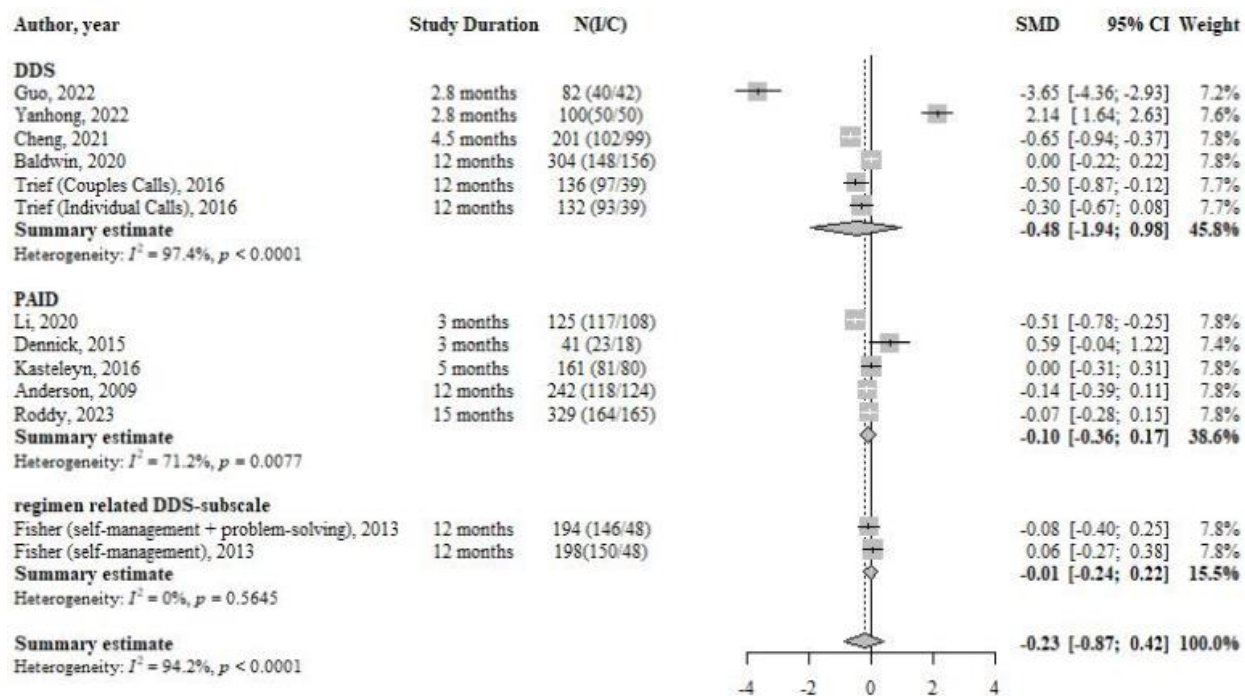


Figure 4f: Standardized mean difference sensitivity analysis for psychological interventions compared to educational interventions for T2D including the study of Dennick et al.

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 2.8 months to 15 months; assessed with: DDS-PAID)												
10	randomised trials	very serious ^a	very serious ^b	serious ^c	very serious ^d	none	1359	1060	-	SMD 0.29 SD lower (0.98 lower to 0.39 higher)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL

CI: confidence interval; SMD: standardised mean difference

Explanations

a. Most at high risk of bias

b. Very high $I^2 = 94.5\%$

c. different comparators, subgroup effect among outcome scales,

d. CI crosses MCID for benefit (-0.5) and for harm (0.5)

Figure 4g: GRADE evidence profile for psychological interventions compared to educational interventions for T2D

Psychological interventions compared to usual care for type 2 diabetes

Twenty seven studies were found that compared psychological interventions to usual care in adults with T2D [21, 41-43, 46, 48, 53, 66-85]. Of these, 21 studies were included in the meta-analysis, in which a significant effect in favor of psychological interventions was found for the reduction of DD (-0.31 (95% CI: -0.50 to -0.13)) (figure 5) [21, 41-43, 46, 48, 53, 66, 67, 69, 71-80, 85]. The respective GRADE evidence profile is shown in figure 5f. Subgroup analyses revealed no significant subgroup effects by baseline DD, study duration, intervention delivery format or risk of bias score ($P > 0.05$). Narrative analysis of the six studies that could not be included in the meta-analysis, all showed a similar effect as the meta-analysis of psychological interventions in the reduction of DD [68, 70, 81-84].

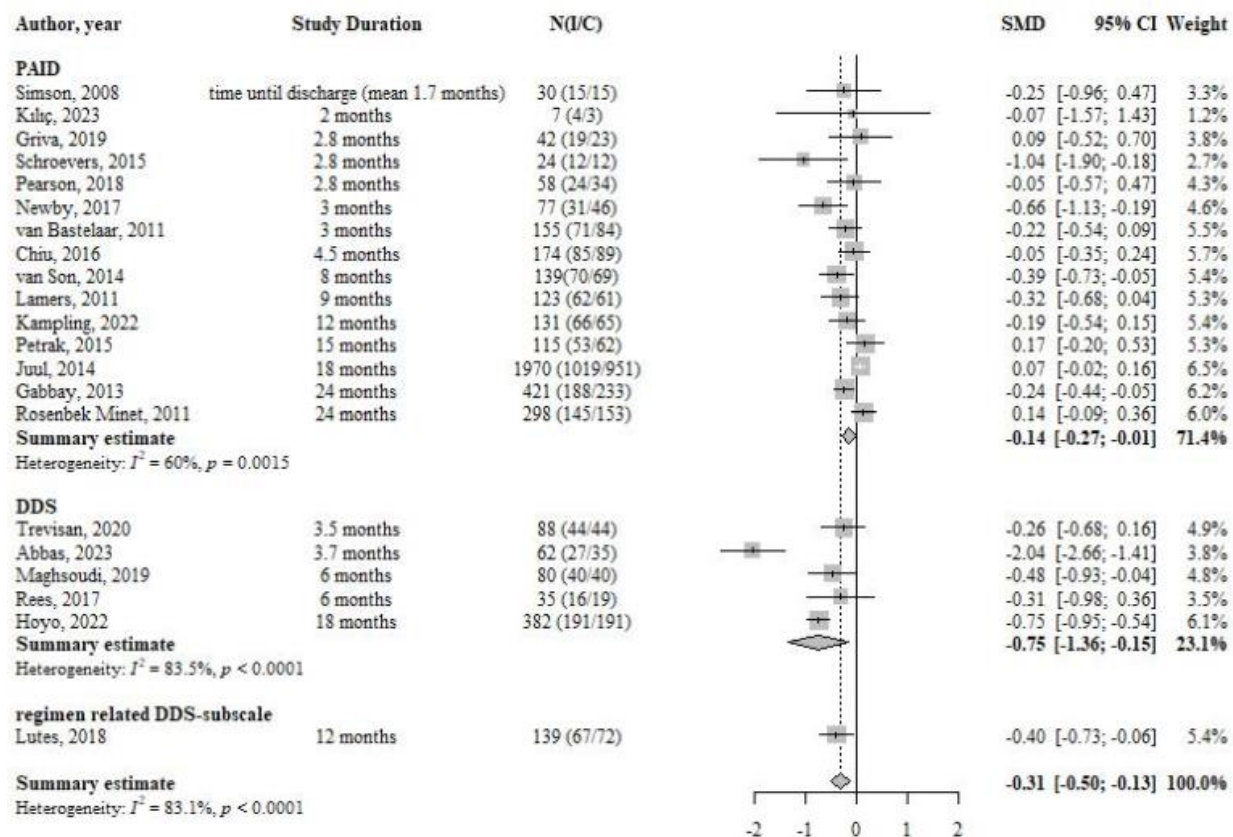


Figure 5: Standardized mean difference for psychological interventions compared to usual care for T2D

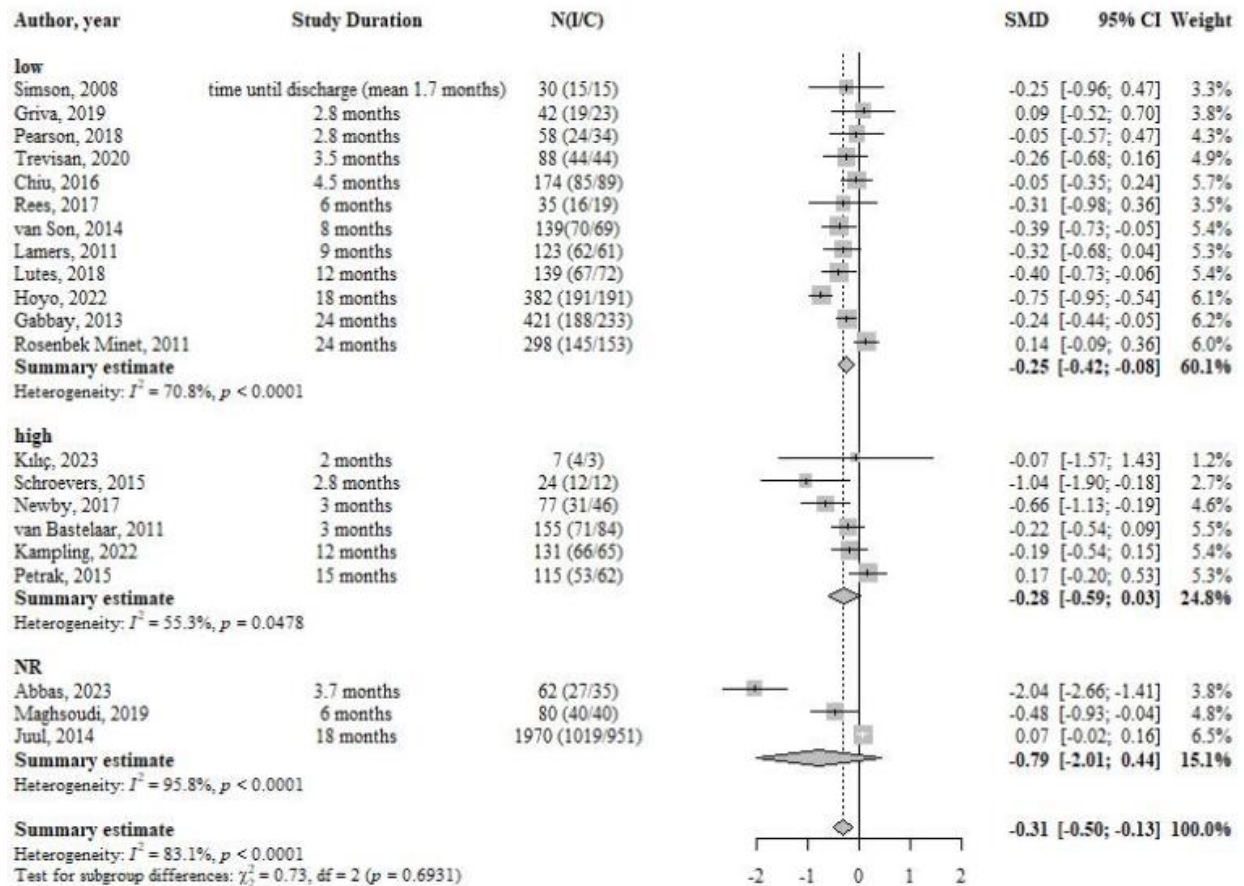


Figure 5b: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T2D stratified by baseline distress level

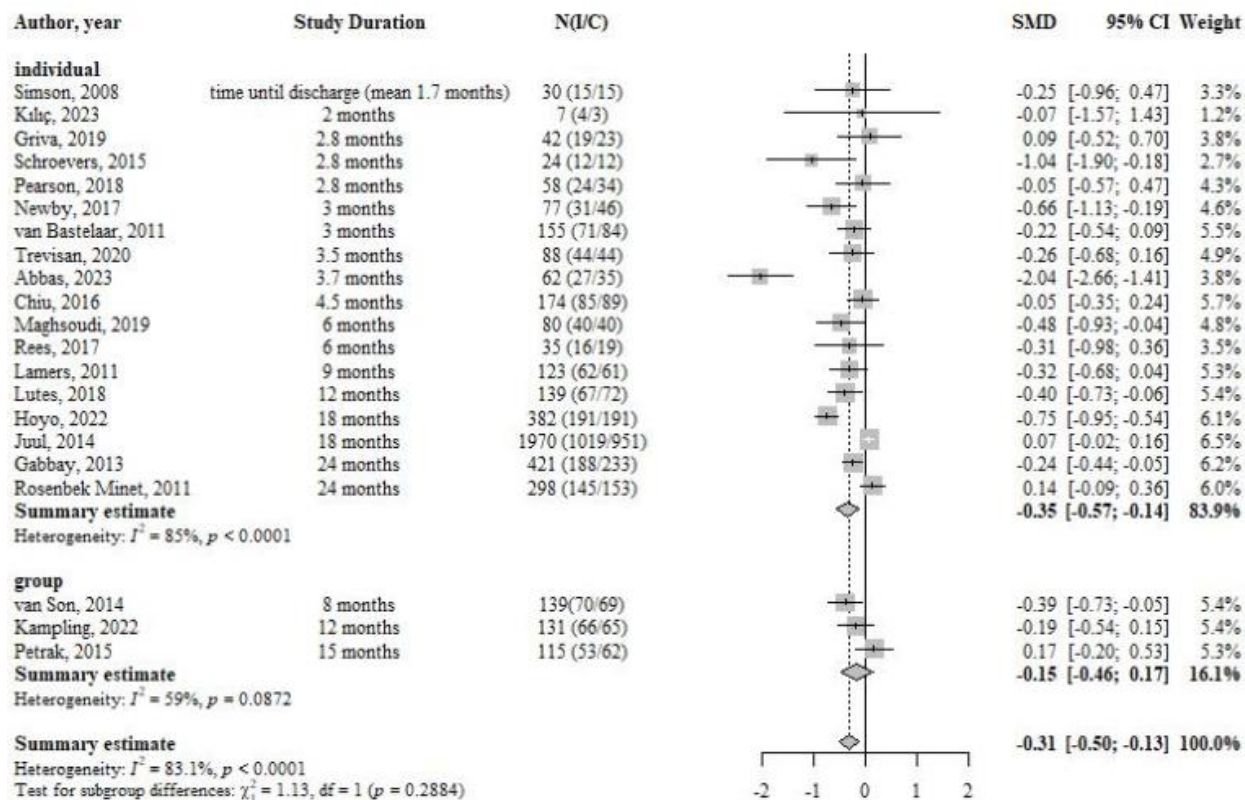


Figure 5c: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T2D stratified by risk of delivery format

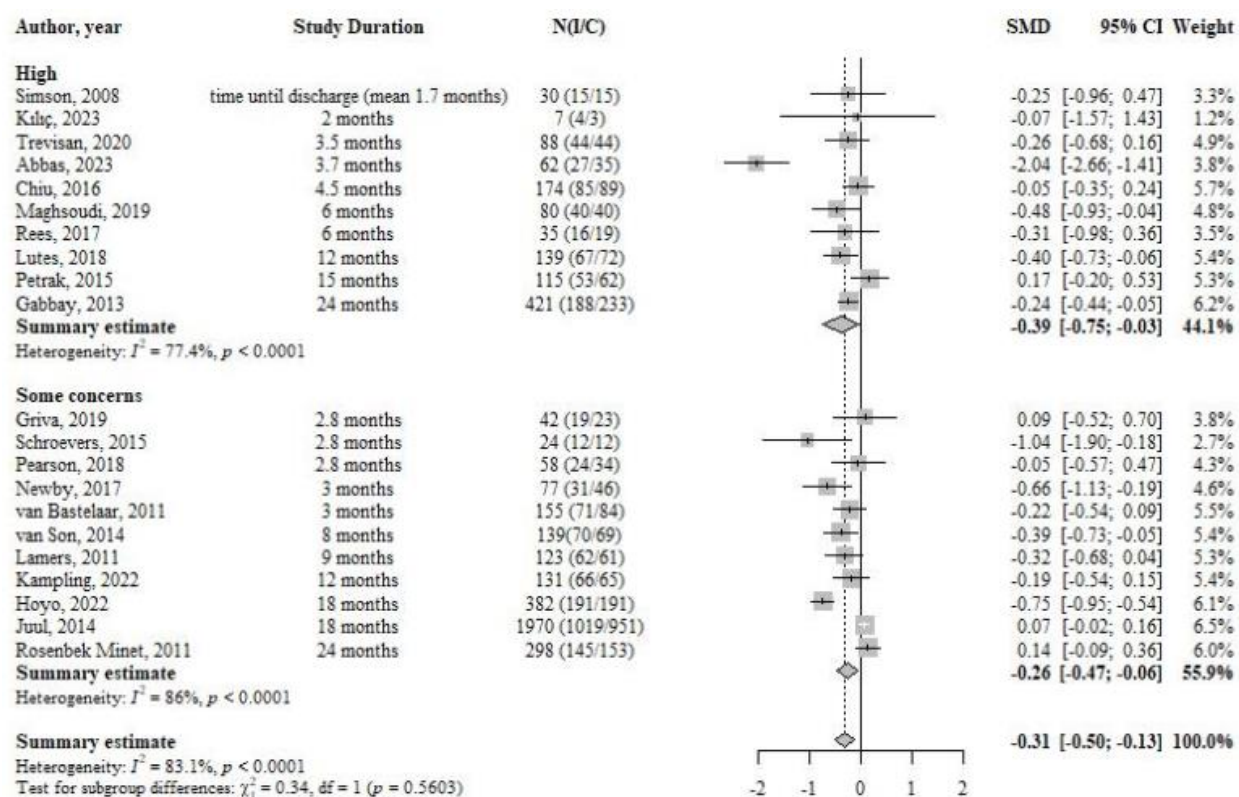


Figure 5d: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T2D stratified by risk of bias assessment

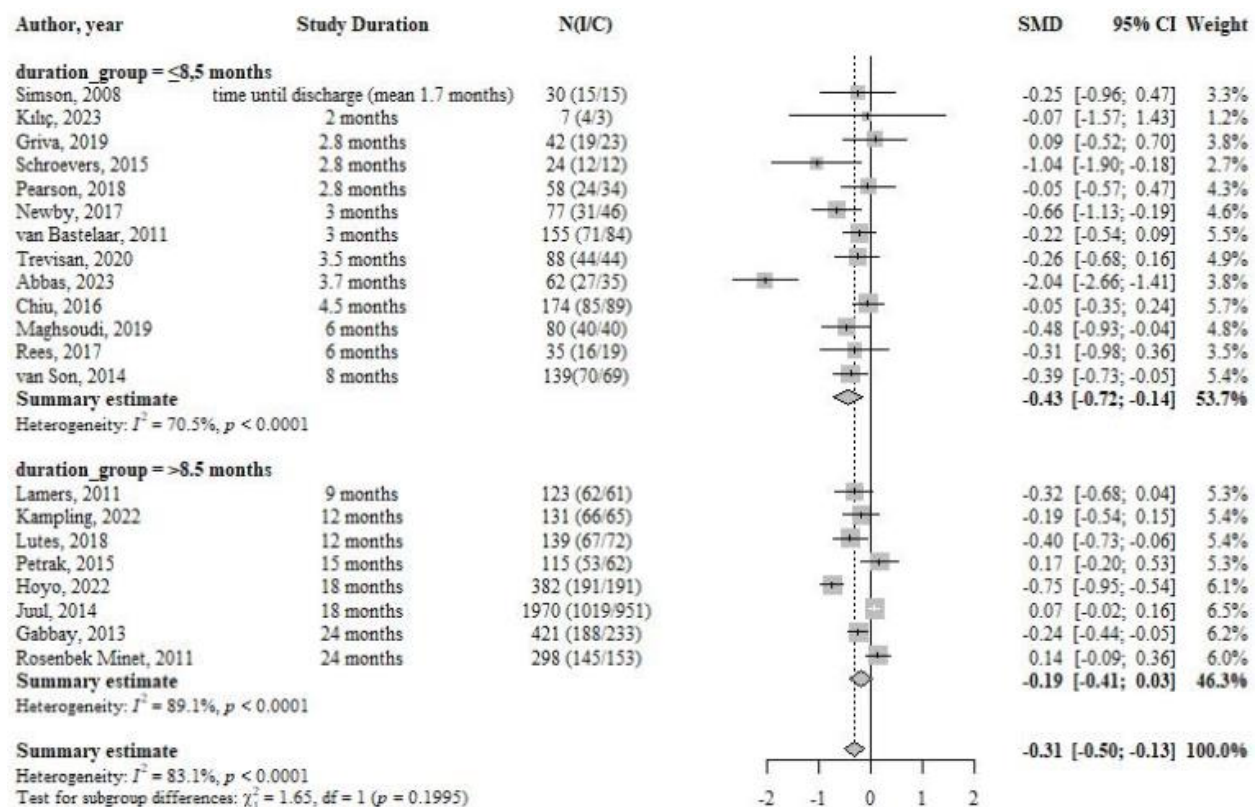


Figure 5e: Standardized mean difference subgroup analysis for psychological interventions compared to usual care for T2D stratified by study duration

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 1.7 months to 24 months; assessed with: DDS-PAID)												
21	randomised trials	very serious ^a	very serious ^b	not serious ^c	serious ^d	none	2196	2239	-	SMD 0.31 SD lower (0.5 lower to 0.13 lower)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL

CI: confidence interval; SMD: standardised mean difference

Explanations

a. ROB: Many studies at high risk

b. inconsistency: I^2 83.1%

c. different types of psychological interventions, however not considered a reason to downgrade

d. Imprecision: CI crosses MCID (0.3) and does not cross null effect

Figure 5f: GRADE evidence profile for psychological interventions compared to usual care for T2D

Psychoeducational interventions

Psychoeducational interventions compared to educational interventions for type 1 diabetes

Four studies were found that compared psychoeducational interventions to educational interventions (without psychological component) in adults with T1D [86-89]. Meta-analysis of three studies (figure 6a) showed a non-significant effect in favor of psychoeducational interventions (-0.02 (95% CI: -0.23 to 0.20)) for the reduction of DD [86-88]. The respective GRADE evidence profile is shown in figure 6f. Subgroup analyses revealed no significant subgroup effects by baseline DD, study duration, intervention delivery format or risk of bias score (P>0.05). Narrative analysis of the study that could not be included in the meta-analysis showed a similar favoring the psychoeducational interventions [89].

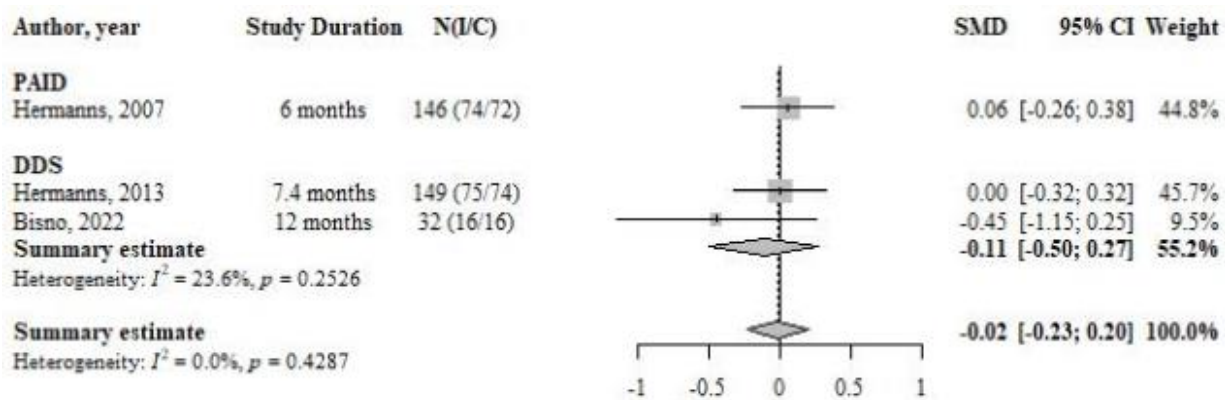


Figure 6a: Standardized mean difference for psychoeducational interventions compared to educational interventions for T1D

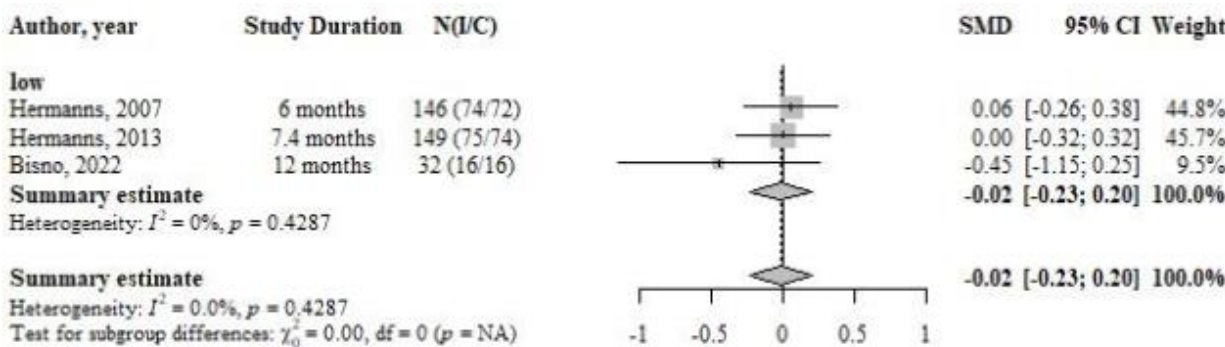


Figure 6b: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T1D stratified by baseline distress level

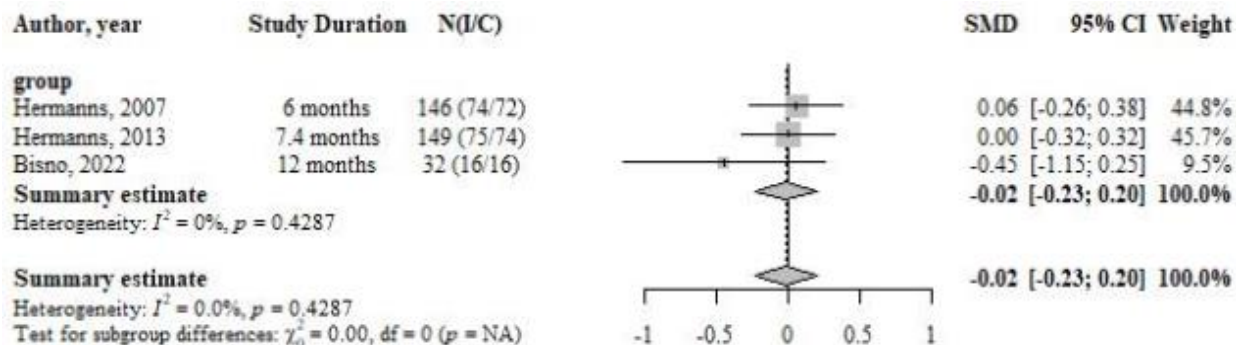


Figure 6c: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T1D stratified by delivery format

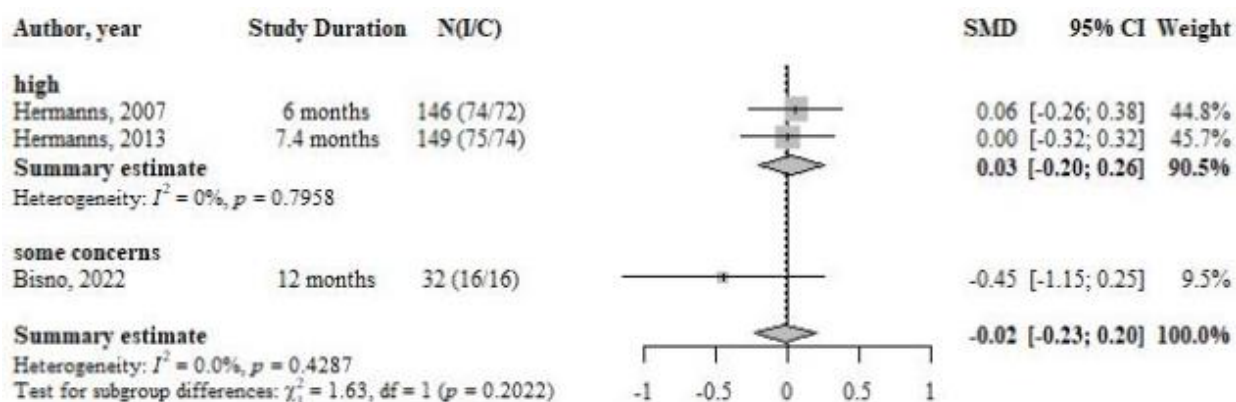


Figure 6d: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T1D stratified by risk of bias assessment

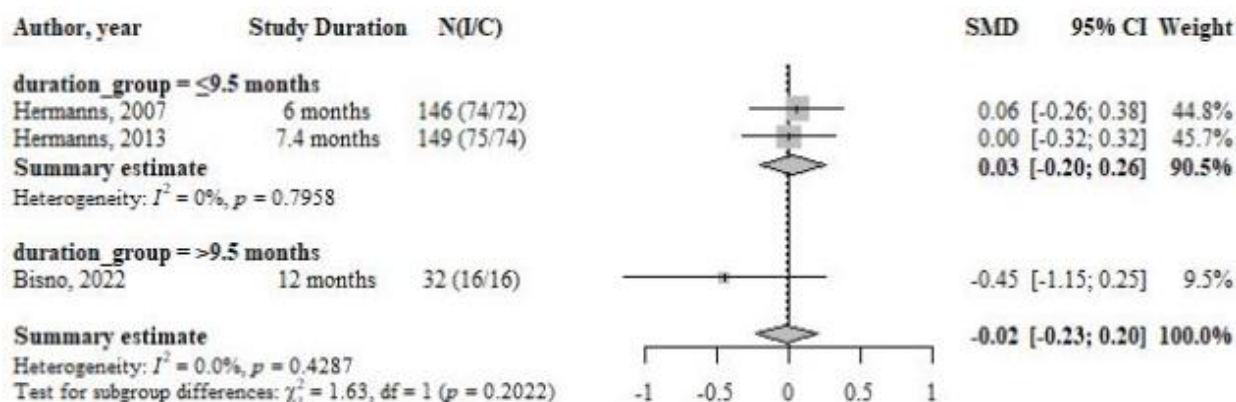


Figure 6e: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T1D stratified by study duration

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 6 months to 12 months; assessed with: DDS-PAID)												
3	randomised trials	very serious ^a	not serious ^b	not serious ^c	not serious ^d	none	165	162	-	SMD 0.02 SD lower (0.23 lower to 0.2 higher)	 Low ^{a,b,c,d}	CRITICAL

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. most studies at high rob
- b. $i^2 = 0$
- c. different comparators.
- d. CI crosses null but not MCID

Figure 6f: GRADE evidence profile for psychoeducational interventions compared to educational interventions for T1D

Psychoeducational interventions compared to usual care for type 1 diabetes

Six studies were found that compared psychoeducational interventions to usual care in adults with T1D [90-95]. Meta-analysis of two studies (figure 7a) showed a non-significant effect in favor of psychoeducational interventions (-0.17 (95%CI: -0.62 to 0.28) [92, 93]. The respective GRADE evidence profile is shown in figure 7b. No subgroup analyses were conducted due to only two studies being included in the meta-analysis. Narrative analysis of the other four studies also showed a small non-significant effect in the reduction of DD in favor of psychoeducational interventions [90, 91, 94, 95].

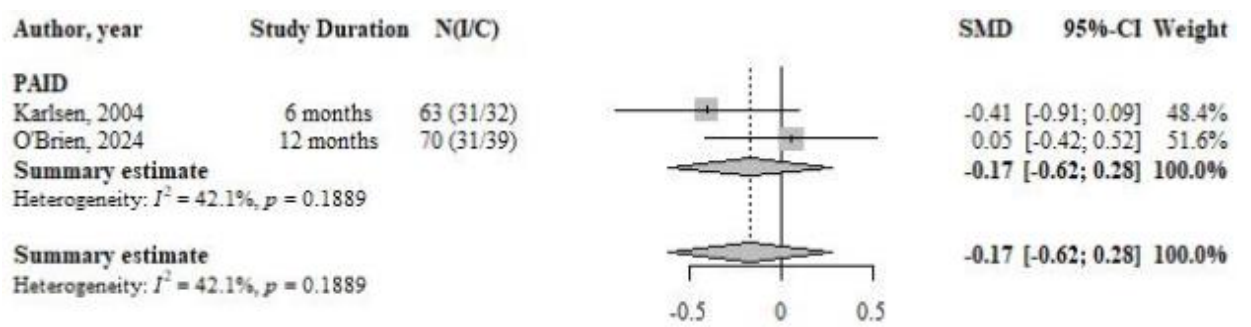


Figure 7a: Standardized mean difference for psychoeducation interventions compared to usual care T1D

Certainty assessment							N# of patients		Effect		Certainty	Importance
N# of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 12 months to 12 months; assessed with: DDS-PAID)												
2	randomised trials	serious ^a	serious ^b	serious ^c	serious ^d	none	62	71	-	SMD 0.17 SD lower (0.62 lower to 0.28 higher)	⊕○○○ Very low ^{a,b,c,d}	

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. Some concerns in both studies
- b. I2 42.1% with no large effect (serious)
- c. some variations in psychoeducational interventions
- d. CI crosses -MCID and null but not +MCID

Figure 7b: GRADE evidence profile for psychoeducational interventions compared to usual care for T1D

Psychoeducational interventions compared to educational interventions in type 2 diabetes

Twenty studies were found that compared psychoeducational interventions to miscellaneous interventions in adults with T2D [89, 96-114]. Meta-analysis of 13 of these studies comparing psychoeducational interventions to educational interventions (without psychological component) showed a non-significant effect (-0.15 (95% CI: -0.34 to 0.03)) (figure 8a) in favor of psychoeducational interventions for reducing DD [96-98, 100, 102, 104-107, 111-114]. The respective GRADE evidence profile is shown in figure 8g. A sensitivity meta-analysis of the same 13 studies including an extra comparator arm (with a health behaviour intervention, i.e., walking) in one study showed a similar effect. Subgroup analyses revealed no significant subgroup effects by baseline DD, study duration, intervention delivery format or risk of bias score ($P > 0.05$). Narrative analysis of the seven studies that could not be included in the meta-analysis all showed a similar effect as the meta-analysis for the reduction of DD [89, 99, 101, 103, 108-110].

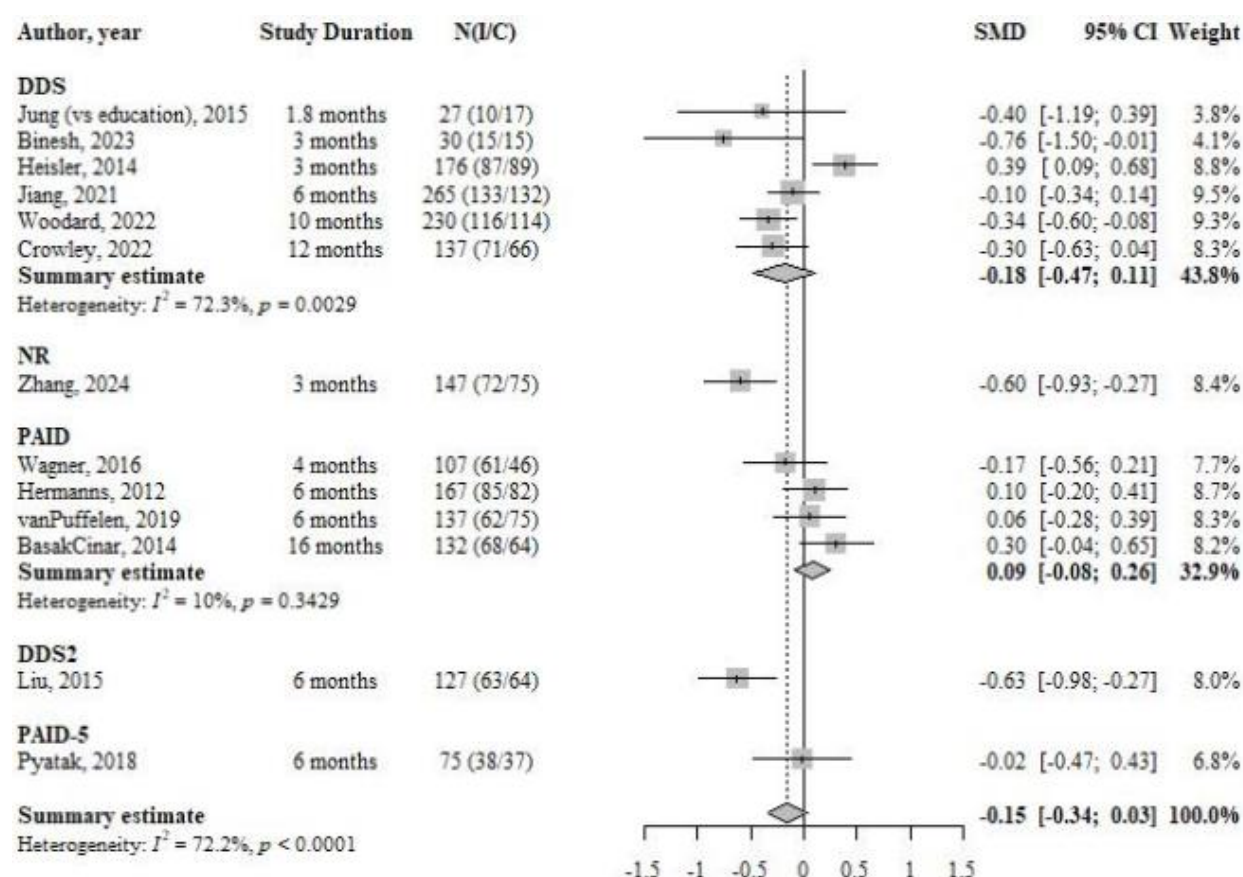


Figure 8a : Standardized mean difference for psychoeducational interventions compared to educational interventions for T2D

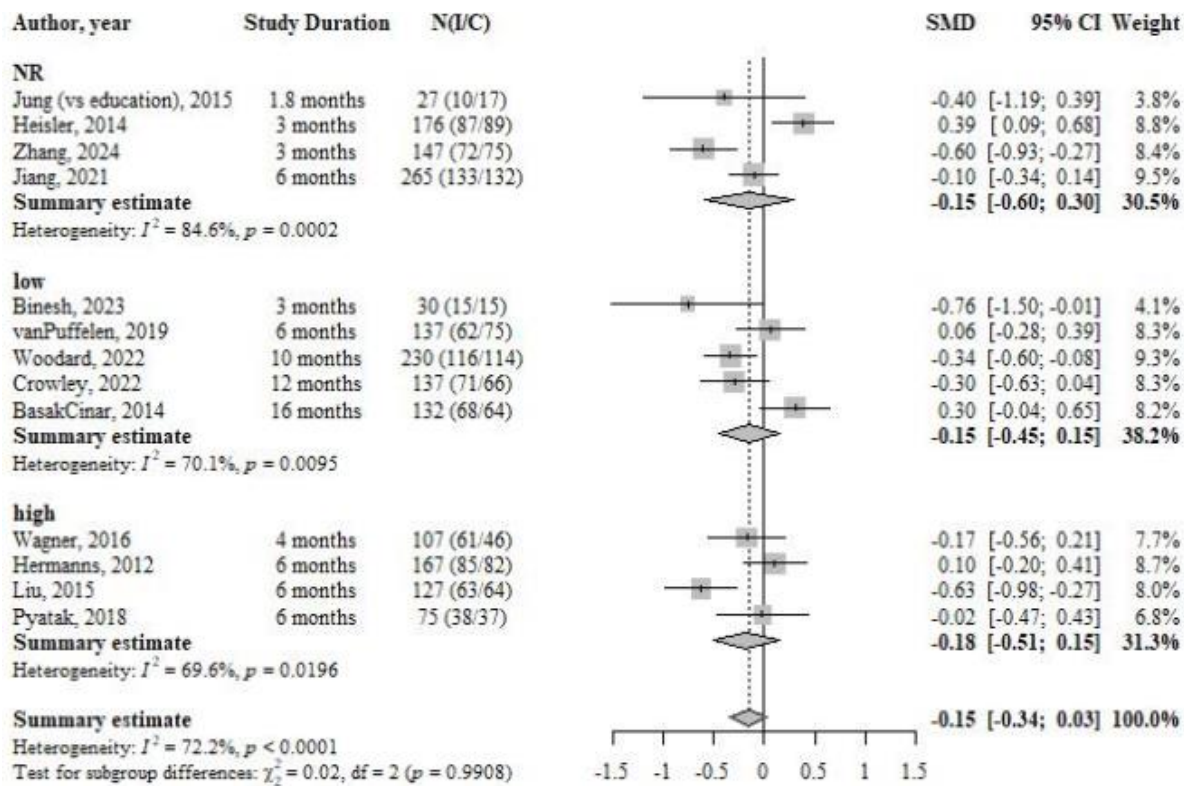


Figure 8b: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T2D stratified by baseline distress level

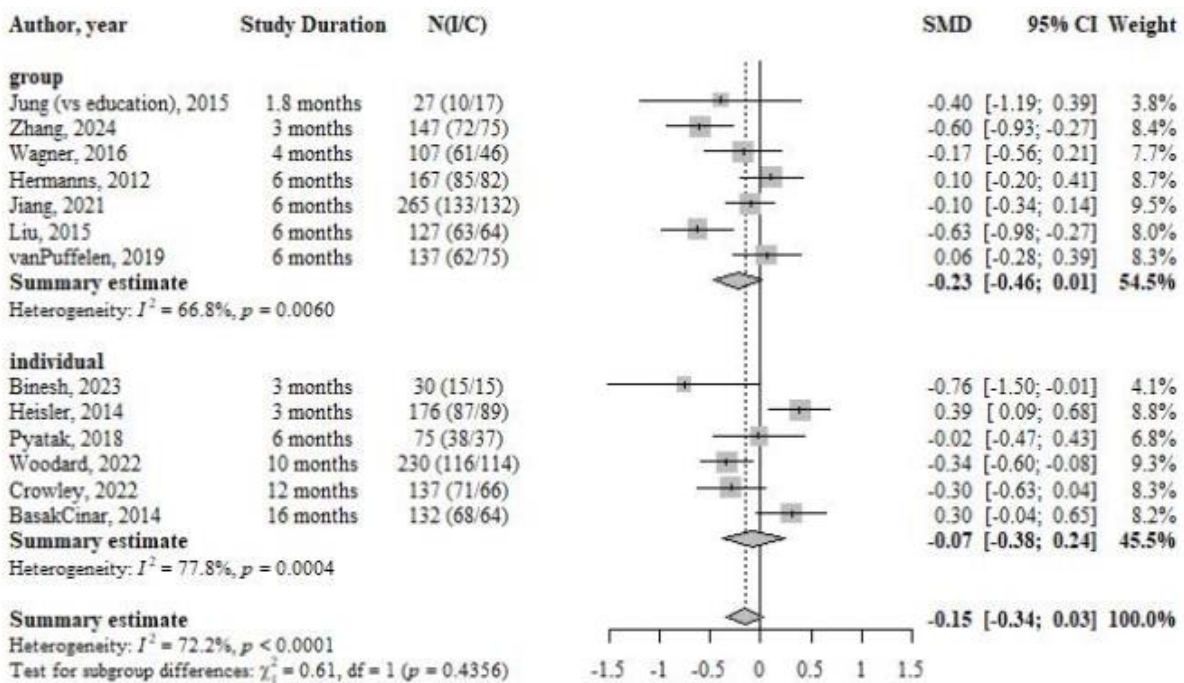


Figure 8c: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T2D stratified by delivery format

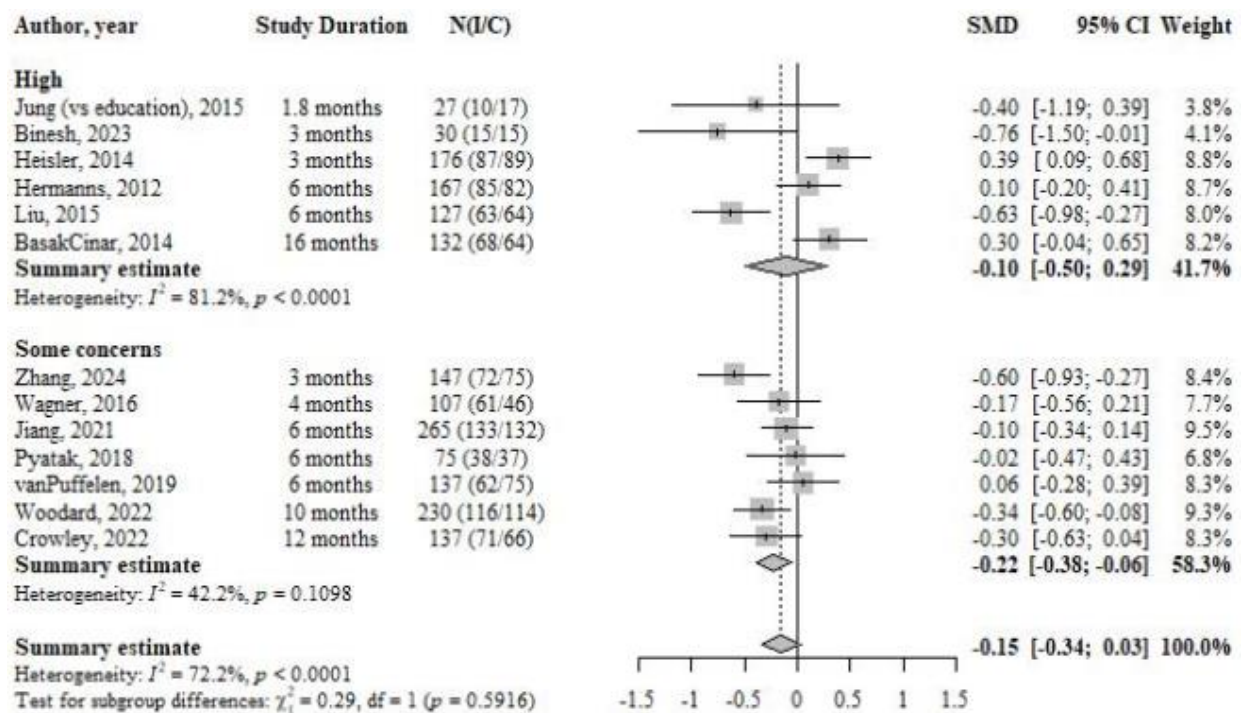


Figure 8d: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T2D stratified by risk of bias assessment

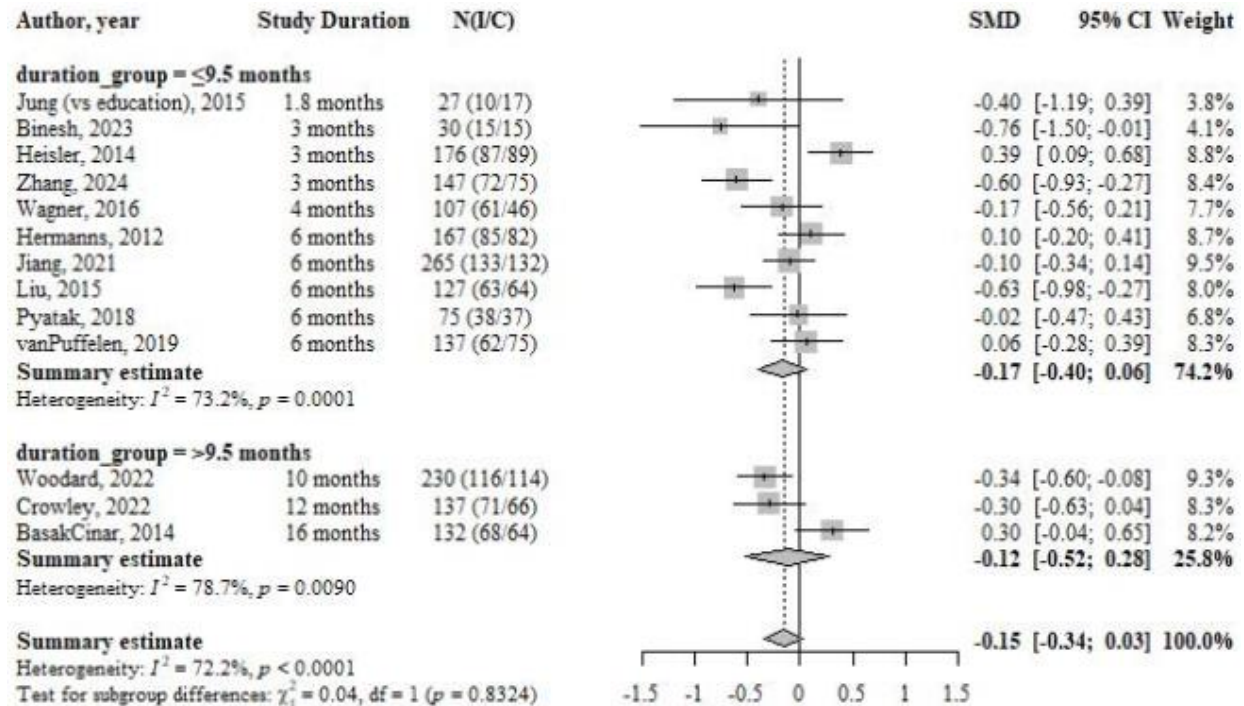


Figure 8e: Standardized mean difference subgroup analysis for psychoeducational interventions compared to educational interventions for T2D stratified by study duration

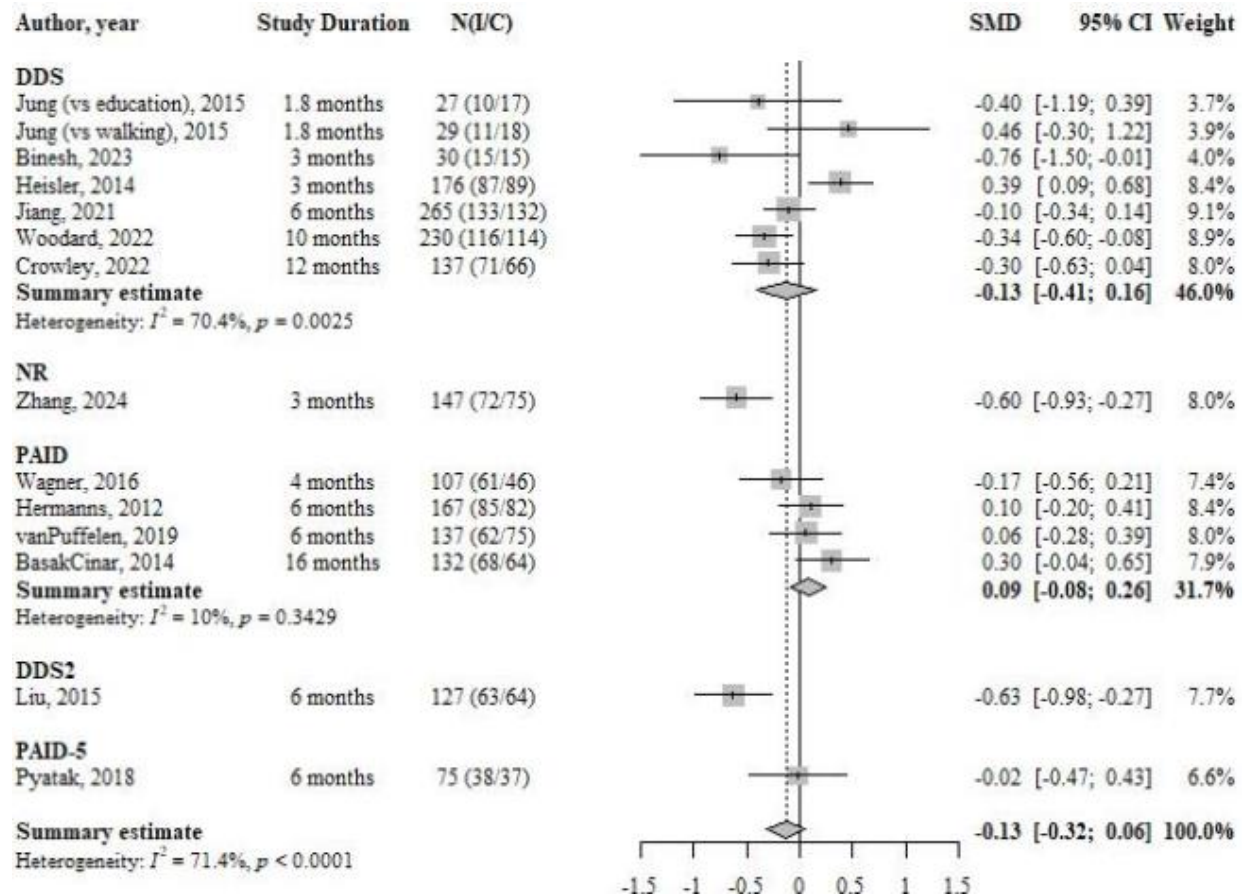


Figure 8f: Standardized mean difference sensitivity analysis for psychoeducational interventions compared to educational interventions for T2D including walking arm

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 1.8 months to 16 months; assessed with: SMD DDS-PAID)												
13	randomised trials	very serious ^a	very serious ^a	serious ^c	not serious ^d	none	881	812	-	SMD 0.15 SD lower (0.34 lower to 0.03 higher)	⊕○○○ Very low ^{a,b,c,d}	

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. almost half studies at high rob
- b. $i^2 = 72.2\%$
- c. different comparators and interventions
- d. CI crosses null but not MCID

Figure 8g: GRADE evidence profile for psychoeducational interventions compared to educational interventions for T2D

Psychoeducational interventions compared to usual care in type 2 diabetes

Thirty six studies were found that compare psychoeducational interventions to usual care in adults with T2D [26, 92-94, 115-146]. Of these, we could meta-analyze 23 studies, including 26 comparisons (figure 9a), in which we found a non-significant effect (-0.19 (95% CI: -0.40 to 0.02)) in favor of psychoeducational interventions for reducing DD [26, 93, 115, 118-121, 123, 124, 126-129, 131, 134-136, 138, 140, 143-145]. The respective GRADE evidence profile is shown in figure 9f. Subgroup analyses revealed no significant subgroup effects by baseline DD, intervention delivery format, study duration or risk of bias score ($P > 0.05$). Narrative analysis of the thirteen studies that could not be included in the meta-analysis, all showed a similar effect in the reduction of DD.

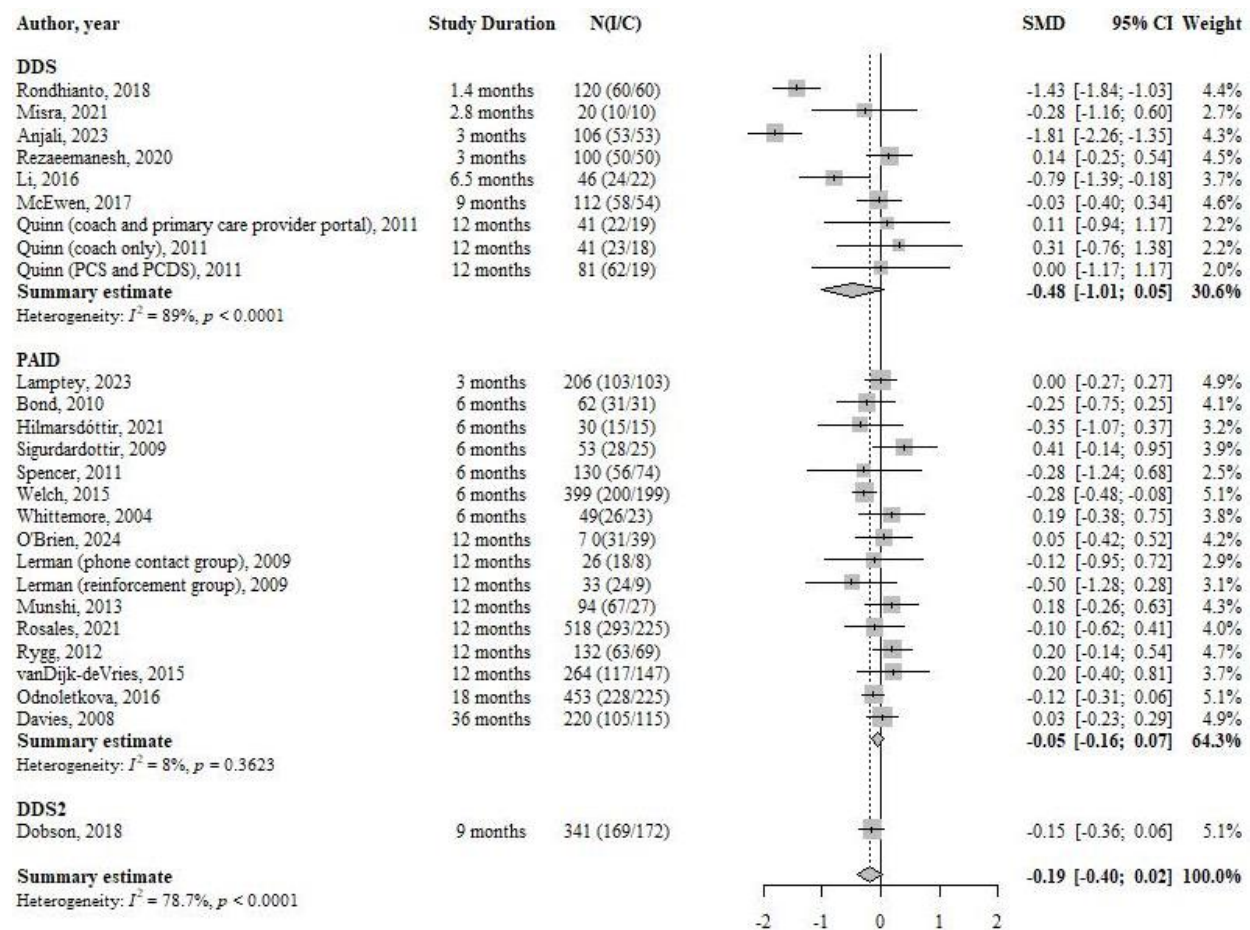


Figure 9a: Standardized mean difference for psychoeducational interventions compared to usual care for T2D

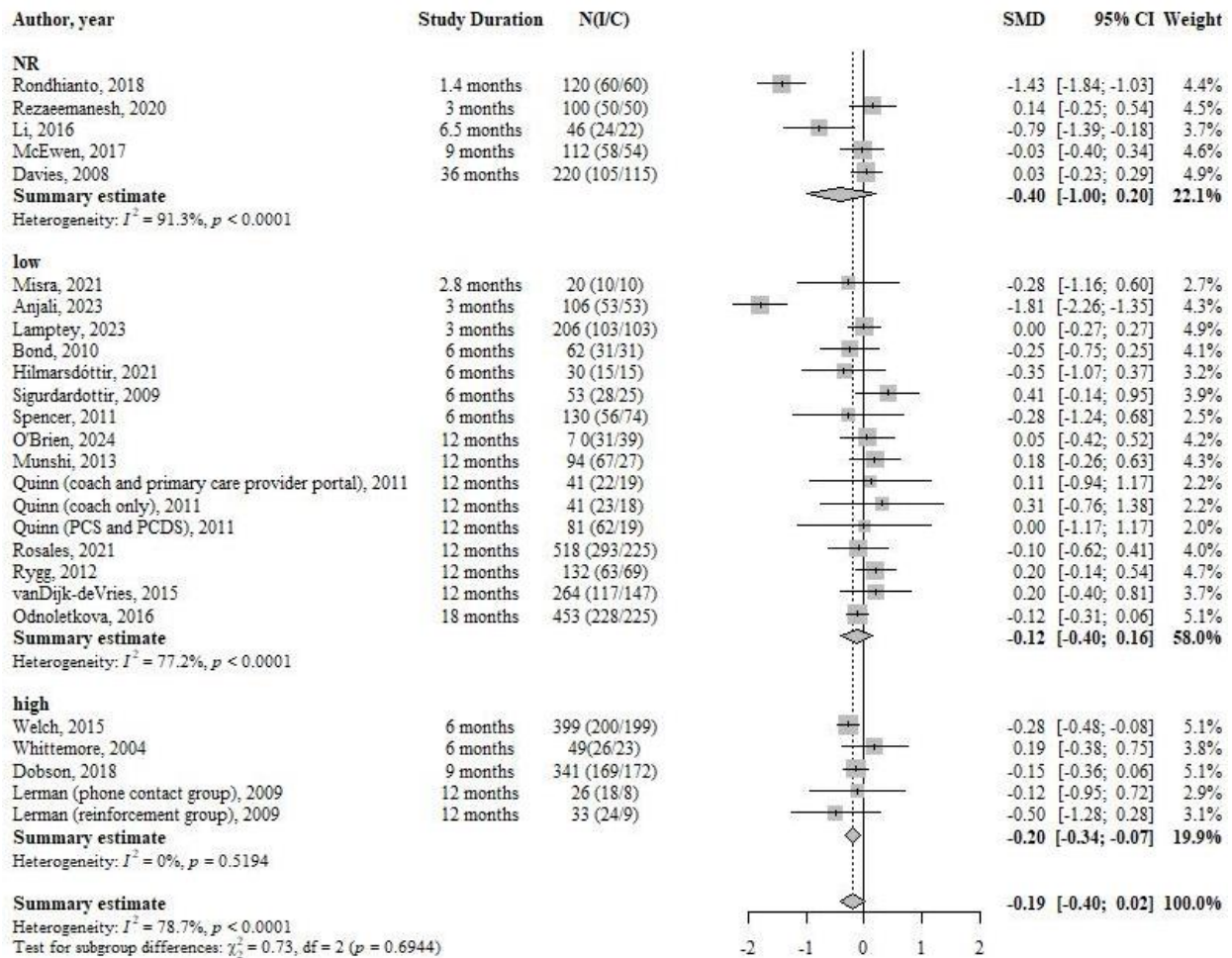


Figure 9b: Standardized mean difference subgroup analysis for psychoeducational interventions compared to usual care for T2D stratified by baseline distress level

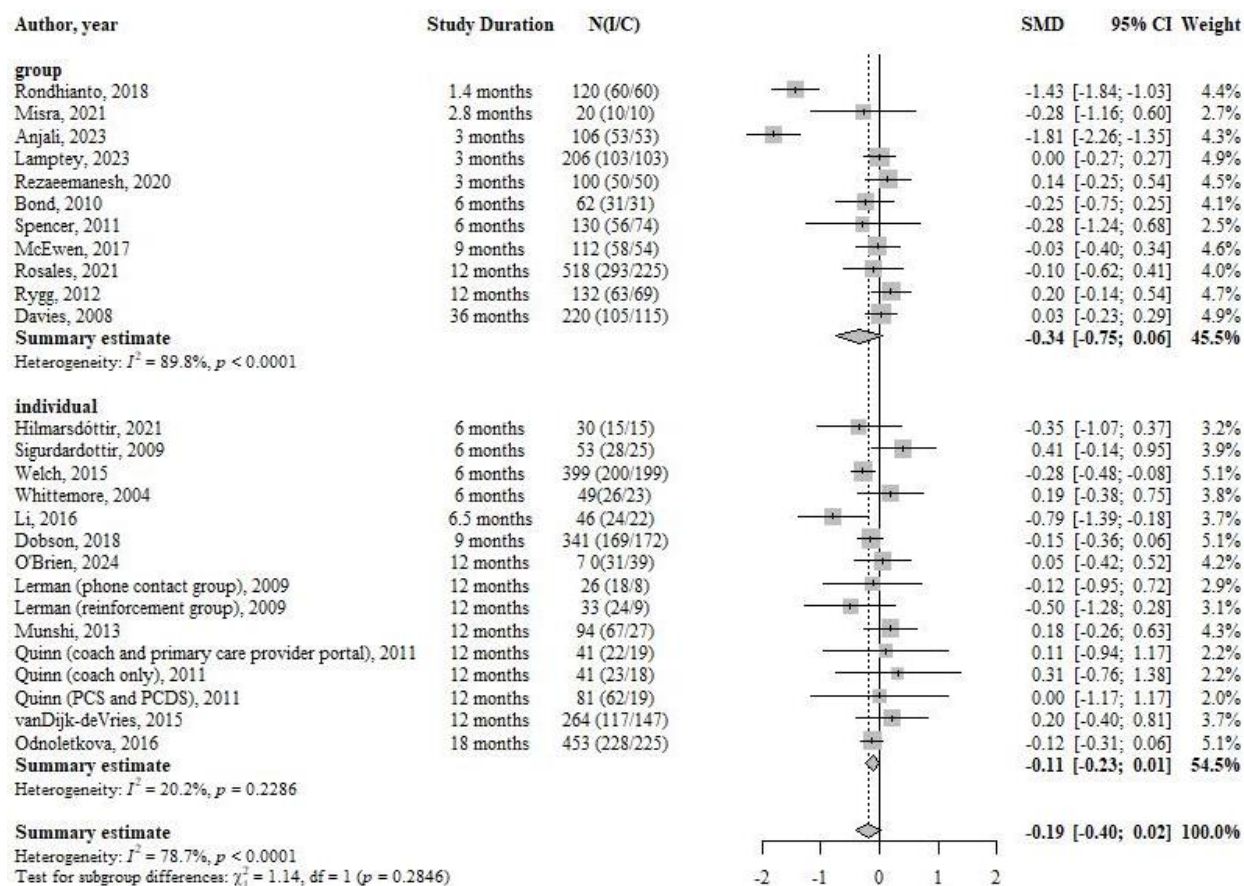


Figure 9c: Standardized mean difference subgroup analysis for psychoeducational interventions compared to usual care for T2D stratified by delivery format

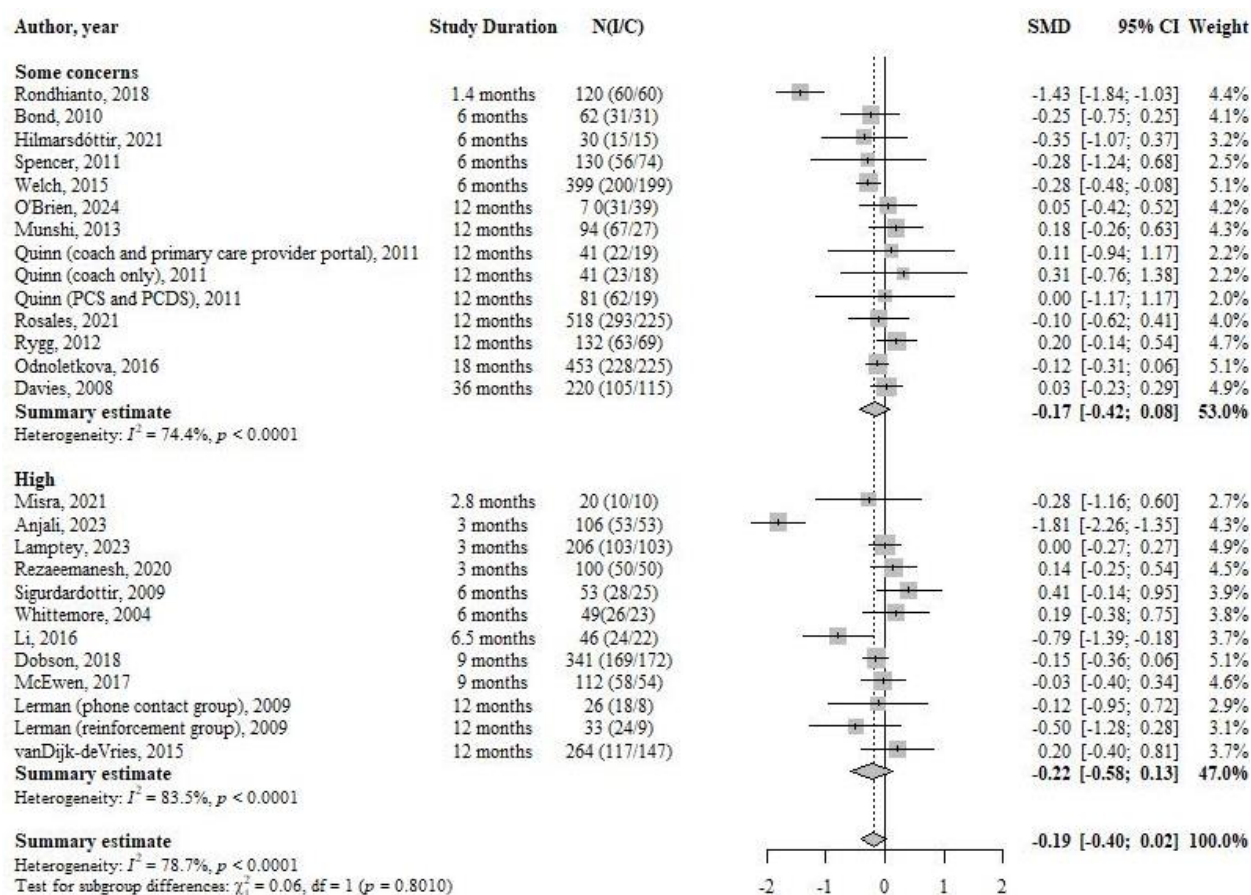


Figure 9d: Standardized mean difference subgroup analysis for psychoeducational interventions compared to usual care for T2D stratified by risk of bias assessment

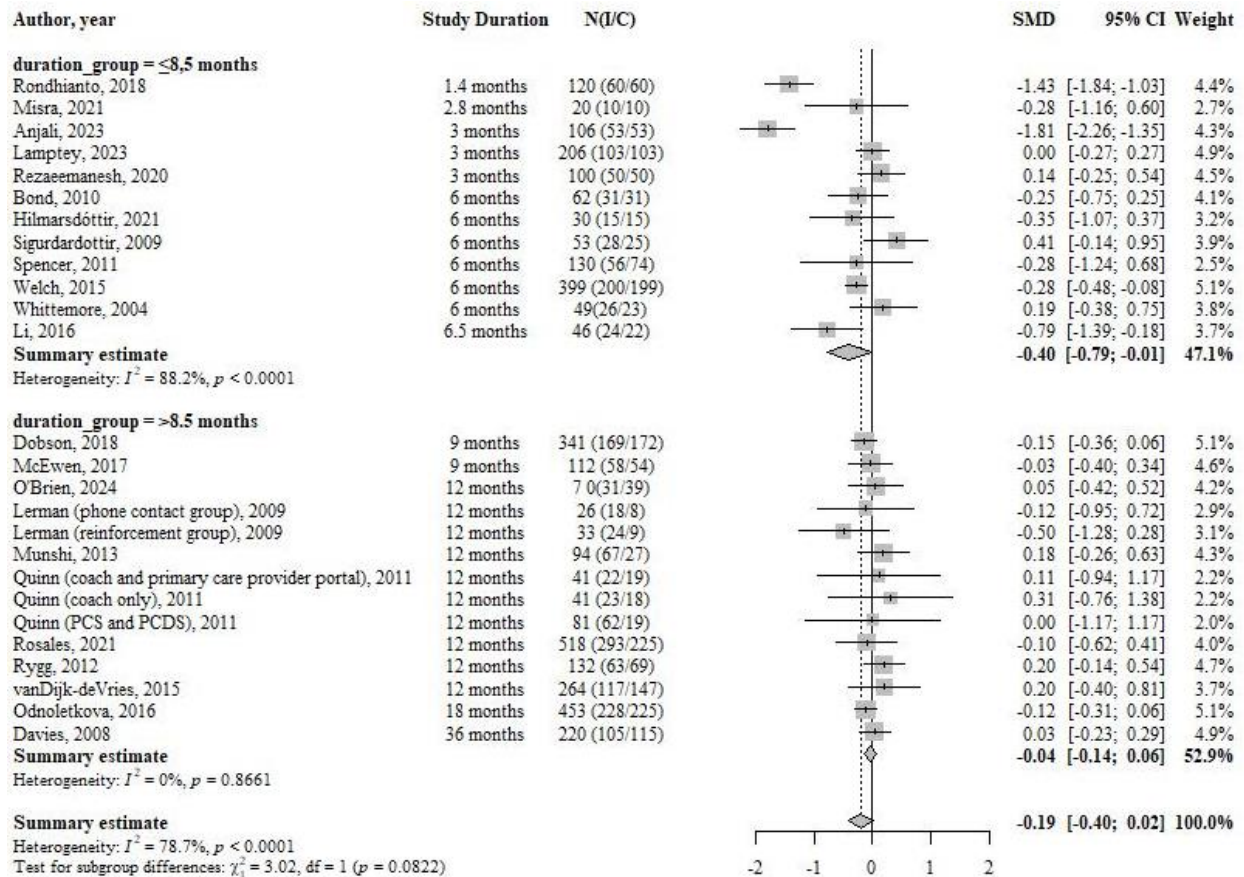


Figure 9e: Standardized mean difference subgroup analysis for psychoeducational interventions compared to usual care for T2D stratified by study duration

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID T2D overall (follow-up: range 1.4 months to 36 months; assessed with: SMD DDS-PAID)												
23	randomised trials	very serious ^a	very serious ^b	serious ^c	serious ^d	none	1880	1737	-	SMD 0.19 SD lower (0.40 lower to 0.02 higher)	⊕○○○ Very low ^{a,b,c,d}	

CI: confidence interval; SMD: standardised mean difference

Explanations

a. almost half studies at high rob

b. $I^2 = 78.7\%$

c. heterogenous interventions

d. CI crosses MCID and does not cross null effect

Figure 9f: GRADE evidence profile for psychoeducational interventions compared to usual care for T2D

Miscellaneous interventions

Due to the small number of studies in certain subcategories and heterogeneity in others, we only meta-analyzed the interventions focusing on devices, peer support (without psychological component) and education (without psychological component). The other subcategories (telehealth, complex health service interventions, health behaviour interventions, methods of insulin titration, medications, surgery, PROMS) were described narratively.

Devices in T1D

Twenty-one studies were found that compared different methods on glucose monitoring and insulin delivery devices in adults with T1D, including studies on self-monitoring, intermittently scanned glucose monitoring, Continuous Glucose Monitoring (CGM), bionic pancreas and hybrid loops. These studies include automated insulin delivery (AID), compared to no use of AID [147-153], CGM compared to other types of CGM or Flash glucose monitoring [154-157], and CGM/ flash glucose monitoring compared to capillary glucose monitoring [158-167].

Automated insulin delivery compared to no automated insulin delivery

Seven studies were found that compared AID to no use of AID in T1D [147-153]. Meta-analysis of five of these studies showed a non-significant effect (-0.15 (95% CI: -0.33 to 0.02)) in favor of AID for reducing DD in T1D (figure 10a) [147-153]. The respective GRADE evidence profile is shown in figure 10d.

Subgroup analyses revealed no significant subgroup effects by baseline DD, study duration or risk of bias score ($P > 0.05$). Narrative analysis of the other two studies found one study in favor of automated insulin delivery and one not in favor [147, 152].

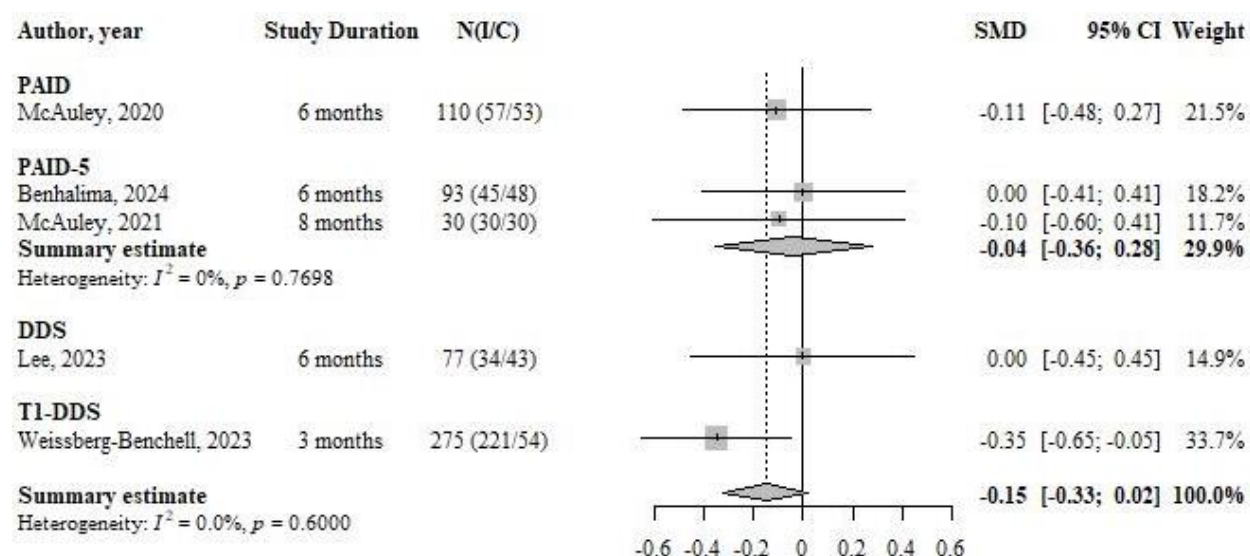


Figure 10a: Standardized mean difference for AID compared to no use of AID in T1D

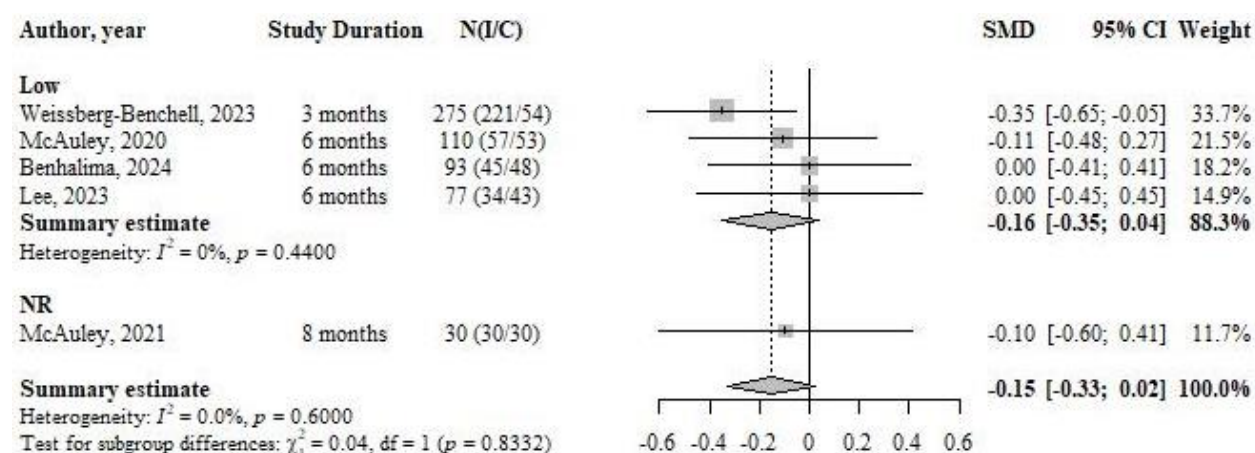


Figure 10b: Standardized mean difference subgroup analysis for AID compared to no use of AID in T1D stratified by baseline distress level

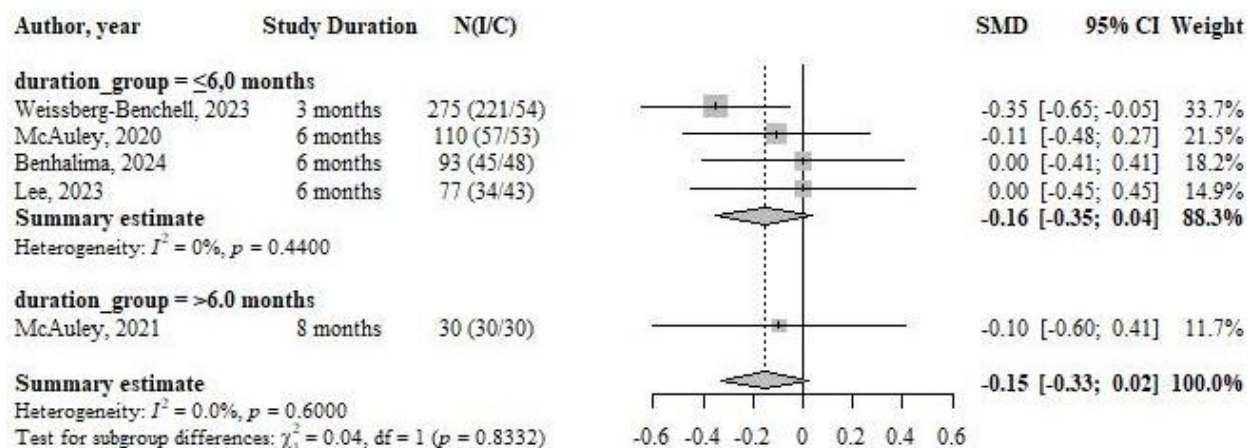


Figure 10c: Standardized mean difference subgroup analysis for AID compared to no use of AID in T1D stratified by study duration

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Automated insulin delivery systems	no use of automated insulin delivery systems	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 6 months to 6 months; assessed with: DDS-PAID)												
5	randomised trials	serious ^a	not serious ^b	not serious ^c	not serious ^d	none	387	198	-	SMD 0.15 SD lower (0.33 lower to 0.02 higher)	⊕⊕⊕○ Moderate ^{a,b,c,d}	IMPORTANT

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. some concerns, no interaction by ROB
- b. $I^2 = 0.0\%$
- c. check detailed assessment
- d. CI crosses MCID and null effect.

Figure 10d: GRADE evidence profile for AID compared to no use of AID in T1D

Continuous glucose monitoring compared to other types of continuous glucose monitoring or intermittently scanned monitoring

Narrative analysis of four studies comparing different CGM and insulin delivery methods showed no significant differences when implanted glucose sensors were compared to wearable ones, when access to live CGM data was compared to retrospective access, when CGMs with hypoglycemia alerts was

compared to CGMs without hypoglycemia alerts or when a CGM was compared to intermittently scanned glucose monitoring devices in T1D [154-157].

Continuous glucose/intermittently scanned glucose monitoring compared to standard blood glucose measurement for type 1 diabetes

Ten studies were found that compared CGM or intermittently scanned glucose monitoring to capillary glucose monitoring [158-167]. Meta-analysis of six studies [158-163] showed a significant effect (−0.26 (95% CI: −0.41 to −0.11)) in favor of CGM or intermittently scanned CGM for reducing DD in T1D (figure 11a). The respective GRADE evidence profile is shown in figure 11e. Subgroup analyses revealed no significant subgroup effects by baseline DD, study duration, intervention delivery format or risk of bias score for both analyses (p>0.05). Narrative analysis of the four studies on CGM or intermittently scanned glucose monitoring that could not be included in the meta-analysis, all showed a similar effect in the reduction of DD [164-167]

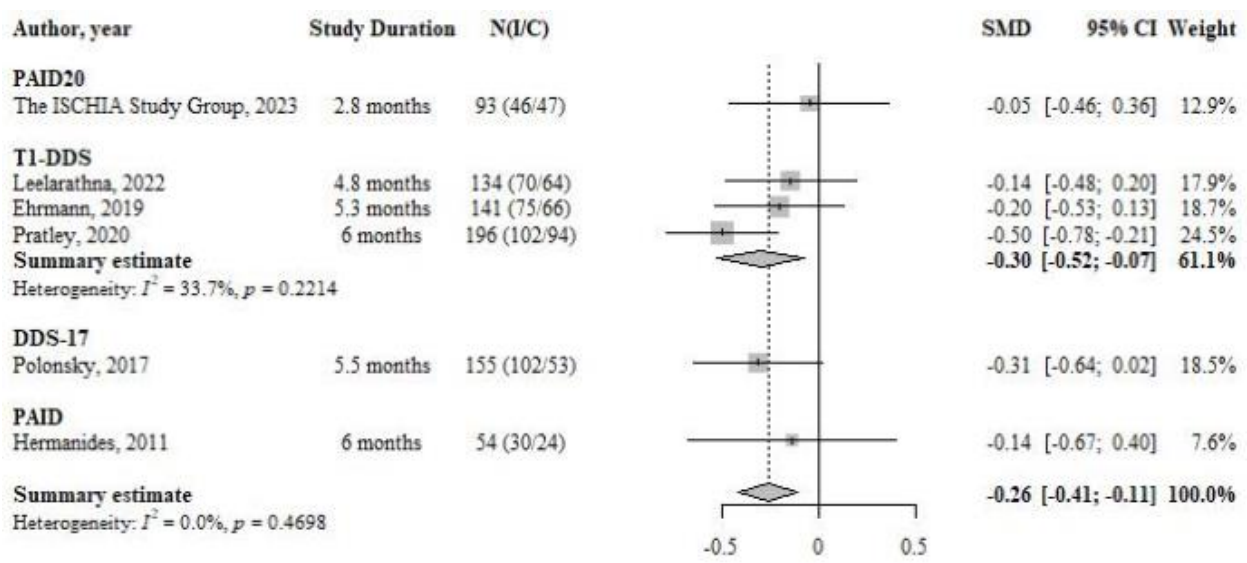


Figure 11a: Standardized mean difference for CGM/intermittently scanned glucose monitoring compared to capillary glucose monitoring in T1D

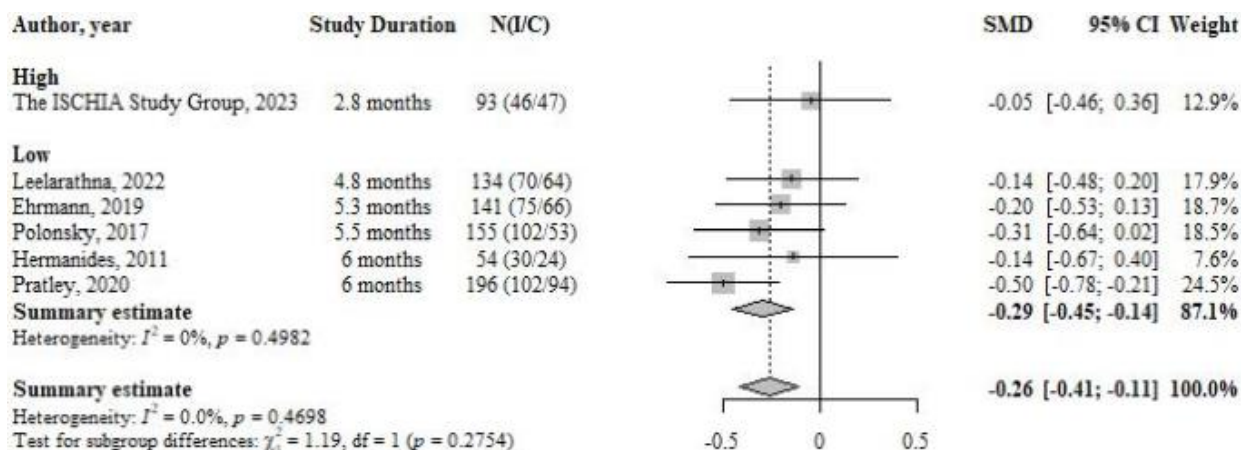


Figure 11b: Standardized mean difference subgroup analysis CGM/intermittently scanned glucose monitoring compared to capillary glucose monitoring in T1D stratified by baseline distress level

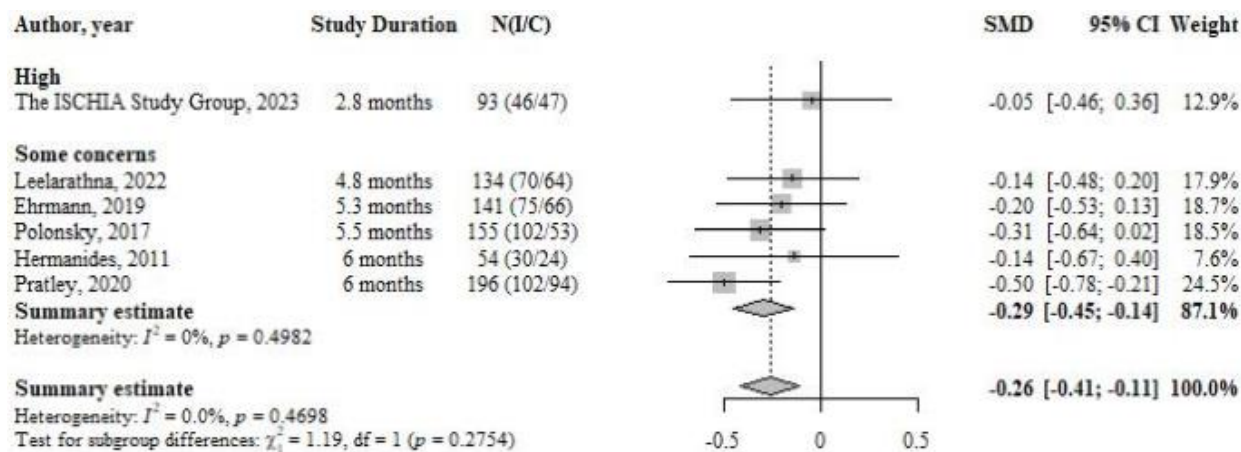


Figure 11c: Standardized mean difference subgroup analysis CGM/intermittently scanned glucose monitoring compared to capillary glucose monitoring in T1D stratified by risk of bias assessment

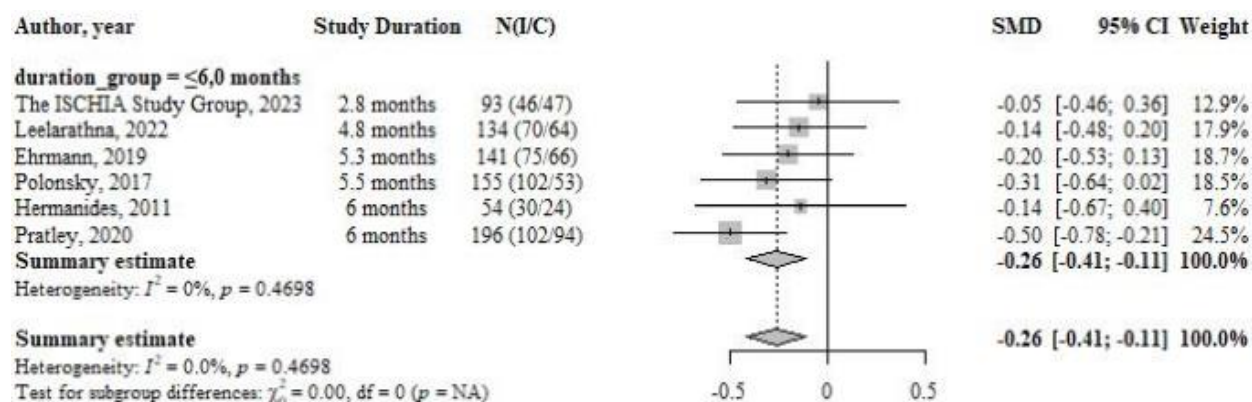


Figure 11d: Standardized mean difference subgroup analysis for CGM/ intermittently scanned glucose monitoring compared to capillary glucose monitoring in T1D stratified by study duration

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Continuous glucose monitoring	Self-monitoring of blood glucose (SMBG)	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 2.8 months to 6 months; assessed with: DDS-PAID)												
6	randomised trials	not serious ^a	not serious ^b	not serious ^c	serious ^d	none	425	348	-	SMD 0.26 SD lower (0.41 lower to 0.11 higher)	⊕⊕⊕○ Moderate ^{a,b,c,d}	IMPORTANT

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. Most trials with some concerns
- b. $I^2 = 0\%$
- c. check detailed assessment
- d. CI crosses -MCID but not null effect

Figure 11e: GRADE evidence profile for CGM/ intermittently scanned glucose monitoring compared to capillary glucose monitoring in T1D

Devices compared to usual care for T2D

Six studies were found that compared devices to usual care in adults with T2D [22, 168-172]. Meta-analysis of three of these studies showed a significant effect (-0.35 (95% CI: -0.98 to 0.28)) for the use of CGM compared to capillary glucose monitoring for reducing DD in T2D (figure 12a) [22, 168, 172]. The respective GRADE evidence profile is shown in figure 12e. Narrative analysis of the other studies on CGM

or intermittently scanned glucose monitoring that could not be included in the meta-analysis all showed a similar effect as the meta-analysis in the reduction of DD [169-171].

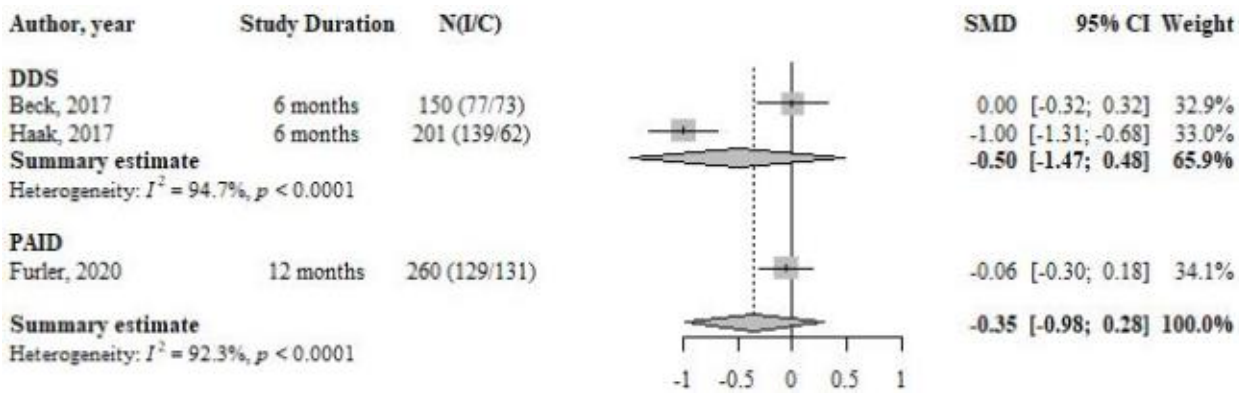


Figure 12a: Standardized mean difference for CGM compared to capillary glucose monitoring in T2D

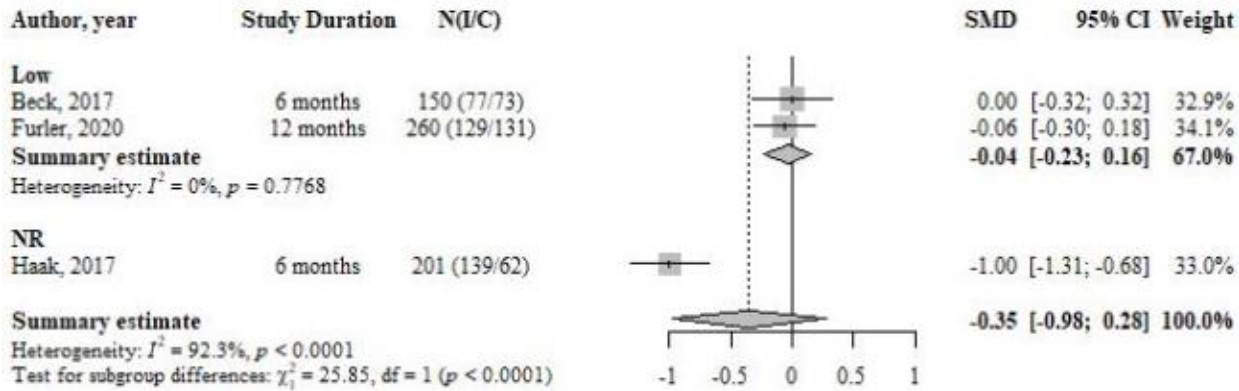


Figure 12b: Standardized mean difference subgroup analysis for CGM compared to capillary glucose monitoring in T2D stratified by baseline distress level

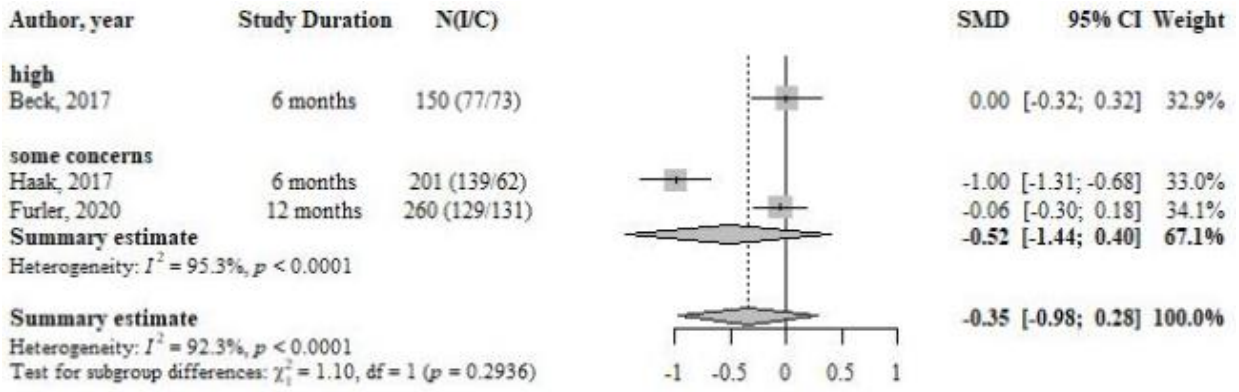


Figure 12c: Standardized mean difference subgroup analysis for CGM compared to capillary glucose monitoring in T2D stratified by risk of bias assessment

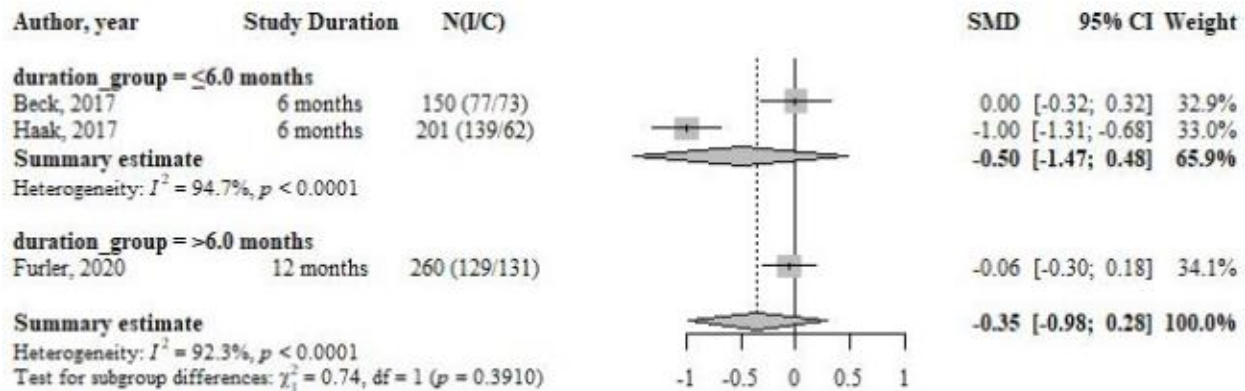


Figure 12d: Standardized mean difference subgroup analysis for devices compared to usual care in T2D stratified by study duration

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Continuous Glucose Monitoring	Self-monitoring of blood glucose (SMBG)	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 6 months to 12 months; assessed with: DDS-PAID)												
3	randomised trials	serious ^a	very serious ^b	not serious ^c	serious ^d	none	345	266	-	SMD 0.35 SD lower (0.98 lower to 0.28 higher)	⊕○○○ Very low ^{a,b,c,d}	IMPORTANT

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. 1 high, 2 some concerns
- b. $I^2 = 92.3\%$
- c. check detailed assessment
- d. CI crosses MCID and null effect

Figure 12e: GRADE evidence profile for CGM compared to capillary glucose monitoring in T2D

Peer Support Interventions compared to usual care for type 1 diabetes

Two studies were found that compared peer support (without psychological component) to usual care in adults with T1D [173]. Narrative analysis showed no difference in the reduction of DD when reciprocal peer support was compared to nurse care management or when peer leader-led diabetes self-management support was compared to traditional self-management support [173, 174].

Peer Support interventions compared to educational interventions for type 2 diabetes

Six studies were found that compared peer support interventions (without psychological component) to educational interventions (without psychological component) in adults with T2D [173, 175-179]. Meta-analysis of three of these studies (figure 13a), showed a non-significant effect (0.10, 95% CI: -0.28 to 0.08) in favor of educational interventions in the reduction of DD [173, 176, 177]. The respective GRADE evidence profile for the comparison of peer support interventions compared to educational interventions is shown in figure 13e. Subgroup analyses revealed no significant subgroup effects by baseline DD, study duration, intervention delivery format or risk of bias score ($p > 0.05$). Narrative analysis of the studies that could not be included in the meta-analysis, showed similar effects in the reduction of DD [175, 178, 179].

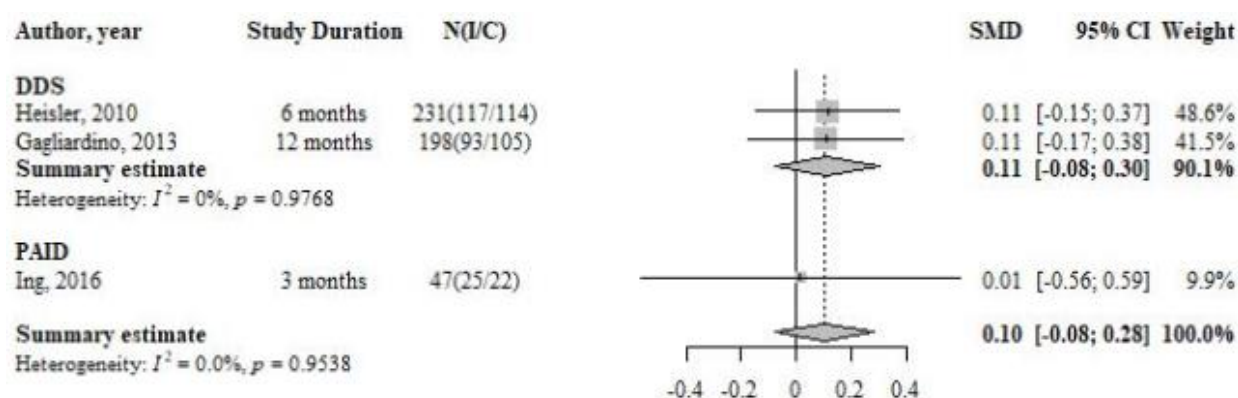


Figure 13a: Standardized mean difference for peer support compared to educational interventions for T2D

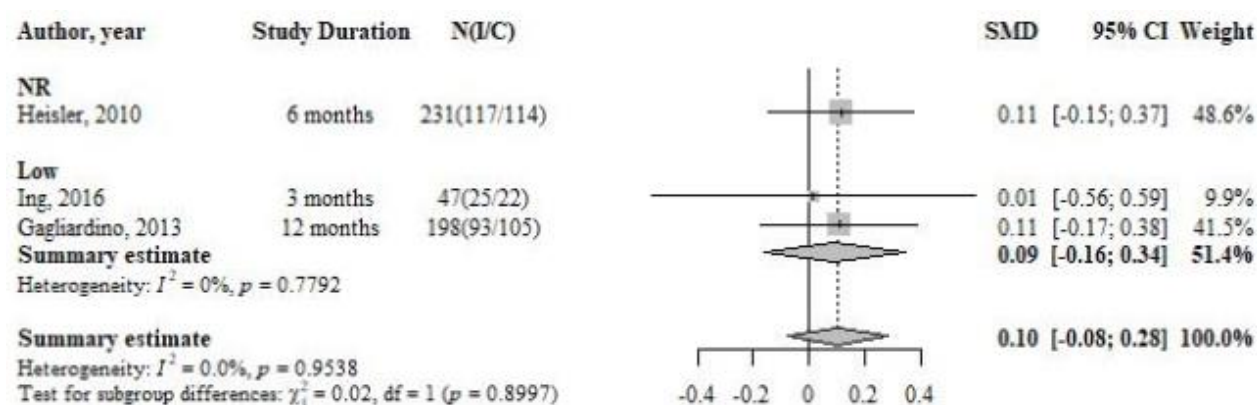


Figure 13b: Standardized mean difference for peer support compared to educational interventions for T2D stratified by baseline distress level

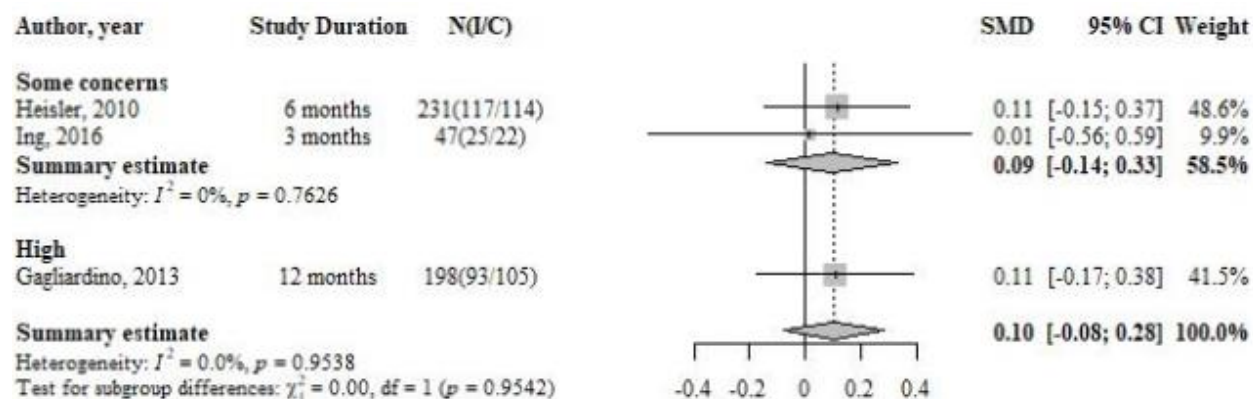


Figure 13c: Standardized mean difference for peer support compared to educational interventions for T2D stratified by risk of bias assessment

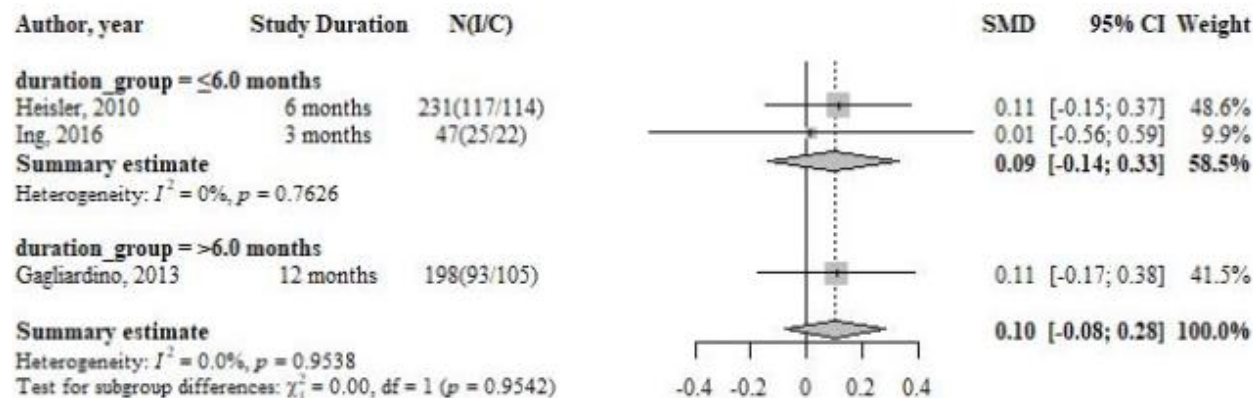


Figure 13d: Standardized mean difference for peer support compared to educational interventions for T2D stratified by study duration

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	educational interventions	peer support interventions	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 3 months to 12 months; assessed with: DDS-PAID)												
3	randomised trials	serious ^a	not serious ^b	serious ^c	not serious ^d	none	241	235	-	SMD 0.1 SD lower (0.28 lower to 0.08 higher)	⊕⊕○○ Low ^{a,b,c,d}	IMPORTANT

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. 1 high, 2 some concerns
- b. I² = 0%
- c. check details
- d. CI crosses null but not MCID, meaning neither benefit nor harm

Figure 13e: GRADE evidence profile for educational interventions compared to peer support interventions for T2D

Peer Support Interventions compared usual care for type 2 diabetes

Seven studies were found comparing peer support interventions (without psychological component) to usual care in adults with T2D [28, 174, 179-183]. Meta-analysis of four of these studies, including 5 comparisons (figure 14a), showed a non-significant effect (−0.03, 95% CI: −0.19 to 0.13) on DD in T2D (figure 4e) [28, 180, 181, 183]. The respective GRADE evidence profile is shown in figure 14f. Subgroup analyses revealed no significant subgroup effects by baseline DD, intervention delivery format, study duration or risk of bias score ($P>0.05$). Narrative analysis of the studies that could not be included in the meta-analysis showed similar effects as the meta-analysis in the reduction of DD [174, 179, 182]

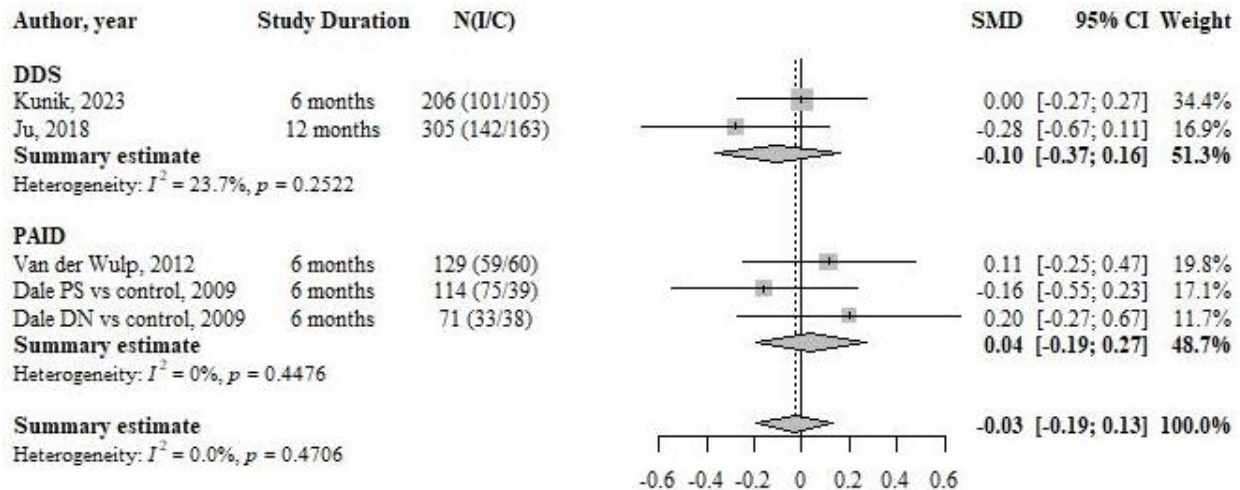


Figure 14a: Standardized mean for peer support compared to usual care for T2D

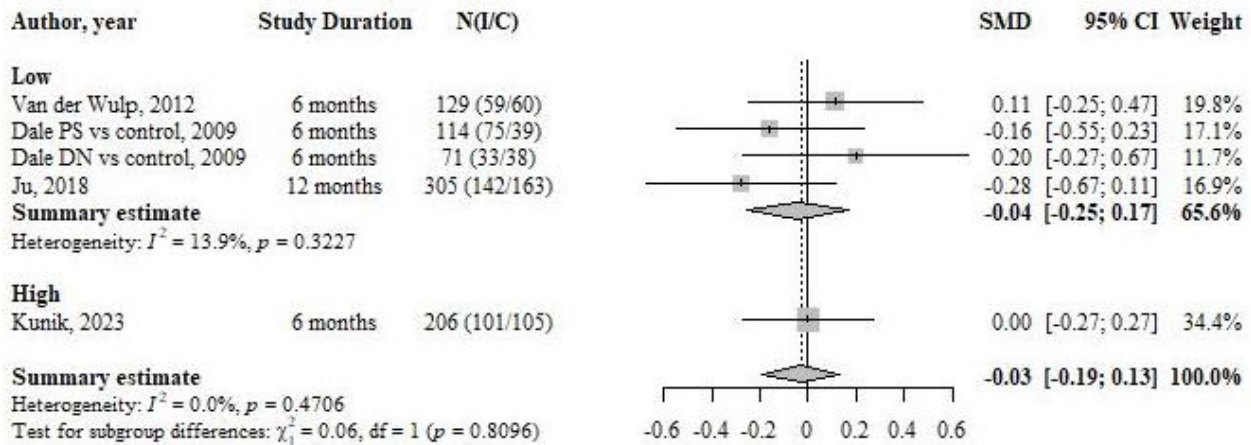


Figure 14b: Standardized mean difference subgroup analysis for peer support compared to usual care for T2D stratified by baseline distress level

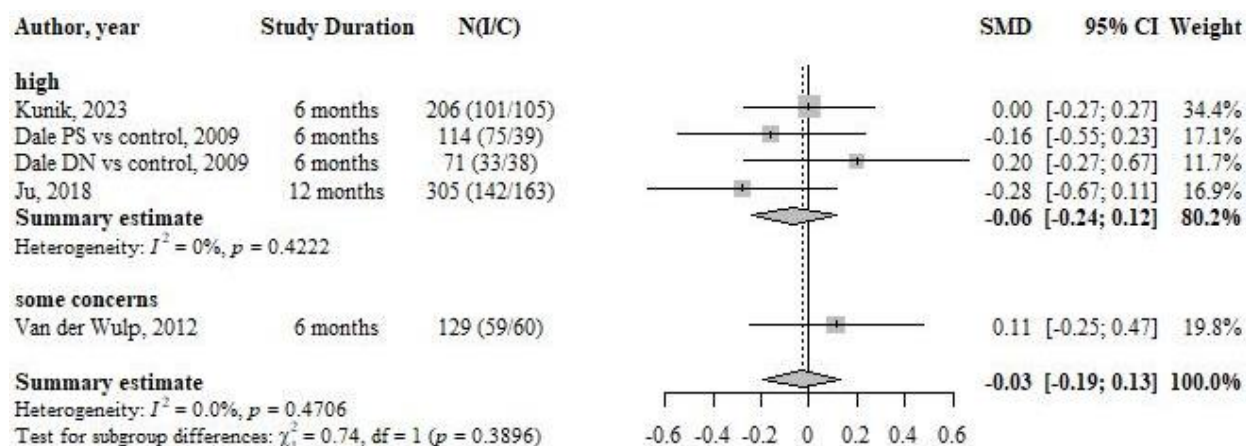


Figure 14c: Standardized mean difference subgroup analysis for peer support compared to usual care for T2D stratified by risk of bias assessment

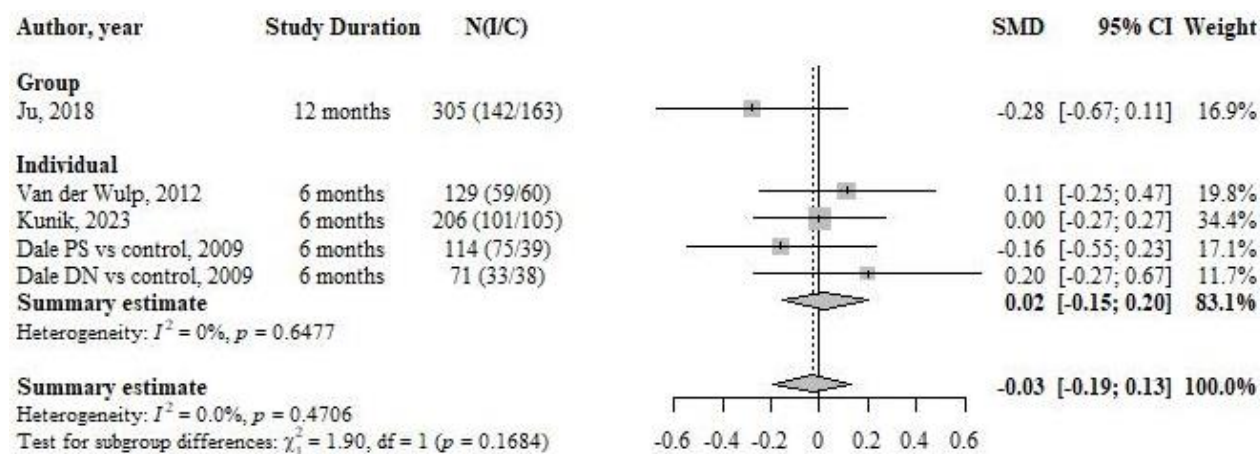


Figure 14d: Standardized mean difference subgroup analysis for peer support compared to usual care for T2D stratified by delivery format

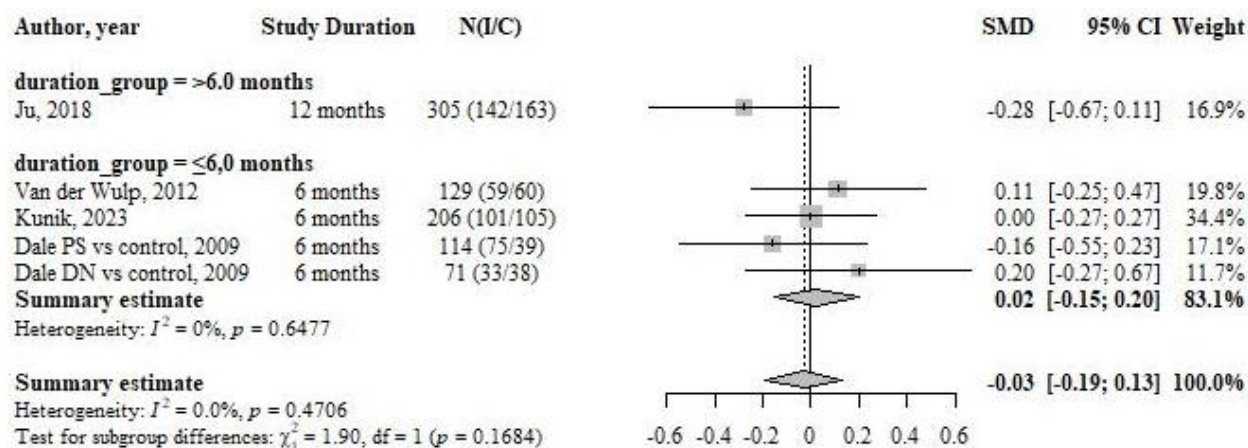


Figure 14e: Standardized mean difference subgroup analysis for peer support compared to usual care for T2D stratified by study duration

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	peer support interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 6 months to 12 months; assessed with: DDS-PAID)												
4	randomised trials	very serious ^a	not serious ^b	not serious ^c	not serious ^d	none	410	405	-	SMD 0.03 SD lower (0.19 lower to 0.13 higher)	⊕⊕○○ Low ^{a,b,c,d}	IMPORTANT

CI: confidence interval; SMD: standardised mean difference

Explanations

a. most trials at high rob

b. $I^2 = 0.0\%$

c. check details

d. CI crosses null but not MCID, meaning neither benefit nor harm

Figure 14f: GRADE evidence profile for peer support compared to usual care for T2D

Educational interventions compared to other interventions for type 2 diabetes

Four studies were found that compared educational interventions (without psychological component) to other miscellaneous interventions in adults with T2D [184-187]. Meta-analysis of these studies was not possible. Narrative analysis showed a small positive effect in favor of educational interventions (without psychological component) for the reduction of DD [184-187].

Educational interventions compared to usual care for type 2 diabetes

Six studies were found on education interventions (without psychological component) versus usual care in adults with T2D [188-193]. Meta-analysis of three of these studies (figure 15a) showed a significant effect (−0.34 (95% CI: −0.56 to −0.11) on DD in T2D [188, 191, 193]. The respective GRADE evidence profile is shown in figure 15c. Subgroup analyses revealed no significant subgroup effects risk of bias score ($P>0.05$). Narrative analysis of the studies that could not be included in the meta-analysis, showed similar effects in the reduction of DD as the meta-analysis [189, 190, 192].

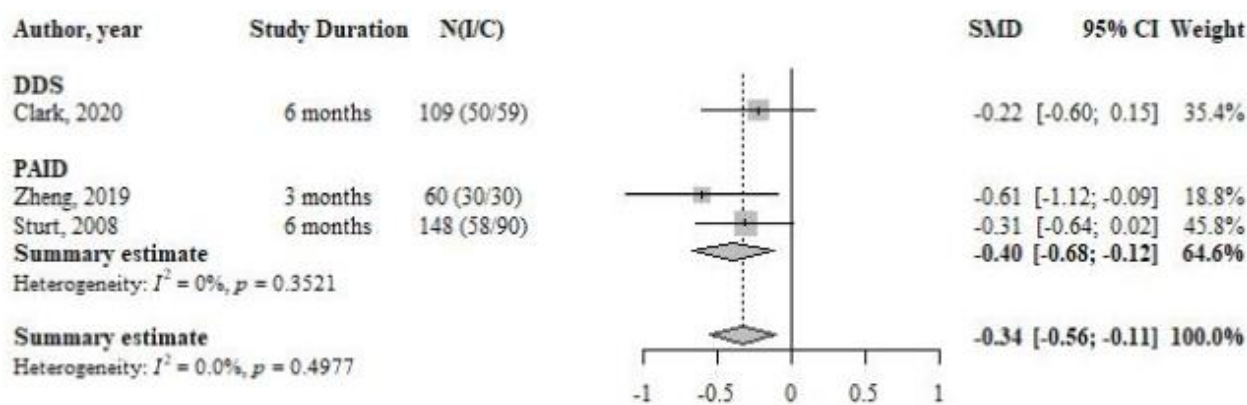


Figure 15a: Standardized mean for educational interventions compared to usual care for T2D

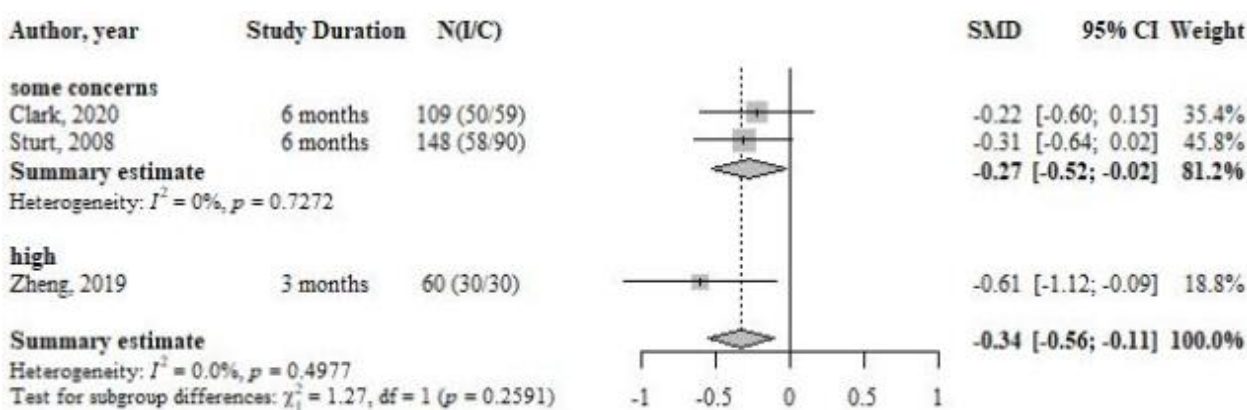


Figure 15b: Standardized mean difference subgroup analysis for educational interventions (non-psychological) compared to usual care for T2D stratified by risk of bias assessment

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	educational interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
SMD DDS-PAID (follow-up: range 3 months to 6 months; assessed with: DDS-PAID)												
3	randomised trials	serious ^a	not serious ^b	not serious ^c	serious ^d	none	138	179	-	SMD 0.34 SD lower (0.56 lower to 0.11 lower)	⊕⊕○○ Low ^{a,b,c,d}	IMPORTANT

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. 1 high, 2 some concerns
- b. I² = 0%
- c. check details
- d. CI crosses MCID and does not cross null effect

Figure 15c: GRADE evidence profile for educational interventions compared to usual care for T2D

Discussion

In this review, we systematically identified, summarized and critically appraised all available evidence from RCTs assessing the efficacy of different types of interventions for reducing DD among adults with T1D or T2D. This resulted in the inclusion of nearly 250 studies, reporting on psychological therapeutic interventions, psychoeducational interventions as well as miscellaneous interventions in adults with T1D and T2D. Compared to usual care, psychological interventions reduced DD in adults with T1D and T2D. Additionally, continuous glucose monitoring or intermittently scanned glucose monitoring reduced DD in adults with T1D, while educational interventions reduced DD in adults with T2D. Other comparisons, including those of psychological, psychoeducational, peer support, educational, and device-based interventions against various active controls or usual care did not show statistically significant effects. Results did not differ meaningfully across predefined subgroups. For all studies there was some concern or high risk of bias and certainty of evidence assessed by GRADE methodology was moderate, low or very low. No meta-analyses could be conducted for telehealth, health behaviours and the assorted mix interventions, due to heterogeneity or an insufficient number of studies.

Our results are in line with earlier performed systematic reviews. For instance, the large Cochrane review, specifically focused on psychological interventions for DD in adults with T2D, found a small but significant effect on DD in favor of psychological interventions, when compared to usual care [13]. Also the reviews by Zu et al. and Schmidt et al. on psychological interventions in adults with T2D with elevated DD showed positive effects on DD as well as Mathiesen et al. on cognition-focused and emotion-focused interventions in vulnerable adults with T2D [14, 17, 19]. Furthermore, several reviews found motivational interviewing to have a beneficial effect on DD [14, 15, 18]. In contrast to previous reviews, we did not find a significant effect of psychoeducational interventions on DD, while Sturt et al. and Perrin et al. found a small reduction in DD [16, 18]. Despite some overlap, our search was broader and more recent, possibly diluting the effect due to additional studies included, causing heterogeneity. This heterogeneity also made it difficult to determine which specific elements contribute to intervention effectiveness between categories. Even within the same category, e.g. psychological interventions, there was considerable diversity; interventions varied in focus (e.g. targeting DD versus depression, anxiety, or eating behaviors), duration (ranging from brief sessions to multi-year programs), delivery format (e.g. in-person vs telehealth, individual vs group-based), and provider type (e.g. physician, psychologist, or multidisciplinary teams).

With regard to subgroup differences, we observed no meaningful differences across predefined subgroups. Subgroup analyses showed no significant subgroup effects in nearly all predefined comparisons (i.e. p for subgroup interaction > 0.05). Some but not all previous reviews had similar findings; for example, Sturt et al. did not find strong differences between formats or individual versus group interventions while Yakubu et al. only found small differences due to baseline DD or study duration [18, 20]. By contrast, Zu et al. suggested that interventions delivered in groups using a technology component enhanced DD reduction [19], and Mathiesen et al. showing the largest reductions after individual interventions [14]. These differences may be caused by differences in (sub)categorization, which hinders comparability. Also, the broad scope of our study resulted in inclusion of many studies with low baseline levels of DD, which made it difficult to detect a meaningful reduction in DD.

Finally, for all studies included in our review, there was a risk of bias and the evidence certainty was low. The risk of bias was downgraded for all studies, due to the use of PROMs as an outcome measure, as this always led to “some concern for risk of bias” based on the standard applications of the ROB2 assessment. Another problem with the PROMs is that we included studies using both DDS and PAID,

which are two distinct PROMs that have not been calibrated against each other, making direct comparison of their scores problematic. For this reason, we used SMDs to allow for pooled analysis across studies using different instruments and performed subgroup analyses based on PROM. Additionally, the two PROMs may differ in specificity and psychometric behavior; for example, they may plateau at different levels or capture overlapping, but not identical aspects of the construct of DD. Therefore, future studies should include either both PROMS or calibration needs to be done. Finally, the strength of evidence of the studies using GRADE is rated as limited due to the small number of studies in certain intervention categories. For example, within psychological interventions, only one study compared a psychological intervention to a psychoeducational intervention in people with T1D. As a result, more research is needed before firm conclusions can be made in these areas.

Strengths and limitations

Our systematic review and meta-analysis provides an extensive overview on the topic of DD. We took great effort to provide a high quality review, by using validated tools, such as GRADE for certainty assessment as well as categorization of interventions verified by clinical experts. Our review is the most comprehensive paper to date and evaluates different types of interventions for both types of diabetes, where earlier systematic reviews were more limited to one population or incomplete by restricting to certain categories. However, there were also some limitations. First, in contrast to our original plans, we could only use post-intervention (endpoint) values in our meta-analyses, as many studies did not report baseline values or changes from baseline for DD. We were also unable to extract HbA1c data from studies in which DD was the primary outcome, due to variability in reporting (with some not measuring HbA1c or reporting it inadequately).

Second, despite considerable effort by the research team, including contacting study authors at least twice, only a subset responded. As a result, a substantial amount of data remains missing. Many studies did not report absolute numbers, or reported only means or medians without accompanying measures of variability. This issue was particularly pronounced in the "miscellaneous interventions" category, where DD was often not the primary outcome. For these studies, DD was often reported only in supplementary materials and not in the abstract or the main text of the articles. As such, although we have also conducted manual reference screening, we cannot rule out the possibility that additional relevant studies may have been missed, particularly for interventions that do not primarily target DD (e.g., devices). This challenge is illustrated in the

review by Olsen 2024 [194] on PROMS in diabetes technology which helped us to identify trials with devices reporting on DD. Notably, we also identified studies that were not captured in their review, for example the Boscari et al. [154], highlighting the difficulty of identifying studies when key outcomes like DD are not mentioned in the main text, even by strenuous reference list checking and appropriate search strategy.

Third, we included all types of RCT designs, including crossover and cluster trials. Each design has its own strengths and limitations, which may have influenced the results. However, the vast majority of the included RCTs used a parallel design, which likely minimized the overall impact of design heterogeneity on the findings. Moreover, cluster RCTs reporting an intraclass correlation (ICC) were adjusted for clustering using the design effect [26, 136, 143, 180]. For cluster RCTs without an reported ICC, we assumed that the ICC was small and therefore unlikely to significantly influence the estimated effect sizes [105, 114, 172]. No adjustment was applied to cross-over trials because only endpoint data combined across periods were reported, precluding a paired analysis. Since only a small number of cross-over trials were included, their potential impact on the overall results is likely limited [150, 160, 195]. Also, we noted that a considerable number of included studies were pilot or feasibility studies, primarily designed to test the implementation or feasibility of interventions rather than to evaluate effectiveness. These studies generally had small sample sizes. However, since meta-analytic methods can account for small studies through appropriate weighting, we do not expect this to have significantly impacted the results.

Fourth, as outlined in the PROSPERO protocol, we predefined a categorization of intervention types. Nevertheless, in some cases, insufficient detail was provided about the underlying psychological theory or intervention content. Due to the heterogeneous nature of interventions, some studies could have been assigned to more than one category. In particular, peer support interventions could fit within either the psychoeducational or the miscellaneous category, in which case the classification decisions were guided by the presence of an explicit underlying psychological theory. To facilitate meta-analysis, we aimed to limit subcategorization and combine studies where methodologically reasonable. However, in some cases the heterogeneity was too great to allow meaningful pooling. Nevertheless, We believe the categories we used best reflect the current landscape and types of interventions in the field and re-categorization would have limited effect on the results.

Finally, the literature search used the term "distress" as part of the strategy. However, the term was not widely adopted to describe the constructs measured by instruments like the PAID until the publication of

the DDS17 around 2007. As a result, relying on "distress" as a search term may have led to the omission of some earlier studies. That said, we believe the risk of missing relevant studies is attenuated, as the search strategy also included a range of related terms (e.g., psychological stress, burnout) and specific scale names and acronyms (e.g., PAID, PAID-20, T1-DDS, T2-DDS). Moreover, at that time there were no validated PROMs yet, so these studies could not have been included in this paper. This approach is consistent with previous high-quality systematic reviews on DD, including a Cochrane review.

Overall, this review provides an up-to-date evidence-based evidence synthesis that reflects current practices and innovations in the management of DD and it will serve as the basis for the evidence-based clinical guideline from the EASD, to enable healthcare professionals to optimize their support of people living with diabetes [12]. Given the high prevalence of DD and its negative emotional impact, we in congruence with the ADA and NICE guidelines believe it is important to implement frequent screening on DD in people with diabetes using validated tools. Our review findings also support the use of psychological interventions, such as cognitive behavioral therapy or mindfulness as first-line treatment for adults with T1D and T2D reporting DD. Clinicians are encouraged to integrate these interventions in their routine diabetes care or through referral to mental health professionals. Moreover, clinicians are encouraged to make CGM easily available for people with T1D as our findings suggest a beneficial effect on DD reduction. Among adults with T2D, diabetes education programs have shown to reduce DD levels. These programs likely benefit people with diabetes by improving self-efficacy and disease understanding. Therefore, clinicians are encouraged to provide diabetes education tailored to the needs of the patients. Other intervention types showed inconsistent or limited effects on DD. Therefore, a firm clinical recommendation cannot be made for these categories at this time and more research is needed. However, our results should be interpreted with caution because of the high heterogeneity between studies. Therefore, we encourage clinicians to take the evidence of this review into account, but beware of the specific needs of the person with diabetes and to refer to mental health professionals or tailor interventions accordingly.

To conclude, this systematic review and meta-analysis shows that psychological interventions consistently reduced DD among adults with T1D and T2D, while devices did in adults with T1D and education in adults with T2D. Most other interventions showed little or no clear effect and several categories could not be analysed due to heterogeneity or limited data.

Declarations

Funding

The EASD has provided financial support to enable SS, SR and FR to work on the protocol and the systematic review. The EASD did not contribute to the development of the protocol or to the manuscript. The two methodologists in the Guideline Development Panel (TK and FZ) received financial reimbursement from the EASD for their contribution to the guideline development. The remaining members of the Guideline Development Panel did not receive financial reimbursement by the EASD.

Declarations of interest

SS, SR, MB, ND, LS, ML, PE, JWB, FR declared no conflict of interest

Authors' contributions

The EASD Guideline Oversight Committee conceived the idea for the guideline, which was operationalized by the Guideline Development Panel. The Guideline Development Panel developed the concept and design of the systematic review. SS: acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, technical report drafting, and future review updates. SR: trial selection, data extraction, data analysis, technical report drafting, and future review updates. MB: trial selection, data extraction, technical report drafting, and future review updates. ND: acquiring trial reports, trial selection, data extraction, technical report drafting, and future review updates. LS: search strategy development, technical report drafting and future review updates. ML: data interpretation, technical report drafting, and future review updates. PE: data interpretation, technical report drafting, and future review updates. JB: data analysis, data interpretation, technical report drafting, and future review updates. FR: acquiring trial reports, trial selection, data extraction, data analysis, data interpretation, technical report drafting, and future review updates.

Differences between protocol and review

In the section we discuss the deviations from the protocol, as the protocol is presented on Prospero and as it has been submitted to the journal Trials (currently under review).

- 1) We were unable to conduct an analysis on DD as a binary outcome, as hardly any studies report binary outcomes (e.g. high versus low DD) and those that did also reported on DD as a continuous outcome, resulting in a decision of the evidence synthesis team to include the latter.

- 2) No additional outcomes were extracted (depression, anxiety, general health status, treatment satisfaction and diabetes self-management). Together with the Guideline Development Panel, we decided to only extract DD and only to extract HbA1c in those papers where DD was the main outcome, due to time and personnel restrictions. However, as too little of these studies reported on HbA1c, this left us unable to do meta-analyses for HbA1c.
- 3) After data-extraction, we were able to only meta-analyze post-intervention (endpoint) values, as too many studies did not report on baseline values of DD or reported change from baseline for DD. As the Cochrane handbook advises that 'post-intervention value and change scores should not in principle be combined using standard meta-analysis approaches when the effect measure is an SMD (Cochrane handbook).
- 4) We conducted an additional subgroup analysis, namely based on baseline score DD (low vs high). This was done after the data extraction had been completed, because the Guideline Development Panel considered that the large heterogeneity across studies may have been due to many studies including participants with low level of baseline DD, which in turn might influence the effect size in reduction of diabetes distress (i.e. participants with low baseline levels of distress being less likely to improve compared to those with higher baseline levels of distress).

Appendix S1 Search strategy

Diabetes Distress, search Histories and details conducted on September 23, 2024

Results

Database	Results	Records removed
PubMed	3384	
PsycInfo (Ebsco)	794	
Cinahl (Ebsco)	1491	
The Cochrane Library (Wiley)	2232	
Total	7901	
After deduplication DedupEndNote	6015	1886
After deduplication manually in Endnote	5893	122

PubMed History and Search Details September 23, 2024

Search	Query PubMed	Results
#1	"Diabetes Mellitus"[Mesh:NoExp] OR "Diabetes Mellitus, Type 1" OR "Diabetes Mellitus, Type 2"[Mesh] OR diabet*[tiab] OR dm2[tiab] OR niddm[tiab] OR "dm 2"[tiab] OR t2d[tiab] OR "dm type 2"[tiab] OR "dm type II"[tiab] OR dm1[tiab] OR iddm[tiab] OR "dm 1"[tiab] OR t1d[tiab] OR "dm type 1"[tiab] OR "dm type I"[tiab]	883,347
#2	("Psychological Distress"[Mesh] OR "Stress, Psychological"[Mesh] OR distress*[tiab] OR "problem area*" [tiab] OR "problems area*" [tiab] OR "burnout"[tiab] OR "burn-out"[tiab] OR burned-out[tiab] OR "DDS-2"[tiab] OR "DDS-17"[tiab] OR "T1-DDS"[tiab] OR "T2-DDS"[tiab] OR "PAID"[tiab] OR "PAID-1"[tiab] OR "PAID-5"[tiab] OR "PAID-11"[tiab] OR "PAID-20"[tiab] OR "CDSS"[tiab] OR "QSD"[tiab] OR "Questionnaire on Stress in Diabet*") NOT ("oxidative distress"[tiab] OR "oxidative stress"[tiab] OR "respiratory distress"[tiab] OR "respiratory stress"[tiab])	352,234
#3	("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR "Clinical Trial" [pt] OR "clinical trials as topic"[mesh:noexp] OR "Controlled Clinical Trials	6,058,038

Search	Query PubMed	Results
	as Topic"[Mesh] OR "Meta-Analysis" [pt] OR "Meta-Analysis as Topic"[Mesh] OR "Review"[pt] OR "Review Literature as Topic"[Mesh] OR trial[tiab] OR rct[tiab] OR random*[tiab] OR placebo[tiab] OR meta-analys*[tiab] OR metaanalys*[tiab] OR review[tiab] OR "literature study"[tiab]) NOT (animals[mh] NOT humans [mh])	
#4	#1 AND #2 AND #3	3,384

APA PsycInfo History and Search Details September 23, 2024

Search	APA PsycInfo (Ebsco) Query	Results
S1	DE ("Diabetes" OR "Diabetes Mellitus" OR "Type 1 Diabetes" OR "Type 2 Diabetes") OR TI (diabet* OR dm2 OR niddm OR "dm 2" OR t2d OR "dm type 2" OR "dm type II" OR dm1 OR iddm OR "dm 1" OR t1d OR "dm type 1" OR "dm type I") OR AB (diabet* OR dm2 OR niddm OR "dm 2" OR t2d OR "dm type 2" OR "dm type II" OR dm1 OR iddm OR "dm 1" OR t1d OR "dm type 1" OR "dm type I") OR KW (diabet* OR dm2 OR niddm OR "dm 2" OR t2d OR "dm type 2" OR "dm type II" OR dm1 OR iddm OR "dm 1" OR t1d OR "dm type 1" OR "dm type I")	39,526
S2	(DE ("Distress" OR "Burnout") OR TI (distress* OR "problem* area*" OR "burnout" OR "burn-out" OR "burned out" OR "DDS-2" OR "DDS-17" OR "T1-DDS" OR "T2-DDS" OR "PAID" OR "PAID-1" OR "PAID-5" OR "PAID-11" OR "PAID-20" OR "CDSS" OR "QSD" OR "Questionnaire on Stress in Diabet*") OR AB ((distress* OR "problem* area*" OR "burnout" OR "burn-out" OR "burned out" OR "DDS-2" OR "DDS-17" OR "T1-DDS" OR "T2-DDS" OR "PAID" OR "PAID-1" OR "PAID-5" OR "PAID-11" OR "PAID-20" OR "CDSS" OR "QSD" OR "Questionnaire on Stress in Diabet*") OR KW (distress* OR "problem* area*" OR "burnout" OR "burn-out" OR "burned out" OR "DDS-2" OR "DDS-17" OR "T1-DDS" OR "T2-DDS" OR "PAID" OR "PAID-1" OR "PAID-5" OR "PAID-11" OR "PAID-20" OR "CDSS" OR "QSD" OR "Questionnaire on Stress in Diabet*")) NOT (TI ((oxidative OR respiratory) N1 (distress OR stress)) OR AB ((oxidative OR respiratory) N1 (distress OR stress)) OR KW ((oxidative OR respiratory) N1 (distress OR stress)))	149,584
S3	S2 NOT (TI ((oxidative OR respiratory) N1 (distress OR stress)) OR AB ((oxidative OR respiratory) N1 (distress OR stress)) OR KW ((oxidative OR respiratory) N1 (distress OR stress)))	148,829

Search	APA PsycInfo (Ebsco) Query	Results
S4	DE ("Meta Analysis") OR TI (trial OR rct OR control* OR random* OR review OR meta-analys* OR metaanalys*) OR AB (trial OR rct OR control* OR random* OR meta-analys* OR metaanalys* OR review) OR KW (trial OR rct OR control* OR random* OR meta-analys* OR metaanalys* OR review) OR ZC ("clinical trial" OR "meta analysis" OR "metasynthesis" OR "literature review")	1,593,556
S5	S1 AND S3 AND S4	794

CINAHL PLUS History and Search Details September 23, 2024

Search	CINAHL Plus (Ebsco) Query	Results
S1	MH ("Diabetes Mellitus" OR "Diabetes Mellitus, Type 1" OR "Diabetes Mellitus, Type 2") OR TI (diabet* OR dm2 OR niddm OR "dm 2" OR t2d OR "dm type 2" OR "dm type II" OR dm1 OR iddm OR "dm 1" OR t1d OR "dm type 1" OR "dm type I") OR AB (diabet* OR dm2 OR niddm OR "dm 2" OR t2d OR "dm type 2" OR "dm type II" OR dm1 OR iddm OR "dm 1" OR t1d OR "dm type 1" OR "dm type I")	281,764
S2	(MH ("Psychological Distress" OR "Symptom Distress") OR TI (distress* OR "problem* area*" OR "burnout" OR "burn-out" OR "burned out" OR "DDS-2" OR "DDS-17" OR "T1-DDS" OR "T2-DDS" OR "PAID" OR "PAID-1" OR "PAID-5" OR "PAID-11" OR "PAID-20" OR "CDSS" OR "QSD" OR "Questionnaire on Stress in Diabet*")) OR AB (distress* OR "problem* area*" OR "burnout" OR "burn-out" OR "burned out" OR "DDS-2" OR "DDS-17" OR "T1-DDS" OR "T2-DDS" OR "PAID" OR "PAID-1" OR "PAID-5" OR "PAID-11" OR "PAID-20" OR "CDSS" OR "QSD" OR "Questionnaire on Stress in Diabet*")) NOT (TI ((oxidative OR respiratory) N1 (distress OR stress)) OR AB ((oxidative OR respiratory) N1 (distress OR stress)))	97,969
S3	MH ("Clinical Trials+" OR "Randomized Controlled Trials" OR "Therapeutic Trials" OR "Meta Analysis" OR "Meta Synthesis" OR "Literature Review+") OR TI (trial OR rct OR control* OR random* OR meta-analys* OR metaanalys* OR review OR "literature study") OR AB (trial OR rct OR control* OR random* OR meta-analys* OR metaanalys* OR review OR "literature study")	1,838,828
S4	S1 AND S2 AND S3	1,491

Search	The Cochrane Library (Wiley) Query	Results
#1	((diabet* OR dm2 OR niddm OR "dm 2" OR t2d OR "dm type 2" OR "dm type II" OR dm1 OR iddm OR "dm 1" OR t1d OR "dm type 1" OR "dm type I")) :ti,ab,kw (Word variations have been searched)	125,957
#2	((distress* OR problem* NEXT area* OR "burnout" OR "burn-out" OR "burned out" OR "DDS-2" OR "DDS-17" OR "T1-DDS" OR "T2-DDS" OR "PAID" OR "PAID-1" OR "PAID-5" OR "PAID-11" OR "PAID-20" OR "CDSS" OR "QSD" OR "Questionnaire on Stress" NEAR/2 Diabet*)) :ti,ab,kw NOT (((oxidative OR respiratory) NEXT (distress OR stress))):ti (Word variations have been searched)	38,424
#3	(oxidative OR respiratory) NEXT (distress OR stress) :ti (Word variations have been searched)	6,316
	#1 AND (#2 NOT #3)	2,234
	Results: 20 Cochrane Reviews 2212 Trials	



PROSPERO

International prospective register of systematic reviews

Interventions to reduce diabetes-related distress among adults with type 1 or type 2 diabetes: a systematic review and meta-analysis

Femke Rutters , Petra Elders, Sharon Remmelzwaal, Marieke Blom, Miranda Langendam, Joline Beulens, Lenka Groeneveld, Samantha Schipper, Martin Jensen

To enable PROSPERO to focus on COVID-19 submissions, this registration record has undergone basic automated checks for eligibility and is published exactly as submitted. PROSPERO has never provided peer review, and usual checking by the PROSPERO team does not endorse content. Therefore, automatically published records should be treated as any other PROSPERO registration. Further detail is provided [here](#).

Citation

Femke Rutters , Petra Elders, Sharon Remmelzwaal, Marieke Blom, Miranda Langendam, Joline Beulens, Lenka Groeneveld, Samantha Schipper, Martin Jensen. Interventions to reduce diabetes-related distress among adults with type 1 or type 2 diabetes: a systematic review and meta-analysis. PROSPERO 2024 Available from <https://www.crd.york.ac.uk/PROSPERO/view/CRD42024598512>

REVIEW TITLE AND BASIC DETAILS

Review title

Interventions to reduce diabetes-related distress among adults with type 1 or type 2 diabetes: a systematic review and meta-analysis

Original language title

English

Review objectives

What is the efficacy of various types of interventions for reducing diabetes-related distress among adults with type 1 or type 2 diabetes?

Keywords

Diabetes, Distress, interventions, type 1, type 2

SEARCHING AND SCREENING

Searches

MEDLINE (via PubMed), Cochrane Library, PsycINFO, CINAHL

Study design

Randomised controlled trials reporting the effect of an eligible intervention on diabetes-related distress (either as a primary or secondary endpoint), irrespective of duration, type or modality of intervention, or the type of randomisation (e.g. individual, cluster).

ELIGIBILITY CRITERIA

Condition or domain being studied

Diabetes distress refers to the emotional and psychological burden experienced by individuals living with diabetes. It encompasses a wide range of negative feelings, including frustration, anxiety, guilt, and fear, arising from (the challenges associated with) living with and managing diabetes. Unlike clinical depression or anxiety disorders, diabetes distress is specific to diabetes, requiring an attribution to the daily demands of, and concerns related to, diabetes. Factors contributing to diabetes distress can include worries about acute and long-term complications, frustrations with managing blood glucose, the burden of self-care, social interactions (including with health professionals, family, friends, and others), the financial burden of diabetes and its management, feelings of isolation or overwhelm, stigma, and not feeling sufficient perceived control over the condition.

Population

Adults (>18 years) with type 1 or type 2 diabetes irrespective of duration of diabetes, glycemic levels, comorbidities, or level of diabetes distress at baseline. Participants aged <18 years or with other types of diabetes (e.g., gestational diabetes) will be excluded.

Intervention(s) or exposure(s)

- Psychological: These include cognition-focused, emotion-focused, or emotion-cognition therapeutic interventions. Examples include but are not limited to cognitive behavioral therapy, motivational interviewing, supportive counselling, psychotherapy, mindfulness, acceptance and commitment therapy.
- Diabetes self-management education or psycho-educational: These include a diabetes-related educational component (e.g., carbohydrate counting, insulin dose adjustment) with or without a psychological/behavioral component (e.g. cognitive reframing, goal setting, planning, problem solving) as described in psychological interventions.
- Other types (miscellaneous): Interventions that cannot be categorized as psychological, educational or psycho-educational. Examples include but are not limited to medications (e.g. insulins, antidiabetic medications) and devices (for the administration of insulin or for glucose monitoring or both), as well as peer support, or complex health service interventions (e.g., healthcare pathways, models of care).

Eligible interventions can be:

- generic or diabetes-specific
- delivered to individuals (one-to-one) or in groups
- delivered in-person, online, via digital applications ('apps'), or in combination of various methods
- facilitated by specialist mental health professionals; specialist diabetes health professionals; general health professionals; or expert peers (i.e. people with lived experience of diabetes who are trained to deliver the intervention).

Comparator(s) or control(s)

- Usual care or waiting list
- An active comparator (i.e., another intervention known (or expected) to reduce diabetes-related distress).

OUTCOMES TO BE ANALYSED

Main outcomes

1. Diabetes-related distress, assessed using a validated measure. These may include (but are not limited to) the Diabetes Distress Scale (DDS), the Problem Areas In Diabetes (PAID) scale and Questionnaire on Stress in Diabetic Patients; or their subscales; or their derivatives (including short-form measures and versions developed for specific populations, e.g. for adults with type 1 diabetes); or other measures identified as being validated for the assessment of the construct described in Section 18.

Measures of effect

The outcome (diabetes-related distress) may be assessed as a:

- continuous outcome (i.e., calculated as between-arm difference at a given timepoint; or change from baseline (i.e. follow-up minus baseline); or post-intervention score)
- binary outcome (i.e., number/proportion of participants with a score (pre- or post-intervention) above or below a pre-specified threshold value deemed indicative of presence/absence of diabetes distress).

Effect sizes (mean differences between intervention and comparator in terms of change from baseline value or post-intervention value) alongside 95% confidence intervals will be calculated for continuous outcomes. In cases of different scales used for the assessment of the same outcome, standardized mean differences (SMDs) will be used. For binary outcomes, risk ratios with 95% confidence intervals will be generated.

Additional outcomes

Change from baseline or post-intervention value in the following outcomes (measured with validated tools):

1. HbA1c
2. Depression or depressive symptoms
3. Anxiety or anxiety symptoms
4. Generic health status; generic and diabetes-specific quality of life
5. Satisfaction (e.g. with diabetes management or treatment)
6. Diabetes self-management or confidence / self-efficacy in managing diabetes.

Measures of effect

Effect sizes (mean differences between intervention and comparator in terms of change from baseline value or post-intervention value) alongside 95% confidence intervals will be calculated for continuous outcomes. In cases of different scales used for the assessment of the same outcome, standardized mean differences (SMDs) will be used.

DATA COLLECTION PROCESS

Data extraction (selection and coding)

After deduplication of search records retrieved, at least two EST members will independently review the title and abstract of each record. Those screened negatively will be excluded at this stage. Those screened positively and those for which eligibility is unclear (to one or both reviewers) will be assessed for eligibility in full-text by two independent EST members. Reasons for exclusion during the full-text screening will be recorded. Any discrepancies will be resolved through consensus or recourse to a third reviewer.

Data extraction items (Appendix 2) will include:

- Study characteristics (e.g., [NCT] trial identifier, trial duration, duration of intervention, definition of intervention and comparator, geographical location, number of participants with type 1 or type 2 diabetes)
- Participants' baseline characteristics (e.g., demographics, duration of diabetes, diabetes therapy (i.e. management regimen / medications), and other relevant clinical characteristics such as level of diabetes distress/depression/anxiety (continuous or categorical))
- Outcome-related data for each trial arm:
 - o Baseline and end-of-study mean, change from baseline value, 95% confidence interval / standard deviation / standard error, and number of participants analyzed for continuous outcomes
 - o Number of participants with outcome and number analysed for binary outcomes
 - o Time-point of outcome assessment for all outcomes.

Risk of bias (quality) assessment

Risk of bias assessment will be completed at a study level and for each outcome using the Cochrane RoB 2 tool for RCTs. Two independent review team members will assess the risk of bias, and any discrepancies will be resolved through discussion or consultation if necessary.

PLANNED DATA SYNTHESIS

Strategy for data synthesis

Quantitative data synthesis will be conducted using random effects meta-analysis, if feasible and appropriate. Heterogeneity between studies will be assessed using the I^2 statistic. Separate analyses will be conducted based on:

- Type of diabetes
- Type of intervention (i.e., psychological; structured diabetes education and psycho-educational interventions; and other interventions)
- Type of comparator (i.e., usual care and waiting list; active comparators)

Certainty of Evidence Assessment (GRADE): The certainty of meta-analyses findings will be rated as high, moderate, low, or very low, based on factors such as risk of bias, inconsistency, indirectness, and publication bias.

Analysis of subgroups or subsets

Where possible, subgroup analyses will be considered based on intervention characteristics as described in “Eligibility Criteria” section (e.g., one-to-one vs group-based; in-person vs online vs application) or study and participants’ baseline characteristics (e.g., study duration, duration of diabetes, age, sex). Sensitivity analyses will be considered by excluding studies at high risk of bias.

REVIEW AFFILIATION, FUNDING AND PEER REVIEW

Review team members

- Dr Femke Rutters, VUMC
- Professor Petra Elders, Amsterdam UMC
- Dr Sharon Remmelzwaal, Amsterdam UMC
- Dr Marieke Blom, Amsterdam UMC
- Dr Miranda Langendam, Amsterdam UMC
- Professor Joline Beulens, Amsterdam UMC
- Dr Lenka Groeneveld, Amsterdam UMC

- Miss Samantha Schipper, Amsterdam UMC
- Mr Martin Jensen, Aarhus University

Review affiliation

Amsterdam University Medical Center

Funding source

European Association for the Study of Diabetes (EASD)

Named contact

Femke Rutters. Department Epidemiology & Data Science Location AMC | J1B-225 | Meibergdreef 9 |
1105 AZ AMSTERDAM
f.rutters@vumc.nl

TIMELINE OF THE REVIEW**Review timeline**

Start date: 01 September 2024. End date: 31 March 2025

Date of first submission to PROSPERO

07 October 2024

Date of registration in PROSPERO

18 October 2024

CURRENT REVIEW STAGE**Publication of review results**

The intention is to publish the review once completed. The review will be published in English

Stage of the review at this submission

Review stage	Started	Completed
Pilot work	✓	✓
Formal searching/study identification	✓	
Screening search results against inclusion criteria		
Data extraction or receipt of IP		
Risk of bias/quality assessment		
Data synthesis		

Review status

The review is currently planned or ongoing.

ADDITIONAL INFORMATION

Additional information

part of the EASD guideline development, plus previous reviews were too restrictive.

Collaborators

- **Mr Walther Jensen**, European Association for the Study of Diabetes
- **Professor Norbert Hermanns**, University of Bamberg and Research Institute of the Diabetes Academy Mergentheim (FIDAM)
- **Professor Richard Holt**, University of Southampton
- **Dr Karin Kanc**, Jazindiabetes Private Diabetes Centre
- **Dr Thomas Karagiannis**, Aristotle University of Thessaloniki
- **Miss Michelle Law**, European Association for the Study of Diabetes
- **Dr Andreia Mocan**, Center for Diabetes, Nutrition and Metabolic Diseases, Emergency Clinical County Hospital, Cluj-Napoca

- **Professor Jane Speight**, The Australian Centre for Behavioural Research in Diabetes: Diabetes Victoria and Deakin University
- **Professor Jackie Sturt**, King's College London
- **Dr Francesco Zaccardi**, University of Leicester

PROSPERO version history

- Version 1.1 published on 18 Oct 2024; Version 1.0 published on 18 Oct 2024

Review conflict of interest

None known

Country

Netherlands

Medical Subject Headings

Adult; Diabetes Mellitus, Type 1; Diabetes Mellitus, Type 2; Glycated Hemoglobin; Humans

Details of any existing review of the same topic by the same authors

NA

Disclaimer

The content of this record displays the information provided by the review team. PROSPERO does not peer review registration records or endorse their content.

PROSPERO accepts and posts the information provided in good faith; responsibility for record content rests with the review team. The owner of this record has affirmed that the information provided is truthful and that they understand that deliberate provision of inaccurate information may be construed as scientific misconduct.

PROSPERO does not accept any liability for the content provided in this record or for its use. Readers use the information provided in this record at their own risk.

Any enquiries about the record should be referred to the named review contact

Appendix S3 Reasons for exclusion of full text papers

Study	Exclusion reason
Afshar 2022	Wrong Study Design
Aikens 1997	Wrong outcome
Alessi 2022	Duplicate
Allen 2017	Wrong outcome
Alloway 2001	Wrong outcome
An 2023	Review
Anderbro 2022	Only abstract/thesis/design
Arora 2013	Only abstract/thesis/design
Ayala 2022	Wrong study design
Azadbakht 2023	Wrong study design
Baca 2007	Only abstract/thesis/design
Baig 2020	Only abstract/thesis/design
Baig 2021	Only abstract/thesis/design
Baig 2021	Only abstract/thesis/design
Bajaj 2016	Only abstract/thesis/design
Banks 2023	Wrong study design
Barcena 2021	Only abstract/thesis/design
Barrett 1995	Wrong outcome
Bassi 2021	Review
Bastian 2020	Only abstract/thesis/design
Benhalima 2021	Only abstract/thesis/design
Benhalima 2025	Duplicate
Bergis 2019	Wrong population
Bilgin 2022	Review
Bisno 2019	Only abstract/thesis/design
Bisno 2023	Wrong population
Bogusch 2019	Review
Bowyer 2014	Only abstract/thesis/design
Browning 2016	Wrong outcome
Burner 2015	Only abstract/thesis/design
Bykowski 2017	Only abstract/thesis/design
Carreira 2014	Only abstract/thesis/design
Castensøe-Seidenfaden 2018	Wrong population
Celik 2020	Review
Cheng 2017	Review
Cheng 2017	Only abstract/thesis/design
Chew 2017	Review
Chew 2017	Only abstract/thesis/design

Chiu 2014	Only abstract/thesis/design
Cho 2021	Review
Cohen 2023	Only abstract/thesis/design
Cowart 2020	Review
Cox 2020	Only abstract/thesis/design
Cummings 2015	Only abstract/thesis/design
Cummings 2017	Wrong Intervention
Cummings 2017	Only abstract/thesis/design
Cummings 2018	Only abstract/thesis/design
Cummings 2019	Only abstract/thesis/design
Curtis 2022	Only abstract/thesis/design
Dafoulas 2014	Only abstract/thesis/design
Dafoulas 2014	Only abstract/thesis/design
DeGroot 2017	Only abstract/thesis/design
DeGroot 2018	Only abstract/thesis/design
Delgado 2018	Only abstract/thesis/design
Dennick 2013	Only abstract/thesis/design
DeVries 2014	Only abstract/thesis/design
Diribe 2024	Review
Efthymiadis 2022	Review
Ehrmann 2016	Wrong study design
Ehrmann 2018	Only abstract/thesis/design
Ehrmann 2018	Only abstract/thesis/design
Ehrmann 2023	Only abstract/thesis/design
Ehrmann 2023	Only abstract/thesis/design
Ehrmann 2024	Wrong population
Ewen 2023	Only abstract/thesis/design
Farzaneh 2023	Wrong study design
Fernandez-Rodrigo 2022	Only abstract/thesis/design
Fernández-Rodríguez 2024	Review
Fisher 2012	Only abstract/thesis/design
Fisher 2015	Only abstract/thesis/design
Fisher 2018	Only abstract/thesis/design
Fisher 2019	Duplicate
Fisher 2020	Wrong outcome
Fortmann 2016	Only abstract/thesis/design
Franceschi 2023	Review
Freckmann 2018	Only abstract/thesis/design
Glasgow 2009	Wrong study design
Godoi 2023	Review
GonçalvesdeBrito 2016	Wrong study design

Gonzalez 2024	Wrong study design
Gray 2021	Wrong outcome
Groeneveld 2024	Wrong outcome
Gulde 2009	Review
Guo 2019	Review
Gutierrez 2019	Review
Hadjiconstantinou 2016	Review
Hall 2024	Wrong outcome
Halliday 2022	Wrong population
Hambidge 2016	Only abstract/thesis/design
Hambidge 2017	Only abstract/thesis/design
Hamdy 2015	Only abstract/thesis/design
Hartmann 2012	Wrong outcome
Hawkins 2022	Only abstract/thesis/design
Heitkemper 2017	Only abstract/thesis/design
Herder 2018	Wrong Intervention
Hermanns 2011	Only abstract/thesis/design
Hermanns 2011	Only abstract/thesis/design
Hermanns 2014	Only abstract/thesis/design
Hermanns 2016	Only abstract/thesis/design
Hermanns 2016	Only abstract/thesis/design
Hermanns 2019	Wrong population
Hermanns 2019	Only abstract/thesis/design
Hessler 2020	Only abstract/thesis/design
Hessler 2023	Only abstract/thesis/design
Hilmarsdottircc 2020	Only abstract/thesis/design
Hinsch 2015	Only abstract/thesis/design
Hood 2021	Wrong population
Hopkins 2012	Wrong study design
Hur 2020	Only abstract/thesis/design
Ismail 2004	Review
Iversen 2019	Only abstract/thesis/design
Jenkinson 2022	Review
Johnson 2013	Only abstract/thesis/design
jRct 2023	Only abstract/thesis/design
Jugnee 2017	Only abstract/thesis/design
Jugnee 2018	Only abstract/thesis/design
Karahan 2009	Wrong outcome
Kaselitz 2019	Wrong outcome
Kasteleyn 2014	Only abstract/thesis/design
Katz 2017	Only abstract/thesis/design

Kelly 2023	Only abstract/thesis/design
Kempf 2013	Only abstract/thesis/design
Khan 2022	Only abstract/thesis/design
Khunti 2010	Only abstract/thesis/design
Kong 2020	Review
Kopf 2014	Wrong outcome
Koscielniak 2018	Only abstract/thesis/design
Kotsanos 1997	Wrong outcome
Kudva 2021	Wrong population
Kulzer 2012	Only abstract/thesis/design
Kulzer 2014	Only abstract/thesis/design
Kulzer 2014	Only abstract/thesis/design
Kulzer 2019	Only abstract/thesis/design
Kulzer 2023	Only abstract/thesis/design
Kulzer 2023	Only abstract/thesis/design
Lee 2014	Wrong study design
Lei 2019	Only abstract/thesis/design
Li 2016	Only abstract/thesis/design
Li 2017	Review
Li 2022	Review
Liang 2021	Review
Liang 2021	Review
Lim 2023	Only abstract/thesis/design
Lind 2020	Only abstract/thesis/design
Lind 2021	Wrong study design
Litchman 2020	Review
Littlewood 2018	Only abstract/thesis/design
Liu 2020	Review
Long 2018	Only abstract/thesis/design
Long 2018	Only abstract/thesis/design
Long 2021	Review
LozanoDelHoyo 2022	Only abstract/thesis/design
Lutes 2018	Only abstract/thesis/design
Mader 2020	Only abstract/thesis/design
Mahr 2011	Wrong outcome
Martyn-Nemeth 2020	Only abstract/thesis/design
Massey 2019	Review
Mathiesen 2019	Review
Mathiesen 2023	Review
McAuley 2020	Only abstract/thesis/design
McGowan 2009	Only abstract/thesis/design

Mizokami-Stout 2021	Wrong Intervention
Munshi 2010	Only abstract/thesis/design
Munshi 2011	Only abstract/thesis/design
Naik 2023	Wrong outcome
New 2013	Only abstract/thesis/design
Newton 2013	Only abstract/thesis/design
Ngan 2021	Review
Ni 2021	Review
Noordali 2017	Review
Nurchis 2022	Review
O'Connor 2023	Only abstract/thesis/design
O'Neal 2020	Only abstract/thesis/design
Oyedeki 2022	Review
Pang 2023	Wrong population
Pereira 2018	Only abstract/thesis/design
Perrin 2019	Review
Pfutzner 2014	Only abstract/thesis/design
Philis-Tsimikas 2023	Only abstract/thesis/design
Piatt 2021	Only abstract/thesis/design
Pibernik-Okanovic 2013	Only abstract/thesis/design
Piette 2013	Wrong outcome
Plack 2010	Review
Polonsky 2010	Only abstract/thesis/design
Polonsky 2017	Only abstract/thesis/design
Presswala 2018	Only abstract/thesis/design
Pyatak 2017	Only abstract/thesis/design
Pyatak 2023	Only abstract/thesis/design
Quinn 2012	Only abstract/thesis/design
Racey 2022	Review
Rahmani 2013	Only abstract/thesis/design
Reed 2024	Wrong study design
Reimer 2017	Wrong study design
Rogers 2014	Wrong outcome
Saha 2024	Wrong outcome
Samuel-Hodge 2006	Only abstract/thesis/design
Schmidt 2018	Review
Schmidt 2020	Review
Sharp 2018	Wrong outcome
Siaw 2015	Only abstract/thesis/design
Siaw 2015	Only abstract/thesis/design
Sieber 2016	Only abstract/thesis/design

Sieber 2016	Only abstract/thesis/design
Simmons 2013	Only abstract/thesis/design
Simonson 2014	Only abstract/thesis/design
Simonson 2015	Only abstract/thesis/design
Simonson 2016	Only abstract/thesis/design
Simonson 2017	Only abstract/thesis/design
Skelly 2005	Wrong outcome
Skinner 2010	Wrong study design
Spaic 2017	Only abstract/thesis/design
Spaic 2019	Wrong population
Speight 2023	Review
Sperl-Hillen 2010	Only abstract/thesis/design
Sperl-Hillen 2011	Only abstract/thesis/design
Sperl-Hillen 2012	Only abstract/thesis/design
Spiess 1995	Wrong outcome
Sturt 2015	Review
Sudhir 2017	Review
Swoboda 2018	Only abstract/thesis/design
Takano 2017	Only abstract/thesis/design
Tang 2015	Only abstract/thesis/design
Tang 2022	Wrong study design
Tasya 2021	Review
TavaresFranquez 2023	Review
Taylor 2005	Wrong outcome
Taylor 2006	Only abstract/thesis/design
Tolentino 2022	Review
Trief 2006	Wrong study design
Trief 2011	Wrong outcome
Trief 2016	Only abstract/thesis/design
Trief 2017	Only abstract/thesis/design
Trief 2019	Wrong population
Trump 2017	Review
Uchendu 2017	Review
Vakharia 2022	Only abstract/thesis/design
VanAlphen 2007	Only abstract/thesis/design
vanBeers 2017	Wrong outcome
vanBon 2024	Wrong Study Design
VanSon 2012	Only abstract/thesis/design
vanVugt 2016	Wrong study design
Verma 2022	Review
Vieira 2020	Review

Vlachou 2022	Review
Wagner 2019	Wrong study design
Walker 2013	Only abstract/thesis/design
Wang 2024	Review
Weinger 2004	Review
Wermeling 2013	Wrong study design
Westall 2023	Only abstract/thesis/design
Wicaksana 2024	Review
Wilmoth 2019	Only abstract/thesis/design
Wilmoth 2022	Only abstract/thesis/design
Winkley 2006	Review
Winkley 2020	Review
Winkley 2022	Only abstract/thesis/design
Wong 2020	Review
Yang 2018	Only abstract/thesis/design
Yao 2014	Only abstract/thesis/design
Yap 2024	Review
Yu 2017	Wrong outcome
Yu 2024	Review
Zagarins 2010	Only abstract/thesis/design
Zenasni 2022	Only abstract/thesis/design
Zhang 2022	Review
Zheng 2023	Review
Zoffmann 2013	Only abstract/thesis/design
葛艳红 2020	Duplicate

Appendix S4 Baseline characteristics



Baseline table.csv

Appendix S5 Risk of bias assessment

Intention-to-treat	Unique ID	Study ID	Experimental	Comparator	Outcome	Weight	D1	D2	D3	D4	D5	Overall	
	751	Abbas 2023	CBT	Waitlist	distress	1	+	+	+	+	+	+	Low risk
	2153	Amsberg 2009	CBT	NA	Distress	1	+	+	+	+	+	+	Some concerns
	2329	Anderson 2009	DSME	NA	distress	1	+	+	+	+	+	+	High risk
	763	Baldwin 2020	springboard	NA	distress	1	+	+	+	+	+	+	
	631	Bendig 2021	ACT	NA	distress	1	+	+	+	+	+	+	D1 Randomisation process
	1091	Callan 2022	CBT	NA	distress	1	+	+	+	+	+	+	D2 Deviations from the intended interventions
	2938	Carreira 2938	I CBT	NA	Distress	1	+	+	+	+	+	+	D3 Missing outcome data
	241	Cheng 2021	empowerment-based	NA	distress	1	+	+	+	+	+	+	D4 Measurement of the outcome
	5716	Chiu 2016	minimal psych interventional	NA	distress	1	+	+	+	+	+	+	D5 Selection of the reported result
	959	Coccaro 2022	Emotion-Focused Behavior	NA	distress	1	+	+	+	+	+	+	
	5896	Cohn 2014	DAHUA	wait list	distress	1	+	+	+	+	+	+	
	3133	Cornely 2022	cognitive behavioral therapy	NA	distress	1	+	+	+	+	+	+	
	1685	Crawford 2019	Web-Based Benefit-Finder	NA	distress	1	+	+	+	+	+	+	
	5899	deGroot	CBT with or without exercise	usual care	NA	1	+	+	+	+	+	+	
	1038	Dennick 2015	WED	control	Diabetes distress	1	+	+	+	+	+	+	
	1254	DiNardo 2022	Mindfulness	NA	distress	1	+	+	+	+	+	+	
	991	Fisher 2013	redeem	NA	distress	1	+	+	+	+	+	+	
	378	Friis 2016	kindness	NA	distress	1	+	+	+	+	+	+	
	870	Gabbay 2013	nurse led	NA	distress	1	+	+	+	+	+	+	
	2294	Griva 2019	C-DIRECT	NA	distress	1	+	+	+	+	+	+	
	768	Guo 2022	mindfulness	NA	distress	1	+	+	+	+	+	+	
	5905	Heinrich 2010	Motivational Interviewing	NA	distress	1	+	+	+	+	+	+	
	663	Hermans 2015	DIAMOS	NA	distress	1	+	+	+	+	+	+	
	644	Hoyo 2022	tele dd	NA	distress	1	+	+	+	+	+	+	
	67	Fisher 2018	Redeem	NA	distress	1	+	+	+	+	+	+	
	526	Ismael 2018	nurse led psych intervent	NA	distress	1	+	+	+	+	+	+	
	776	Jul 2014	nurse led	NA	distress	1	+	+	+	+	+	+	
	152	Kamplung 2022	psy-PAD	NA	Distress	1	+	+	+	+	+	+	
	382	Kasteleyn 2016	Diacourse ACE	NA	distress	1	+	+	+	+	+	+	
	2207	Kilic 2023	ACE	NA	distress	1	+	+	+	+	+	+	
	803	Lamers 2011	nurse-administered mini	NA	distress	1	+	+	+	+	+	+	
	260	Li 2022	motivational interviewing	NA	FR	1	+	+	+	+	+	+	
	326	Lutes 2018	comrade	NA	distress	1	+	+	+	+	+	+	
	2857	Maghsoudi 2019	ACE therapy	NA	distress	1	+	+	+	+	+	+	
	1860	Mohn 2017	guided self-determination	NA	distress	1	+	+	+	+	+	+	
	1818	Newby 2017	Web-Based Cognitive Beh	NA	distress	1	+	+	+	+	+	+	
	3458	Pearson 2018	Mindfulness	NA	distress	1	+	+	+	+	+	+	
	5914	Petrak 2015	diabetes-specific psychot	antidepressant medication	distress	1	+	+	+	+	+	+	
	3498	Popelier 2019	theater	NA	distress	1	+	+	+	+	+	+	
	2763	Rees 2017	Problem-solving therapy	NA	distress	1	+	+	+	+	+	+	
	771	Roddy 2023	Family/friend Activation	t enhanced care as usual	NA	1	+	+	+	+	+	+	
	411	Rosenbek	Minet 20'	motivational interviewing	usual care	NA	1	+	+	+	+	+	
	206	Schmitt 2022	NA	NA	NA	1	+	+	+	+	+	+	
	3513	Schroevens 2015	NA	NA	NA	1	+	+	+	+	+	+	
	719	Shukla 2021	mindfulness	NA	distress	1	+	+	+	+	+	+	
	652	Simson 2008	Psychotherapy interventi	NA	distress	1	+	+	+	+	+	+	
	435	Snoek 2008	CBT	BGAT	distress	1	+	+	+	+	+	+	
	2502	Spencer 2013	Community health worker	6m delayed waitinglist	NA	1	+	+	+	+	+	+	
	418	Tovote 2014	Mindfulness-Based Cogni	NA	distress	1	+	+	+	+	+	+	
	828	Trevisan 2020	implementation intention	NA	distress	1	+	+	+	+	+	+	
	839	Trief 2016	elephonic Couples Behavi	NA	distress	1	+	+	+	+	+	+	
	625	van Bastelaar 2011	CBT intervention	NA	Distress	1	+	+	+	+	+	+	
	372	van Son 2013	van Son	NA	distress	1	+	+	+	+	+	+	
	1569	Wijk 2023	Acceptance	NA	distress	1	+	+	+	+	+	+	
	4052	Yahong 2020	meta awarentess	NA	distress	1	+	+	+	+	+	+	
	5924	Zoffmann 2006	16 h GSD-GT	wait list	distress	1	+	+	+	+	+	+	
	242	Alessi 2021	telehealth intervention	active controlgroup: access	Diabetes distress	1	+	+	+	+	+	+	
	858	Alessi 2022	Telehealth strategy	NA	distress	1	+	+	+	+	+	+	
	1920	Amiel 2022	Hypoglycaemia Awareness	Blood Glucose Awareness	Diabetes distress	1	+	+	+	+	+	+	
	2896	Anjali 2023	DMSE	NA	Diabetes distress	1	+	+	+	+	+	+	
	392	Bae 2024	mobile app	NA	Diabetes distress	1	+	+	+	+	+	+	
	121	Baig 2024	Group visits	Standard care	Diabetes distress	1	+	+	+	+	+	+	
	401	Basak Cinar 2014	Health coaching	NA	Diabetes distress	1	+	+	+	+	+	+	
	925	Beverly 2013	DSME conversation	NA	Diabetes distress	1	+	+	+	+	+	+	
	933	Binesh 2023	Occupational Therapy Dia	Educational program	Diabetes distress	1	+	+	+	+	+	+	
	1698	Biono 2022	TH plus VA	TH	Diabetes distress	1	+	+	+	+	+	+	
	5894	Bond 2010	web-based intervention	usual care	Diabetes distress	1	+	+	+	+	+	+	

1011	Woodard 2022	goal setting	NA	Diabetes distress	1	+	+	+	+	+	+	+
714	Zhang 2024	nudge	NA	Diabetes distress	1	+	+	+	+	+	+	+
672	Zoffmann 2015	guided self-determination	NA	distress	1	+	+	+	+	+	+	+
2038	Boscari 2022	Eversense implantable se	Dexcom G5 transcutaneous	Distress	1	+	+	+	+	+	+	+
739	Chan 2014	Pearl	jade	distress	1	+	+	+	+	+	+	+
146	Clark 2020	Dulce Digital	Standard care	Diabetes distress	1	+	+	+	+	+	+	+
5897	Dale 2009	peer telephone interventi	Care as usual	distress	1	+	+	+	+	+	+	+
1853	Ehrmann 2016	PRIMAS through RCT	PRIMAS through impleme	Diabetes distress	1	+	+	+	+	+	+	+
947	Fisher 2011	STG	CAU	distress	1	+	+	+	+	+	+	+
662	Furler 2020	professional-mode (retro	usual care	NA	1	+	+	+	+	+	+	+
5901	Gagliardino 2013	Peer teacher	prof teachers	distress	1	+	+	+	+	+	+	+
898	GrilloMde 2016	Diabetes self-managemer	No structured diabetes me	Diabetes distress	1	+	+	+	+	+	+	+
5903	Haak 2016	glucose-sensing technolo	SMBG	distress	1	+	+	+	+	+	+	+
1505	Heisler 2010	Peer	nurse	distress	1	+	+	+	+	+	+	+
2100	Hernandes 2011	Sensor-augmented pump	cau	distress	1	+	+	+	+	+	+	+
1096	Hermanns 2009	continuous glucose monit	retrospective access to glu	NA	1	+	+	+	+	+	+	+
3015	Ho 2020	NA	NA	NA	1	+	+	+	+	+	+	+
306	Ing 2016	DSME	NA	Distress	1	+	+	+	+	+	+	+
108	Ju 2018	peer edu	NA	distress	1	+	+	+	+	+	+	+
2487	Kavin 2010	book	CAU	NA	1	+	+	+	+	+	+	+
784	Kunik 2023	Peer	CAU	distress	1	+	+	+	+	+	+	+
352	Malanda 2016	glucose monitor	CAU	distress	1	+	+	+	+	+	+	+
5912	McAuley 2021	closed-loop insulin delive	sensor-augmented pump t	distress	1	+	+	+	+	+	+	+
2173	McAuley 2020	cgm	CAU	distress	1	+	+	+	+	+	+	+
349	Platt 2018	DSME	CAU	distress	1	+	+	+	+	+	+	+
1744	Polonsky 2017	continuous glucose monit	self blood glucose monitor	NA	1	+	+	+	+	+	+	+
5915	Pratley 2020	continuous blood glucose	standard blood glucose mc	NA	1	+	+	+	+	+	+	+
2219	Pylov 2023	continuous glucose monit	self blood glucose monitor	NA	1	+	+	+	+	+	+	+
4743	Sato 2020	Libre flash glucose monit	conventional treatment	NA	1	+	+	+	+	+	+	+
2006	Schneider-Utaka 2C CMG	Flash	distress	1	+	+	+	+	+	+	+	+
1041	Siminerio 2013	diabetes self-managemer	usual care	NA	1	+	+	+	+	+	+	+
833	Simmons	Peer	CAU	distress	1	+	+	+	+	+	+	+
572	Sperli-Hillen 2013	2 interventions: individua	Standard care with no edu	Diabetes distress	1	+	+	+	+	+	+	+
840	Sturt 2008	book	CAU	distress	1	+	+	+	+	+	+	+
5920	Tang 2012	e-health	Usual care	Distress	1	+	+	+	+	+	+	+
1095	Tang 2014	2 interventions: peer lead	NA	Diabetes distress	1	+	+	+	+	+	+	+
5921	van Beers 2016	continuous glucose monit	usual care	NA	1	+	+	+	+	+	+	+
820	van der Wulp 2012	NA	NA	distress	1	+	+	+	+	+	+	+
2187	Weissberg	Bihormonal delivery syste	CAU	distress	1	+	+	+	+	+	+	+
1024	Zheng 2019	edu	CAU	distress	1	+	+	+	+	+	+	+
5933	Aronson 2023	isCGM + DSME	DSME	distress	1	+	+	+	+	+	+	+
5927	Bolinder 2016	flash sensor-based glucos	CAU	distress	1	+	+	+	+	+	+	+
5928	Ischia group 2023	isCGM	SMBG	distress	1	+	+	+	+	+	+	+
5355	Leelarathna 2022	Freestyle	CAU	distress	1	+	+	+	+	+	+	+
5931	Secher 2021	ABC, CGM plus combined	CAU	distress	1	+	+	+	+	+	+	+
5932	Udoku 2023	CGM	CAU	distress	1	+	+	+	+	+	+	+
5930	Rilstone 2024	CGM	CGM without alert	distress	1	+	+	+	+	+	+	+
5929	Reddy 2018	CGM	NA	Distress	1	+	+	+	+	+	+	+
5926	Beck 2017	CGM	CAU	distress	1	+	+	+	+	+	+	+
5934	Benhalima 2023	advanced hybrid closed lc	CAU	distress	1	+	+	+	+	+	+	+
5935	Lee 2023	hybrid closed loop therap	CAU	distress	1	+	+	+	+	+	+	+
5940	Weissberg-Benchell	bihormonal device	usual care	NA	1	+	+	+	+	+	+	+
1258	Welch 2011	Comprehensive Diabetes	Attention control	Diabetes distress	1	+	+	+	+	+	+	+

References

1. Hossain, M.J., M. Al-Mamun, and M.R. Islam, *Diabetes mellitus, the fastest growing global public health concern: Early detection should be focused*. Health Science Reports, 2024. **7**(3): p. e2004.
2. Polonsky, W.H., et al., *Assessment of diabetes-related distress*. Diabetes Care, 1995. **18**(6): p. 754–60.
3. Fisher, L., et al., *When is diabetes distress clinically meaningful?: establishing cut points for the Diabetes Distress Scale*. Diabetes Care, 2012. **35**(2): p. 259–64.
4. Fisher, L., R.E. Glasgow, and L.A. Strycker, *The relationship between diabetes distress and clinical depression with glycemic control among patients with type 2 diabetes*. Diabetes Care, 2010. **33**(5): p. 1034–6.
5. Dennick, K., et al., *High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis*. International Diabetes Nursing, 2015. **12**(3): p. 93–107.
6. Perrin, N.E., et al., *The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis*. Diabet Med, 2017. **34**(11): p. 1508–1520.
7. Skinner, T.C., L. Joensen, and T. Parkin, *Twenty-five years of diabetes distress research*. Diabet Med, 2020. **37**(3): p. 393–400.
8. Aikens, J.E., *Prospective associations between emotional distress and poor outcomes in type 2 diabetes*. Diabetes Care, 2012. **35**(12): p. 2472–8.
9. Todd, P.J., et al., *Evaluating the relationships of hypoglycaemia and HbA1c with screening-detected diabetes distress in type 1 diabetes*. Endocrinol Diabetes Metab, 2018. **1**(1): p. e00003.
10. Young-Hyman, D., et al., *Psychosocial Care for People With Diabetes: A Position Statement of the American Diabetes Association*. Diabetes Care, 2016. **39**(12): p. 2126–2140.
11. *in Type 1 diabetes in adults: diagnosis and management*. 2022: London.
12. Karagiannis, T., et al., *European Association for the Study of Diabetes (EASD) Standard Operating Procedure for the development of guidelines*. Diabetologia, 2025.
13. Chew, B.H., et al., *Psychological interventions for diabetes-related distress in adults with type 2 diabetes mellitus*. Cochrane Database Syst Rev, 2017. **9**(9): p. CD011469.
14. Mathiesen, A.S., et al., *Psychosocial interventions for reducing diabetes distress in vulnerable people with type 2 diabetes mellitus: a systematic review and meta-analysis*. Diabetes Metab Syndr Obes, 2019. **12**: p. 19–33.
15. Ngan, H.Y., Y.Y. Chong, and W.T. Chien, *Effects of mindfulness- and acceptance-based interventions on diabetes distress and glycaemic level in people with type 2 diabetes: Systematic review and meta-analysis*. Diabet Med, 2021. **38**(4): p. e14525.
16. Perrin, N., et al., *Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: A systematic review and meta-analysis*. Prim Care Diabetes, 2019. **13**(6): p. 556–567.
17. Schmidt, C.B., et al., *Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes-distress*. Diabet Med, 2018.
18. Sturt, J., et al., *Effective interventions for reducing diabetes distress: systematic review and meta-analysis*. International Diabetes Nursing, 2015. **12**(2): p. 40–55.
19. Zu, W., et al., *The effectiveness of psychological interventions on diabetes distress and glycemic level in adults with type 2 diabetes: a systematic review and meta-analysis*. BMC Psychiatry, 2024. **24**(1): p. 660.
20. Yakubu, T.I., et al., *Impact of Digitally Enabled Peer Support Interventions on Diabetes Distress and Depressive Symptoms in People Living with Type 1 Diabetes: A Systematic Review*. Curr Diab Rep, 2024. **25**(1): p. 1.

21. Hoyo, M.L.L.d., et al., *The TELE-DD Randomised Controlled Trial on Treatment Adherence in Patients with Type 2 Diabetes and Comorbid Depression: Clinical Outcomes after 18-Month Follow-Up*. International Journal of Environmental Research and Public Health, 2023. **20**(1): p. 328.
22. Haak, T., et al., *Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial*. Diabetes Therapy, 2017. **8**(1): p. 55–73.
23. Polonsky, W.H., et al., *Assessing psychosocial distress in diabetes: development of the diabetes distress scale*. Diabetes Care, 2005. **28**(3): p. 626–31.
24. Duran, G., et al., *Assessing daily problems with diabetes: A subject-oriented approach to compliance*. 1995. **76**: p. 515–521.
25. *Covidence systematic review software*. 2025, Veritas Health Innovation.
26. Quinn, C.C., et al., *Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control*. Diabetes Care, 2011. **34**(9): p. 1934–1942.
27. Higgins JPT, T.J., Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of Interventions version 6.5 (updated August 2024)*. 2024.
28. Dale, J., et al., *Telephone peer-delivered intervention for diabetes motivation and support: The telecare exploratory RCT*. Patient Education and Counseling, 2009. **75**(1): p. 91–98.
29. Sterne, J.A.C., et al., *RoB 2: a revised tool for assessing risk of bias in randomised trials*. BMJ, 2019. **366**: p. l4898.
30. Schandelmaier, S., et al., *Development of the Instrument to assess the Credibility of Effect Modification Analyses (ICEMAN) in randomized controlled trials and meta-analyses*. CMAJ, 2020. **192**(32): p. E901–E906.
31. Guyatt, G.H., et al., *What is "quality of evidence" and why is it important to clinicians?* BMJ, 2008. **336**(7651): p. 995–8.
32. Snoek, F.J., et al., *Cognitive behavioural therapy (CBT) compared with blood glucose awareness training (BGAT) in poorly controlled Type 1 diabetic patients: long-term effects on HbA1c moderated by depression. A randomized controlled trial*. Diabetic Medicine, 2008. **25**(11): p. 1337–1342.
33. Fisher, L., et al., *T1-REDEEM: A Randomized Controlled Trial to Reduce Diabetes Distress Among Adults With Type 1 Diabetes*. Diabetes Care, 2018. **41**(9): p. 1862–1869.
34. Hermanns, N., et al., *The Effect of a Diabetes-Specific Cognitive Behavioral Treatment Program (DIAMOS) for Patients With Diabetes and Subclinical Depression: Results of a Randomized Controlled Trial*. Diabetes Care, 2015. **38**(4): p. 551–560.
35. Petrak, F., et al., *Cognitive Behavioral Therapy Versus Sertraline in Patients With Depression and Poorly Controlled Diabetes: The Diabetes and Depression (DAD) Study: A Randomized Controlled Multicenter Trial*. Diabetes Care, 2015. **38**(5): p. 767–775.
36. Amsberg, S., et al., *A cognitive behavior therapy-based intervention among poorly controlled adult type 1 diabetes patients—A randomized controlled trial*. Patient Education and Counseling, 2009. **77**(1): p. 72–80.
37. Bendig, E., et al., *ACTonDiabetes—a guided psychological internet intervention based on Acceptance and Commitment Therapy (ACT) for adults living with type 1 or 2 diabetes: results of a randomised controlled feasibility trial*. BMJ Open, 2021. **11**(7): p. e049238.
38. Carreira, M., et al., *Internet-based cognitive-behavioral therapy is effective in reducing depressive symptomatology in type 1 diabetes: results of a randomized controlled trial*. Frontiers in Clinical Diabetes and Healthcare, 2023. **Volume 4 - 2023**.

39. Crawford, J., K. Wilhelm, and J. Proudfoot, *Web-Based Benefit-Finding Writing for Adults with Type 1 or Type 2 Diabetes: Preliminary Randomized Controlled Trial*. JMIR Diabetes, 2019. **4**(2): p. e13857.
40. Friis, A.M., et al., *Kindness Matters: A Randomized Controlled Trial of a Mindful Self-Compassion Intervention Improves Depression, Distress, and HbA1c Among Patients With Diabetes*. Diabetes Care, 2016. **39**(11): p. 1963–1971.
41. Griva, K., et al., *The combined diabetes and renal control trial (C-DIRECT) - a feasibility randomised controlled trial to evaluate outcomes in multi-morbid patients with diabetes and on dialysis using a mixed methods approach*. BMC Nephrology, 2019. **20**(1): p. 2.
42. Kampling, H., et al., *An Integrated Psychosomatic Treatment Program for People with Diabetes (psy-PAD)*. Dtsch Arztebl Int, 2022. **119**(14): p. 245–252.
43. Newby, J., et al., *Web-Based Cognitive Behavior Therapy for Depression in People With Diabetes Mellitus: A Randomized Controlled Trial*. J Med Internet Res, 2017. **19**(5): p. e157.
44. Popelier, M., et al., *Évaluation de deux approches de médecine narrative, le théâtre du vécu et un atelier d'écriture, dans une prise en charge éducative intégrée de patients diabétiques de type 1*. Educ Ther Patient/Ther Patient Educ, 2019. **11**(1).
45. Schmitt, A., et al., *Evaluation of a Stepped Care Approach to Manage Depression and Diabetes Distress in Patients with Type 1 Diabetes and Type 2 Diabetes: Results of a Randomized Controlled Trial (ECCE HOMO Study)*. Psychotherapy and Psychosomatics, 2021. **91**(2): p. 107–122.
46. Schroevers, M.J., et al., *Individual mindfulness-based cognitive therapy for people with diabetes: A pilot randomized controlled trial*. Mindfulness, 2015. **6**(1): p. 99–110.
47. Shukla, R., et al., *Mindfulness Meditation as Adjunctive Therapy to Improve the Glycemic Care and Quality of Life in Patients with Type 1 Diabetes*. Medical Sciences, 2021. **9**(2): p. 33.
48. van Bastelaar, K.M.P., et al., *Web-Based Depression Treatment for Type 1 and Type 2 Diabetic Patients: A randomized, controlled trial*. Diabetes Care, 2011. **34**(2): p. 320–325.
49. Wijk, I., et al., *Impact of an Acceptance and Commitment Therapy programme on HbA1c, self-management and psychosocial factors in adults with type 1 diabetes and elevated HbA1c levels: a randomised controlled trial*. BMJ Open, 2023. **13**(12): p. e072061.
50. Zoffmann, V. and T. Lauritzen, *Guided self-determination improves life skills with Type 1 diabetes and A1C in randomized controlled trial*. Patient Education and Counseling, 2006. **64**(1): p. 78–86.
51. Zoffmann, V., D. Vistisen, and M. Due-Christensen, *Flexible guided self-determination intervention for younger adults with poorly controlled Type 1 diabetes, decreased HbA1c and psychosocial distress in women but not in men: a real-life RCT*. Diabetic Medicine, 2015. **32**(9): p. 1239–1246.
52. Mohn, J., et al., *The effect of guided self-determination on self-management in persons with type 1 diabetes mellitus and HbA_{1c} ≥64 mmol/mol: a group-based randomised controlled trial*. BMJ Open, 2017. **7**(6): p. e013295.
53. Petrak, F., et al., *Cognitive Behavioral Therapy Versus Sertraline in Patients With Depression and Poorly Controlled Diabetes: The Diabetes and Depression (DAD) Study: A Randomized Controlled Multicenter Trial*. Diabetes Care, 2015. **38**(5): p. 767–75.
54. DiNardo, M.M., et al., *Effects of an integrated mindfulness intervention for veterans with diabetes distress: a randomized controlled trial*. BMJ Open Diabetes Research & Care, 2022. **10**(2): p. e002631.
55. Anderson, R.M., et al., *Evaluating the efficacy of an empowerment-based self-management consultant intervention: results of a two-year randomized controlled trial*. Educ Ther Patient/Ther Patient Educ, 2009. **1**(1): p. 3–11.

56. Baldwin, P.A., et al., *A Web-Based Mental Health Intervention to Improve Social and Occupational Functioning in Adults With Type 2 Diabetes (The Springboard Trial): 12-Month Outcomes of a Randomized Controlled Trial*. J Med Internet Res, 2020. **22**(12): p. e16729.
57. Cheng, L., et al., *The effects of an empowerment-based self-management intervention on empowerment level, psychological distress, and quality of life in patients with poorly controlled type 2 diabetes: A randomized controlled trial*. International Journal of Nursing Studies, 2021. **116**: p. 103407.
58. Fisher, L., et al., *REDEEM: A Pragmatic Trial to Reduce Diabetes Distress*. Diabetes Care, 2013. **36**(9): p. 2551–2558.
59. Guo, J., et al., *Effectiveness of a nurse-led mindfulness stress-reduction intervention on diabetes distress, diabetes self-management, and HbA1c levels among people with type 2 diabetes: A pilot randomized controlled trial*. Research in Nursing & Health, 2022. **45**(1): p. 46–58.
60. Kasteleyn, M.J., et al., *Effectiveness of tailored support for people with Type 2 diabetes after a first acute coronary event: a multicentre randomized controlled trial (the Diacourse-ACE study)*. Diabetic Medicine, 2016. **33**(1): p. 125–133.
61. Li, Z., et al., *Effectiveness of motivational interviewing on improving Care for Patients with type 2 diabetes in China: A randomized controlled trial*. BMC Health Services Research, 2020. **20**(1): p. 57.
62. Roddy, M.K., et al., *Well-being outcomes of a family-focused intervention for persons with type 2 diabetes and support persons: Main, mediated, and subgroup effects from the FAMS 2.0 RCT*. Diabetes Research and Clinical Practice, 2023. **204**: p. 110921.
63. Trief, P.M., et al., *Health and Psychosocial Outcomes of a Telephonic Couples Behavior Change Intervention in Patients With Poorly Controlled Type 2 Diabetes: A Randomized Clinical Trial*. Diabetes Care, 2016. **39**(12): p. 2165–2173.
64. Dennick, K., C. Bridle, and J. Sturt, *Written emotional disclosure for adults with Type 2 diabetes: a primary care feasibility study*. Prim Health Care Res Dev, 2015. **16**(2): p. 179–187.
65. Yanhong, G.E., et al., *Curative effects of mindfulness training based on "meta-awareness" combined with intermittent pneumatic compression therapy on TcPO₂, distress, mindful attention awareness and blood glucose in diabetic patients with lower extremity arterial disease*. Chinese Nursing Research, 2020. **34**(7): p. 574–579.
66. Abbas, Q., et al., *Cognitive behavior therapy for diabetes distress, depression, health anxiety, quality of life and treatment adherence among patients with type-II diabetes mellitus: a randomized control trial*. BMC Psychiatry, 2023. **23**(1): p. 86.
67. Chiu, C.-J., et al., *Dissemination of evidence-base minimal psychological intervention for diabetes management in Taiwan adults with type 2 diabetes*. 2016. **9**: p. 14489–14498.
68. de Groot, M., et al., *Program ACTIVE II: Outcomes From a Randomized, Multistate Community-Based Depression Treatment for Rural and Urban Adults With Type 2 Diabetes*. Diabetes Care, 2019. **42**(7): p. 1185–1193.
69. Gabbay, R.A., et al., *Diabetes nurse case management and motivational interviewing for change (DYNAMIC): Results of a 2-year randomized controlled pragmatic trial (糖尿病护士病例管理以及促进改变的动机性会谈 (DYNAMIC) : 一项为期2年的实用随机对照研究)*. Journal of Diabetes, 2013. **5**(3): p. 349–357.
70. Ismail, K., et al., *Nurse-led psychological intervention for type 2 diabetes: a cluster randomised controlled trial (Diabetes-6 study) in primary care*. British Journal of General Practice, 2018. **68**(673): p. e531.
71. Juul, L., et al., *Effectiveness of a training course for general practice nurses in motivation support in type 2 diabetes care: a cluster-randomised trial*. PLoS One, 2014. **9**(5): p. e96683.

72. Lamers, F., et al., *Treating depression in diabetes patients: does a nurse-administered minimal psychological intervention affect diabetes-specific quality of life and glycaemic control? A randomized controlled trial*. Journal of Advanced Nursing, 2011. **67**(4): p. 788–799.
73. Lutes, L.D., et al., *COMRADE: A randomized trial of an individually tailored integrated care intervention for uncontrolled type 2 diabetes with depression and/or distress in the rural southeastern US*. Contemporary Clinical Trials, 2018. **70**: p. 8–14.
74. Maghsoudi, Z., et al., *Efficacy Of Acceptance And Commitment Therapy For Emotional Distress In The Elderly With Type 2 Diabetes: A Randomized Controlled Trial*. Diabetes Metab Syndr Obes, 2019. **12**: p. 2137–2143.
75. Pearson, S., et al., *Effects of mindfulness on psychological distress and HbA1c in people with diabetes*. Mindfulness, 2018. **9**(5): p. 1615–1626.
76. Rees, G., et al., *Problem-solving therapy for adults with diabetic retinopathy and diabetes-specific distress: a pilot randomized controlled trial*. BMJ Open Diabetes Research & Care, 2017. **5**(1): p. e000307.
77. Rosenbek Minet, L.K., et al., *The effect of motivational interviewing on glycaemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education programme: a randomised controlled trial*. Diabetologia, 2011. **54**(7): p. 1620–1629.
78. Simson, U., et al., *Psychotherapy intervention to reduce depressive symptoms in patients with diabetic foot syndrome*. Diabetic Medicine, 2008. **25**(2): p. 206–212.
79. Trevisan, D.D., et al., *Effect of an ‘implementation intention’ intervention on adherence to oral anti-diabetic medication in Brazilians with type 2 diabetes*. Patient Education and Counseling, 2020. **103**(3): p. 582–588.
80. van Son, J., et al., *Mindfulness-based cognitive therapy for people with diabetes and emotional problems: Long-term follow-up findings from the DiaMind randomized controlled trial*. Journal of Psychosomatic Research, 2014. **77**(1): p. 81–84.
81. Callan, J.A., et al., *Cognitive Behavioral Therapy (CBT) Telehealth Augmented With a CBT Smartphone Application to Address Type 2 Diabetes Self-Management: A Randomized Pilot Trial*. The Science of Diabetes Self-Management and Care, 2022. **48**(6): p. 492–504.
82. Coccaro, E.F., et al., *Diabetes distress, emotional regulation, HbA1c in people with diabetes and A controlled pilot study of an emotion-focused behavioral therapy intervention in adults with type 2 diabetes*. Primary Care Diabetes, 2022. **16**(3): p. 381–386.
83. Cohn, M.A., et al., *An online positive affect skills intervention reduces depression in adults with type 2 diabetes*. J Posit Psychol, 2014. **9**(6): p. 523–534.
84. Heinrich, E., et al., *Effect evaluation of a Motivational Interviewing based counselling strategy in diabetes care*. Diabetes Research and Clinical Practice, 2010. **90**(3): p. 270–278.
85. Kılıç, A., et al., *An online acceptance, commitment, and self-compassion based treatment to decrease psychological distress in people with type 2 diabetes: A feasibility randomised-controlled trial*. Internet Interv, 2023. **33**: p. 100658.
86. Bisno, D.I., et al., *Virtual Group Appointments Reduce Distress and Improve Care Management in Young Adults with Type 1 Diabetes*. J Diabetes Sci Technol, 2022. **16**(6): p. 1419–1427.
87. Hermanns, N., et al., *The effect of a diabetes education programme (PRIMAS) for people with type 1 diabetes: results of a randomized trial*. Diabetes Res Clin Pract, 2013. **102**(3): p. 149–157.
88. Hermanns, N., et al., *The effect of an education programme (HyPOS) to treat hypoglycaemia problems in patients with type 1 diabetes*. Diabetes/Metabolism Research and Reviews, 2007. **23**(7): p. 528–538.
89. Safford, M.M., et al., *Peer Coaches to Improve Diabetes Outcomes in Rural Alabama: A Cluster Randomized Trial*. Ann Fam Med, 2015. **13 Suppl 1**(Suppl 1): p. S18–S26.

90. Alessi, J., et al., *Type 1 diabetes and the challenges of emotional support in crisis situations: results from a feasibility study of a multidisciplinary teleintervention*. Sci Rep, 2022. **12**(1): p. 8526.
91. Brennan, M.C., et al., *Self-Management Group Education to Reduce Fear of Hypoglycemia as a Barrier to Physical Activity in Adults Living With Type 1 Diabetes: A Pilot Randomized Controlled Trial*. Can J Diabetes, 2021. **45**(7): p. 619–628.
92. Karlsen, B., et al., *Effects of a group-based counselling programme on diabetes-related stress, coping, psychological well-being and metabolic control in adults with type 1 or type 2 diabetes*. Patient Educ Couns, 2004. **53**(3): p. 299–308.
93. O'Brien, C.L., et al., *Initial evaluation of the Optimal Health Program for people with diabetes: 12-month outcomes of a randomised controlled trial*. Psychol Health, 2024. **39**(3): p. 358–378.
94. Pranata, S., et al., *Effects of the tailored intervention program in lowering blood glucose levels and diabetes distress among patients with diabetes in Indonesia: a randomized controlled trial*. Jurnal Ners, 2023. **18**(1): p. 71–79.
95. Rondags, S.M., et al., *Effectiveness of HypoAware, a Brief Partly Web-Based Psychoeducational Intervention for Adults With Type 1 and Insulin-Treated Type 2 Diabetes and Problematic Hypoglycemia: A Cluster Randomized Controlled Trial*. Diabetes Care, 2016. **39**(12): p. 2190–2196.
96. Basak Cinar, A. and L. Schou, *Health promotion for patients with diabetes: health coaching or formal health education?* Int Dent J, 2014. **64**(1): p. 20–28.
97. Binesh, M., et al., *A randomized controlled trial for evaluating an occupational therapy self management intervention in adults with type 2 diabetes*. Sci Rep, 2023. **13**(1): p. 10128.
98. Crowley, M.J., et al., *Effect of a Comprehensive Telehealth Intervention vs Telemonitoring and Care Coordination in Patients With Persistently Poor Type 2 Diabetes Control: A Randomized Clinical Trial*. JAMA Intern Med, 2022. **182**(9): p. 943–952.
99. D'Eramo Melkus, G., et al., *The effect of a diabetes education, coping skills training, and care intervention on physiological and psychosocial outcomes in black women with type 2 diabetes*. Biol Res Nurs, 2010. **12**(1): p. 7–19.
100. Heisler, M., et al., *Comparison of community health worker-led diabetes medication decision-making support for low-income Latino and African American adults with diabetes using e-health tools versus print materials: a randomized, controlled trial*. Ann Intern Med, 2014. **161**(10 Suppl): p. S13–S22.
101. Hermanns, N., et al., *The effect of an education programme (MEDIAS 2 BSC) of non-intensive insulin treatment regimens for people with Type 2 diabetes: a randomized, multi-centre trial*. Diabet Med, 2017. **34**(8): p. 1084–1091.
102. Hermanns, N., et al., *The effect of an education programme (MEDIAS 2 ICT) involving intensive insulin treatment for people with type 2 diabetes*. Patient Educ Couns, 2012. **86**(2): p. 226–232.
103. Hessler, D., et al., *The impact of enhancing self-management support for diabetes in Community Health Centers through patient engagement and relationship building: a primary care pragmatic cluster-randomized trial*. Transl Behav Med, 2022. **12**(9): p. 909–918.
104. Jiang, X.J., et al., *The Effectiveness of a Self-Efficacy-Focused Structured Education Program (SSEP) in Improving Metabolic Control and Psychological Outcomes of Type 2 Diabetes Patients: A 12-Month Follow-Up of a Multicenter Randomized Controlled Trial*. Diabetes Metab Syndr Obes, 2021. **14**: p. 305–313.
105. Jung, H.Y., H. Lee, and J. Park, *Comparison of the effects of Korean mindfulness-based stress reduction, walking, and patient education in diabetes mellitus*. Nurs Health Sci, 2015. **17**(4): p. 516–525.

106. Liu, Y., et al., *Effect of peer education on self-management and psychological status in type 2 diabetes patients with emotional disorders*. Journal of Diabetes Investigation, 2015. **6**(4): p. 479–486.
107. Pyatak, E.A., et al., *Occupational Therapy Intervention Improves Glycemic Control and Quality of Life Among Young Adults With Diabetes: the Resilient, Empowered, Active Living with Diabetes (REAL Diabetes) Randomized Controlled Trial*. Diabetes Care, 2018. **41**(4): p. 696–704.
108. Skelly, A.H., et al., *Controlled trial of nursing interventions to improve health outcomes of older African American women with type 2 diabetes*. Nurs Res, 2009. **58**(6): p. 410–418.
109. Spencer, M.S., et al., *Outcomes at 18 Months From a Community Health Worker and Peer Leader Diabetes Self-Management Program for Latino Adults*. Diabetes Care, 2018. **41**(7): p. 1414–1422.
110. Swoboda, C.M., C.K. Miller, and C.E. Wills, *Impact of a goal setting and decision support telephone coaching intervention on diet, psychosocial, and decision outcomes among people with type 2 diabetes*. Patient Educ Couns, 2017. **100**(7): p. 1367–1373.
111. van Puffelen, A.L., et al., *Effectiveness of a self-management support program for type 2 diabetes patients in the first years of illness: Results from a randomized controlled trial*. PLoS One, 2019. **14**(6): p. e0218242.
112. Wagner, J.A., et al., *A randomized, controlled trial of a stress management intervention for Latinos with type 2 diabetes delivered by community health workers: Outcomes for psychological wellbeing, glycemic control, and cortisol*. Diabetes Res Clin Pract, 2016. **120**: p. 162–170.
113. Woodard, L., et al., *Comparison of Collaborative Goal Setting With Enhanced Education for Managing Diabetes-Associated Distress and Hemoglobin A1c Levels: A Randomized Clinical Trial*. JAMA Netw Open, 2022. **5**(5): p. e229975.
114. Zhang, Q., et al., *Effects of nudge strategy-based dietary education intervention in patients with type 2 diabetes mellitus: A cluster randomized controlled trial*. Diabetes Metab, 2024. **50**(5): p. 101563.
115. Anjali, M., et al., *Effectiveness of Diabetes Self-Management Education on Distress and HbA1C among Indian Type 2 Diabetes Mellitus Patients: A Randomized Controlled Trial*. Indian J Community Med, 2023. **48**(5): p. 702–708.
116. Bae, J.H., et al., *Enhancing Diabetes Care through a Mobile Application: A Randomized Clinical Trial on Integrating Physical and Mental Health among Disadvantaged Individuals*. Diabetes Metab J, 2024. **48**(4): p. 790–801.
117. Baig, A.A., et al., *Cluster Randomized Trial of Diabetes Group Visits in Community Health Centers across the Midwest*. J Health Care Poor Underserved, 2024. **35**(3s): p. 27–46.
118. Bond, G.E., et al., *The Effects of a Web-Based Intervention on Psychosocial Well-Being Among Adults Aged 60 and Older With Diabetes*. The Diabetes Educator, 2010. **36**(3): p. 446–456.
119. Davies, M.J., et al., *Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial*. BMJ, 2008. **336**(7642): p. 491–495.
120. Dobson, R., et al., *Effectiveness of text message based, diabetes self management support programme (SMS4BG): two arm, parallel randomised controlled trial*. Bmj, 2018. **361**: p. k1959.
121. Hilmarisdóttir, E., K. Sigurðardóttir Á, and R.H. Arnardóttir, *A Digital Lifestyle Program in Outpatient Treatment of Type 2 Diabetes: A Randomized Controlled Study*. J Diabetes Sci Technol, 2021. **15**(5): p. 1134–1141.
122. Kleinman, N.J., et al., *Improved Medication Adherence and Frequency of Blood Glucose Self-Testing Using an m-Health Platform Versus Usual Care in a Multisite Randomized Clinical Trial Among People with Type 2 Diabetes in India*. Telemedicine and e-Health, 2017. **23**(9): p. 733–740.

123. Lamptey, R., et al., *Change in glycaemic control with structured diabetes self-management education in urban low-resource settings: multicentre randomised trial of effectiveness*. BMC Health Services Research, 2023. **23**(1): p. 199.
124. Lerman, I., et al., *[Pilot study of two different strategies to reinforce self care behaviors and treatment compliance among type 2 diabetes patients from low income strata]*. Gac Med Mex, 2009. **145**(1): p. 15–19.
125. Li, D., et al., *Diabetes Nurse Case Management in a Canadian Tertiary Care Setting: Results of a Randomized Controlled Trial*. Can J Diabetes, 2017. **41**(3): p. 297–304.
126. Li, F., et al., *Impact of "Conversation Maps" on diabetes distress and self-efficacy of Chinese adult patients with type 2 diabetes: a pilot study*. Patient Prefer Adherence, 2016. **10**: p. 901–908.
127. McEwen, M.M., et al., *Effects of a Family-based Diabetes Intervention on Behavioral and Biological Outcomes for Mexican American Adults*. Diabetes Educ, 2017. **43**(3): p. 272–285.
128. Misra, R., et al., *Addressing Diabetes Distress in Self-Management Programs: Results of a Randomized Feasibility Study*. J Appalach Health, 2021. **3**(3): p. 68–85.
129. Munshi, M.N., et al., *Assessment of barriers to improve diabetes management in older adults: a randomized controlled study*. Diabetes Care, 2013. **36**(3): p. 543–549.
130. Murray, E., et al., *Web-based self-management support for people with type 2 diabetes (HeLP-Diabetes): randomised controlled trial in English primary care*. BMJ Open, 2017. **7**(9): p. e016009.
131. Odnoletkova, I., et al., *Optimizing diabetes control in people with Type 2 diabetes through nurse-led telecoaching*. Diabetic Medicine, 2016. **33**(6): p. 777–785.
132. Ramallo-Fariña, Y., et al., *Patient-reported outcome measures for knowledge transfer and behaviour modification interventions in type 2 diabetes-the INDICA study: a multiarm cluster randomised controlled trial*. BMJ Open, 2021. **11**(12): p. e050804.
133. Reaney, M., et al., *Impact of Conversation Map™ Education Tools Versus Regular Care on Diabetes-Related Knowledge of People With Type 2 Diabetes: A Randomized, Controlled Study*. Diabetes Spectrum, 2013. **26**(4): p. 236–245.
134. Rezaeemanesh, M., et al., *The effect of educational intervention based on Pender's health promotion model for distress management in patients with type 2 diabetes*. Pakistan journal of medical and health sciences, 2020. **14**(3): p. 969–975.
135. Rondhianto, Kusnanto, and S. Melaniani, *The effect of diabetes self-management education, based on the health belief model, on the psychosocial outcome of type 2 diabetic patients in Indonesia*. Indian journal of public health research and development, 2018. **9**(11): p. 1718–1723.
136. Rosales, C.B., et al., *Meta Salud Diabetes for cardiovascular disease prevention in Mexico: a cluster-randomized behavioural clinical trial*. Int J Epidemiol, 2021. **50**(4): p. 1272–1282.
137. Rosland, A.M., et al., *Effectiveness of a Health Coaching Intervention for Patient-Family Dyads to Improve Outcomes Among Adults With Diabetes: A Randomized Clinical Trial*. JAMA Netw Open, 2022. **5**(11): p. e2237960.
138. Rygg, L.Ø., et al., *Efficacy of ongoing group based diabetes self-management education for patients with type 2 diabetes mellitus. A randomised controlled trial*. Patient Education and Counseling, 2012. **86**(1): p. 98–105.
139. Shibayama, T., et al., *Effectiveness of lifestyle counseling by certified expert nurse of Japan for non-insulin-treated diabetic outpatients: a 1-year randomized controlled trial*. Diabetes Res Clin Pract, 2007. **76**(2): p. 265–268.
140. Sigurdardottir, A.K., R. Benediktsson, and H. Jonsdottir, *Instruments to tailor care of people with type 2 diabetes*. J Adv Nurs, 2009. **65**(10): p. 2118–2130.

141. Spencer, M.S., et al., *Influence of a Community Health Worker Intervention on Mental Health Outcomes among Low-Income Latino and African American Adults with Type 2 Diabetes*. Race Soc Probl, 2013. **5**(2): p. 137–146.
142. Tang, T.S., et al., *From clinic to community: A randomized controlled trial of a peer support model for adults with type 2 diabetes from specialty care settings in British Columbia*. Diabet Med, 2022. **39**(11): p. e14931.
143. van Dijk-de Vries, A., et al., *Lessons learnt from a cluster-randomised trial evaluating the effectiveness of Self-Management Support (SMS) delivered by practice nurses in routine diabetes care*. BMJ Open, 2015. **5**(6): p. e007014.
144. Welch, G., et al., *An internet-based diabetes management platform improves team care and outcomes in an urban Latino population*. Diabetes Care, 2015. **38**(4): p. 561–567.
145. Whittemore, R., et al., *A nurse-coaching intervention for women with type 2 diabetes*. Diabetes Educ, 2004. **30**(5): p. 795–804.
146. Winkley, K., et al., *The diabetes insulin self-management education (DIME) intervention for people with type 2 diabetes starting insulin: a pilot feasibility randomised controlled trial*. Pilot Feasibility Stud, 2023. **9**(1): p. 89.
147. Benhalima, K., et al., *Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial*. The Lancet Diabetes & Endocrinology, 2024. **12**(6): p. 390–403.
148. Lee Tara, T.M., et al., *Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes*. New England Journal of Medicine, 2023. **389**(17): p. 1566–1578.
149. McAuley, S.A., et al., *Six Months of Hybrid Closed-Loop Versus Manual Insulin Delivery With Fingerprick Blood Glucose Monitoring in Adults With Type 1 Diabetes: A Randomized, Controlled Trial*. Diabetes Care, 2020. **43**(12): p. 3024–3033.
150. McAuley, S.A., et al., *Closed-Loop Insulin Delivery Versus Sensor-Augmented Pump Therapy in Older Adults With Type 1 Diabetes (ORACL): A Randomized, Crossover Trial*. Diabetes Care, 2021. **45**(2): p. 381–390.
151. Weissberg-Benchell, J., et al., *Impact of an Automated Bihormonal Delivery System on Psychosocial Outcomes in Adults with Type 1 Diabetes*. Diabetes Technol Ther, 2017. **19**(12): p. 723–729.
152. Schneider-Utaka, A.K., et al., *Patient-reported outcomes for older adults on CamAPS FX closed loop system*. Diabet Med, 2023. **40**(9): p. e15126.
153. Weissberg-Benchell, J., et al., *Psychosocial Impact of the Insulin-Only iLet Bionic Pancreas for Adults, Youth, and Caregivers of Youth with Type 1 Diabetes*. Diabetes Technol Ther, 2023. **25**(10): p. 705–717.
154. Boscari, F., et al., *Implantable and transcutaneous continuous glucose monitoring system: a randomized cross over trial comparing accuracy, efficacy and acceptance*. J Endocrinol Invest, 2022. **45**(1): p. 115–124.
155. Hermanns, N., et al., *Short-term effects on patient satisfaction of continuous glucose monitoring with the GlucoDay with real-time and retrospective access to glucose values: a crossover study*. Diabetes Technol Ther, 2009. **11**(5): p. 275–281.
156. Reddy, M., et al., *A randomized controlled pilot study of continuous glucose monitoring and flash glucose monitoring in people with Type 1 diabetes and impaired awareness of hypoglycaemia*. Diabet Med, 2018. **35**(4): p. 483–490.
157. Rilstone, S., et al., *A Randomized Controlled Trial Assessing the Impact of Continuous Glucose Monitoring with a Predictive Hypoglycemia Alert Function on Hypoglycemia in Physical Activity for People with Type 1 Diabetes (PACE)*. Diabetes Technol Ther, 2024. **26**(2): p. 95–102.

158. Ehrmann, D., et al., *The Effects and Effect Sizes of Real-Time Continuous Glucose Monitoring on Patient-Reported Outcomes: A Secondary Analysis of the HypoDE Study*. Diabetes Technology & Therapeutics, 2019. **21**(2): p. 86–93.
159. Hermanides, J., et al., *Sensor-augmented pump therapy lowers HbA(1c) in suboptimally controlled Type 1 diabetes; a randomized controlled trial*. Diabet Med, 2011. **28**(10): p. 1158–1167.
160. Ischia Study, G., *Prevention of hypoglycemia by intermittent-scanning continuous glucose monitoring device combined with structured education in patients with type 1 diabetes mellitus: A randomized, crossover trial*. Diabetes Res Clin Pract, 2023. **195**: p. 110147.
161. Leelarathna, L., et al., *FLASH GLUCOSE MONITORING WITH THE FREESTYLE LIBRE 2: RESULTS FROM THE FLASH-UK RANDOMISED CONTROLLED TRIAL (ON BEHALF OF THE STUDY GROUP)*. Diabetes technology & therapeutics, 2022. **24**(SUPPL 1): p. A21.
162. Polonsky, W.H., et al., *The Impact of Continuous Glucose Monitoring on Markers of Quality of Life in Adults With Type 1 Diabetes: Further Findings From the DIAMOND Randomized Clinical Trial*. Diabetes Care, 2017. **40**(6): p. 736–741.
163. Pratley, R.E., et al., *Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial*. JAMA, 2020. **323**(23): p. 2397–2406.
164. Bolinder, J., et al., *Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial*. Lancet, 2016. **388**(10057): p. 2254–2263.
165. Pylov, D., et al., *Treatment Satisfaction and Well-Being With CGM in People With T1D: An Analysis Based on the GOLD Randomized Trial*. J Diabetes Sci Technol, 2023: p. 19322968231183974.
166. Secher, A.L., et al., *Flash glucose monitoring and automated bolus calculation in type 1 diabetes treated with multiple daily insulin injections: a 26 week randomised, controlled, multicentre trial*. Diabetologia, 2021. **64**(12): p. 2713–2724.
167. van Beers, C.A.J., et al., *Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial*. The Lancet Diabetes & Endocrinology, 2016. **4**(11): p. 893–902.
168. Beck, R.W., et al., *Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial*. Ann Intern Med, 2017. **167**(6): p. 365–374.
169. Fisher, L., et al., *The impact of blood glucose monitoring on depression and distress in insulin-naïve patients with type 2 diabetes*. Curr Med Res Opin, 2011. **27 Suppl 3**: p. 39–46.
170. Malanda, U.L., et al., *Effects of self-monitoring of glucose on distress and self-efficacy in people with non-insulin-treated Type 2 diabetes: a randomized controlled trial*. Diabet Med, 2016. **33**(4): p. 537–546.
171. Sato, S., et al., *Changes in psychological behavior accompanied by the short-term usage of flash glucose monitoring for newly diagnosed type 2 diabetes mellitus*. Therapeutic research, 2020. **41**(7): p. 577–586.
172. Furler, J., et al., *Use of professional-mode flash glucose monitoring, at 3-month intervals, in adults with type 2 diabetes in general practice (GP-OSMOTIC): a pragmatic, open-label, 12-month, randomised controlled trial*. Lancet Diabetes Endocrinol, 2020. **8**(1): p. 17–26.
173. Heisler, M., et al., *Diabetes control with reciprocal peer support versus nurse care management: a randomized trial*. Ann Intern Med, 2010. **153**(8): p. 507–515.
174. Piatt, G.A., et al., *Integration and Utilization of Peer Leaders for Diabetes Self-Management Support: Results From Project SEED (Support, Education, and Evaluation in Diabetes)*. Diabetes Educ, 2018. **44**(4): p. 373–382.

175. Chan, J.C., et al., *Effects of telephone-based peer support in patients with type 2 diabetes mellitus receiving integrated care: a randomized clinical trial*. JAMA Intern Med, 2014. **174**(6): p. 972–981.
176. Gagliardino, J.J., et al., *Type 2 diabetes patients educated by other patients perform at least as well as patients trained by professionals*. Diabetes/Metabolism Research and Reviews, 2013. **29**(2): p. 152–160.
177. Ing, C.T., et al., *Social Support Groups in the Maintenance of Glycemic Control after Community-Based Intervention*. J Diabetes Res, 2016. **2016**: p. 7913258.
178. Tang, T.S., et al., *Comparative effectiveness of peer leaders and community health workers in diabetes self-management support: results of a randomized controlled trial*. Diabetes Care, 2014. **37**(6): p. 1525–1534.
179. Siminerio, L., K.M. Ruppert, and R.A. Gabbay, *Who can provide diabetes self-management support in primary care? Findings from a randomized controlled trial*. Diabetes Educ, 2013. **39**(5): p. 705–713.
180. Ju, C., et al., *Effect of peer support on diabetes distress: a cluster randomized controlled trial*. Diabet Med, 2018. **35**(6): p. 770–775.
181. Kunik, M.E., et al., *The impact of veteran support and resources for diabetes (iNSPiRED) on diabetes distress: Results from a randomized, parallel-group trial*. Gen Hosp Psychiatry, 2023. **85**: p. 55–62.
182. Simmons, D., et al., *Impact of community based peer support in type 2 diabetes: a cluster randomised controlled trial of individual and/or group approaches*. PLoS One, 2015. **10**(3): p. e0120277.
183. van der Wulp, I., et al., *Effectiveness of peer-led self-management coaching for patients recently diagnosed with Type 2 diabetes mellitus in primary care: a randomized controlled trial*. Diabet Med, 2012. **29**(10): p. e390–e397.
184. Grillo Mde, F., et al., *Diabetes education in primary care: a randomized clinical trial*. Cad Saude Publica, 2016. **32**(5).
185. Ho, E.Y., et al., *Pilot Cluster Randomized Controlled Trial of Integrative Nutritional Counseling Versus Standard Diabetes Self-Management Education for Chinese Americans with Type 2 Diabetes*. Health Equity, 2020. **4**(1): p. 410–420.
186. Welch, G., et al., *Comprehensive diabetes management program for poorly controlled Hispanic type 2 patients at a community health center*. Diabetes Educ, 2011. **37**(5): p. 680–688.
187. Aronson, R., et al., *IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic Therapy (IMMEDIATE): A randomized controlled trial*. Diabetes Obes Metab, 2023. **25**(4): p. 1024–1031.
188. Clark, T.L., et al., *Does Diabetes Distress Influence Clinical Response to an mHealth Diabetes Self-Management Education and Support Intervention?* Diabetes Educ, 2020. **46**(3): p. 289–296.
189. Kavin, M., et al., *Development and pilot of a low-literacy diabetes education book using social marketing techniques*. Diabetes Ther, 2010. **1**(2): p. 93–102.
190. Sperl-Hillen, J., et al., *Are benefits from diabetes self-management education sustained?* Am J Manag Care, 2013. **19**(2): p. 104–112.
191. Sturt, J.A., et al., *Effects of the Diabetes Manual 1:1 structured education in primary care*. Diabet Med, 2008. **25**(6): p. 722–731.
192. Tang, P.C., et al., *Online disease management of diabetes: Engaging and Motivating Patients Online With Enhanced Resources-Diabetes (EMPOWER-D), a randomized controlled trial*. Journal of the American Medical Informatics Association, 2012. **20**(3): p. 526–534.
193. Zheng, F., et al., *Effects of an Outpatient Diabetes Self-Management Education on Patients with Type 2 Diabetes in China: A Randomized Controlled Trial*. J Diabetes Res, 2019. **2019**: p. 1073131.

194. Olsen, M.T., et al., *Implementation Strategies for Inpatient Continuous Glucose Monitoring-based Diabetes Management: A Systematic Review*. J Clin Endocrinol Metab, 2025. **110**(7): p. e2411–e2419.
195. Hermanns, N., et al., *Treatment satisfaction and quality-of-life between type 2 diabetes patients initiating long- vs. intermediate-acting basal insulin therapy in combination with oral hypoglycemic agents--a randomized, prospective, crossover, open clinical trial*. Health Qual Life Outcomes, 2015. **13**: p. 77.

Electronic Supplementary Material 5: Concept evidence to Good Practice Statements for the assessment of clinical questions

In realist evaluations, concepts refer to a key element or component that helps explain how an intervention, such as the assessment of diabetes distress in clinical practice, works (1). Specifically, these concepts are in relation to the intervention context and outcomes. Concepts are often framed as Context, Mechanism & Outcome (CMOs) configurations. CMOs are used to understand not just what an intervention does, but how and why it does it, in specific situations. They are constructed as 'IF..., THEN..., BECAUSE...' statements. Context refers to the situation or setting where the program is implemented. Mechanism explains the underlying reasons why the program produces certain outcomes. Outcomes are the changes observed because of the intervention. The CMOs are particularly relevant for understanding the detail lying beneath the Concept.

Concepts and CMOs for type 1 diabetes (T1D) and type 2 diabetes (T2D) were identified based on the findings of the realist reviews in T1D and T2D (2,3). The preliminary concepts and CMOs were then compared and contrasted to identify where alignment was evident, even if the wording differed. There were eight concepts for T1D and five concepts for T2D, all presented in table 1. All five T2D concepts aligned with the eight T1D Concepts. The CMOs from the matched T1D/T2D concepts were compared for similarity and consistency with each other by two panel members (JSt/JSp) and reviewed by the Guideline Development Panel. From these, Good Practice Statements (GPS) were developed reflecting the review evidence. Eight GPS for the assessment of diabetes distress were developed (labelled A1-A8, as shown in Column 3 of table 1) and incorporated into the Assessment of Diabetes Distress section of the guideline. As the realist review evidence was interpreted by the authors, some concept names changed during development and publication of the manuscripts (2,3) but the underpinning CMOs and initial programme theories generated did not change from those represented in table 1. Each T1D concept is presented first (shown in black text), with its corresponding T2D concept (shown in blue text), along with corresponding CMOs and GPS (shown in italics).

Table 1 Conceptual alignment across type 1 diabetes and type 2 diabetes underpinning eight GPSs

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
1. Increasing expectation that routine diabetes care will address emotional health and well-being of people with T1D 1. Extends the scope of diabetes healthcare professionals' roles to include emotional support	T1D – IF the use of comprehensive assessment within a clinic indicates that HCPs are expected to review DD PROM score and ask about emotional health, THEN the HCP is clear that this is expected and they are supported to review the PROM score and ask about emotional health during consultation time, BECAUSE it raises awareness that assessing and managing emotional issues is part of the diabetes HCP role. T1D – IF a validated PROM DD assessment is undertaken prior to the consultation, THEN the HCP can ask the PwT1D questions about how they are feeling about their diabetes and explore reasons for their distress, BECAUSE they are aware of the PwT1D's level of DD and the scores for specific sub-scores of DD. T1D – IF the PwT1D undertakes the DD assessment before their clinic appointment, THEN they are more prepared to talk about their feelings and concerns about having diabetes which focusses the discussion on actual patient need, BECAUSE the PwT1D has had the opportunity to think about how they are feeling and is expecting to discuss this with the HCP during the appointment T1D – IF the PwT1D is not aware that diabetes distress is a response to having T1D, THEN comprehensive assessment can prompt them to decide what they want to discuss with the HCP during the consultation, BECAUSE comprehensive DD assessment helps them make sense of how they are feeling about living with T1D and prompts them to consider how their feelings about diabetes are influencing aspects of their life and how they manage their condition. T1D – IF the clinic appointment is restricted to a short time and discussion of physical health checks is considered more important or the clinic is running late, THEN the HCP may decide not to ask questions about emotional health, BECAUSE they think that there is not enough time to talk about emotional health as these conversations can take some time.	A7: When diabetes distress is identified, healthcare professionals (HCPs) should make a joint plan with the person living with diabetes about next steps. A8: General and diabetes-specialist HCPs should have the competency to offer psychological support to those experiencing diabetes distress and know how to enlist specialist support when it is needed A5: Healthcare professionals should acknowledge and explore the person's discussion and assessment, irrespective of the findings, as part of effective, person-centred care

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
	T2D – IF there is clear communicates that assessing and discussing diabetes distress is part of a diabetes healthcare professional’s role, that people with type 2 diabetes want to discuss their emotions about diabetes with their familiar diabetes healthcare professionals, and provides diabetes healthcare professionals with sufficient training and support to do so, THEN diabetes healthcare professionals will be more likely to integrate conversations about diabetes distress into routine diabetes care that meet the needs and expectations of people with type 2 diabetes, BECAUSE enhanced usual care extends the scope of professional responsibilities by validating the importance of including emotional support within their role.	A3: HCPs should assess diabetes distress using a valid and reliable tool. A2: HCPs should ask about diabetes distress using open-ended questions, framed around the emotional burden or challenges of living with diabetes.

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
2. Regular, comprehensive screening of diabetes distress and clinical interpretation of the scores	T1D – IF regular, comprehensive screening is carried out for all patients using a validated PROM, THEN low, moderate and high levels of DD will be identified and addressed either through support from the diabetes team or through referral for additional support, BECAUSE PROM assessment of DD will give both PwT1D and HCPs information about the PwT1D's level of distress so that they can take action to address it.	A7: <i>When diabetes distress is identified, HCPs should make a joint plan with the person living with diabetes about next steps.</i>

and sub-scores to ensure early, appropriate intervention for high levels of total DD		
4. Provides a valid and reliable diabetes distress assessment tool that prompts reflection and articulation of feelings for people with type 2 diabetes 5. Regular screening and discussion of diabetes distress	T2D – IF people with type 2 diabetes are introduced to a valid and reliable diabetes distress assessment tool that captures the range of negative emotional responses to diabetes, THEN they will recognise and acknowledge the emotional impact that living with diabetes has on their everyday life, and be able to articulate their feelings about specific areas of concern, BECAUSE the assessment tool prompts this thinking and reflection, and enables the articulation of these feelings using the assessment as structure for conversations about diabetes distress. This recognition and articulation will then lead to an improved understanding, for both people with type 2 diabetes and their healthcare professionals, of how diabetes distress has an impact on their ability, motivation and confidence to carry out self-management behaviours, ensuring the identification of needs for people with type 2 diabetes. T2D – IF diabetes healthcare professionals assess and discuss diabetes distress at regular routine appointments, THEN this demonstrates to people with type 2 diabetes that emotional reactions to living with diabetes are common and normal experiences that are important to talk about when discussing diabetes, which will reduce feelings of isolation and stigma, BECAUSE of the integration of physical and emotional health into routine diabetes care practices. Then, this helps diabetes healthcare professionals to ensure that no one experiencing distress is missed, and to feel a sense of satisfaction in fulfilling a crucial and wanted part of care for people with type 2 diabetes.	A1: <i>HCPs should discuss the emotional side of diabetes at every consultation as an integral component of person-centred diabetes care.</i> A4: <i>Healthcare professionals should assess and monitor diabetes distress at regular intervals, at least annually.</i>

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
3.Enabling the recognition of feelings and emotional responses to living with T1D and identifying priorities to be included in consultations with HCPs 3. Fosters a safe, trusting and collaborative relationship through person-centred, attentive interactions	T1D – IF a PwT1D finds it difficult to reflect on their emotional health and raise these feelings in a consultation, THEN comprehensive assessment can empower and help them prepare for the consultation and decide what they want to discuss in the consultation, BECAUSE the comprehensive focus on DD encourages the PwT1D to recognise how they are feeling and understand how this may affect their day to day life T2D – IF diabetes healthcare professionals delivering enhanced usual care facilitate collaborative, person-centred consultations using their communication skills (<i>concept 2</i>) with empathy, compassion and without rushing, THEN there will be more holistic care, improved communication, and greater satisfaction for both parties, BECAUSE enhanced usual care fosters trusting relationships between diabetes healthcare professionals and people with type 2 diabetes that encourage people with type 2 diabetes to disclose their feelings knowing that they are being listened to. This then allows diabetes healthcare professionals to gain a better understanding of their needs and perspectives, to improve the provision of holistic care.	A5: <i>Healthcare professionals should acknowledge and explore the person's discussion and assessment, irrespective of the findings, as part of effective, person-centred care</i> A1: <i>HCPs should discuss the emotional side of diabetes at every consultation as an integral component of person-centred diabetes care.</i>

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
4.Regular discussion of Diabetes Distress (DD) promoting continuity of care N/A	T1D – IF the PwT1D sees a different member of the diabetes team at each appointment, THEN comprehensive assessment enables the PwT1 to feel that the conversation with the HCP is part of a process irrespective of which HCP they see and ongoing issues are followed up, BECAUSE the regularity of the discussion at each appointment structured by comprehensive assessment promotes continuity of care.	A1: HCPs should discuss the emotional side of diabetes at every consultation as an integral component of person-centred diabetes care.
	T2D – N/A	A6: Healthcare professionals should record the findings of the diabetes distress assessment and discussion in the clinical notes, and communicate them to relevant members of the healthcare team. A3: HCPs should assess diabetes distress using a valid and reliable tool.

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
5. Facilitates a discussion / dialogue on PwT1D's own issues and emotions 4. Provides a valid and reliable diabetes distress assessment tool that prompts reflection and articulation of feelings for people with type 2 diabetes 2. Increases diabetes healthcare professionals' understanding, skills and confidence to address diabetes distress	T1D – IF HCP members of the diabetes team do not have a psychology background, THEN comprehensive assessment supports them to facilitate the tailoring of the conversation about emotional issues and wellbeing to better meet the needs the PwT1D and conveys that the HCP cares about how the PwT1D is feeling; the assessment supports the HCP to feel more prepared and confident to have the conversation, BECAUSE comprehensive assessment provides a structure to give HCPs a conversation starter for an open conversation and having the DD PROM scores before seeing the PwT1D can increase the HCP's understanding of emotional needs. T2D – IF enhanced usual care provides structured, engaging, and evidence-based training on diabetes distress that covers communication techniques, active listening, and emotional validation, THEN diabetes healthcare professionals will feel more confident and competent in discussing diabetes distress and have more meaningful interactions with people with type 2 diabetes who will feel validated and listened to, BECAUSE enhanced usual care equips diabetes healthcare professionals with practical tools they can immediately apply in routine care. T2D – IF enhanced usual care training reframes diabetes distress as an emotional response to the demands of living with diabetes rather than a separate mental health condition, THEN diabetes healthcare professionals will have a more holistic understand of diabetes distress and how it impacts people with type 2 diabetes, and their confidence will increase as they realise they already have many of the necessary communication skills and do not need to overhaul their practice to address diabetes distress, BECAUSE enhanced usual care provides an understanding that emotional responses that are a normal part of living with diabetes, which reduces the perceived complexity of having a discussion about diabetes distress.	A5: <i>Healthcare professionals should acknowledge and explore the person's discussion and assessment, irrespective of the findings, as part of effective, person-centred care</i> A8: <i>General and diabetes-specialist HCPs should have the competency to offer psychological support to those experiencing diabetes distress and know how to enlist specialist support when it is needed.</i> A1: <i>HCPs should discuss the emotional side of diabetes at every consultation as an integral component of person-centred diabetes care.</i> A3: <i>HCPs should assess diabetes distress using a valid and reliable tool.</i>

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
6. Signposts and clarifies expectations of what can be expected from diabetes care T2D – N/A	T1D – IF a PWT1D is unclear about what to expect in their diabetes care, THEN comprehensive assessment can help them manage the emotional and social challenges and be reassured that there is a plan for their care, BECAUSE comprehensive assessment provides a clear pathway of what to expect which helps them anticipate the emotional and social responses to life with the condition. T2D – N/A	A1: <i>HCPs should discuss the emotional side of diabetes at every consultation as an integral component of person-centred diabetes care.</i>

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
7. Acknowledges and normalises the emotional and social responses that a PwT1D may encounter when living with diabetes 1.Extends the scope of diabetes healthcare professionals' roles to include emotional support	T1D – IF a PwT1D has feelings of shame, stigma, powerlessness and being out of control associated with diabetes and comprehensive assessment routinely flags up the importance of emotional health for people with T1D and acknowledges that a diagnosis of T1D has a significant psychological impact which makes it more difficult to self-manage, THEN the PwT1D feels more in control, that their feelings are normalised and they are is more comfortable discussing their emotional health during a consultation, BECAUSE the PwT1D feels understood, listened to and 'seen'. T2D – IF enhanced usual care training clearly communicates that assessing and discussing diabetes distress is part of a diabetes healthcare professional's role, that people with type 2 diabetes want to discuss their emotions about diabetes with their familiar diabetes healthcare professionals, and provides diabetes healthcare professionals with sufficient training and support to do so, THEN diabetes healthcare professionals will be more likely to integrate conversations about diabetes distress into routine diabetes care that meet the needs and expectations of people with type 2 diabetes BECAUSE enhanced usual care extends the scope of professional responsibilities by validating the importance of including emotional support within their role.	A1: HCPs should discuss the emotional side of diabetes at every consultation as an integral component of person-centred diabetes care. A7: When diabetes distress is identified, HCPs should make a joint plan with the person living with diabetes about next steps.

Concepts T1D (black) / T2D (blue)	Context, Mechanism & Outcome configurations (CMOs) for T1D (black) / T2D (blue)	Good Practice Statements (GPS) (n=8) derived from Concepts & CMOs
8. Promoting person-centred and person-directed interactions with clinicians	T1D – IF HCPs use comprehensive assessment of DD to guide the conversation using more open questions THEN the PwT1D will feel able to direct the content of the discussion to issues that are important to them, BECAUSE the PwT1D will feel 'seen' as a whole person and empowered to direct the conversation on a more equal, patient centred basis.	A1: HCPs should discuss the emotional side of diabetes at every consultation as an integral component of person-centred diabetes care.
3. Fosters a safe, trusting and collaborative relationship through person-centred, attentive interactions	T2D – IF diabetes healthcare professionals delivering enhanced usual care facilitate collaborative, person-centred consultations using their communication skills (<i>concept 2</i>) with empathy, compassion and without rushing, THEN there will be more holistic care, improved communication, and greater satisfaction for both parties, BECAUSE enhanced usual care fosters trusting relationships between diabetes healthcare professionals and people with type 2 diabetes that encourage people with type 2 diabetes to disclose their feelings knowing that they are being listened to. This then allows diabetes healthcare professionals to gain a better understanding of their needs and perspectives, to improve the provision of holistic care.	A5: Healthcare professionals should acknowledge and explore the person's discussion and assessment, irrespective of the findings, as part of effective, person-centred care

Legend: CMO: Context, Mechanism & Outcome configuration; DD: Diabetes distress; GPS: Good Practice Statements; HCP: healthcare professional; PwT1D: Person with type 1 diabetes; PwT2D: Person with type 2 diabetes; T1D: Type 1 diabetes; T2D: Type 2 diabetes.

References

1. Saul JE, Willis CD, Bitz J, Best A. A time-responsive tool for informing policy making: rapid realist review. *Implement Sci.* 2013;8:103. doi:[10.1186/1748-5908-8-103](https://doi.org/10.1186/1748-5908-8-103)
2. Harris R, Sims S, Due-Christensen M, Stenov V, Abrams R, Fabian-Therond C, Ahuja S, O'Connor S, Papachristou Nadal I, Peck M, Speight J, Holt RIG, Sturt J, on behalf of D-Stress study group. Introducing diabetes emotional wellbeing into routine consultations for adults with Type 1 Diabetes: A rapid realist review. Under Review *Metabologia*
3. Peck M, Papachristou Nadal I, Stenov V, Due-Christensen M, Sims S, Harris R, Holt RIG, Speight J, Sturt J. Introducing Diabetes Emotional Wellbeing into Routine Consultations for Adults with Type 2 Diabetes: A Rapid Realist Review of what Works, for Whom, and in what Circumstances. Under Review *Metabologia*

Electronic Supplementary Material 6: GRADE Evidence Profiles for the management questions

Table of contents

Psychological interventions for diabetes distress	148
Psychological interventions compared to usual care for type 1 diabetes	148
Psychological interventions compared to usual care for type 2 diabetes	150
Psychological interventions compared to educational interventions for type 2 diabetes	151
Psychoeducational interventions for diabetes distress	152
Psychoeducational interventions compared to usual care for type 1 diabetes	152
Psychoeducational interventions compared to educational interventions for type 1 diabetes	153
Psychoeducational interventions compared to usual care for type 2 diabetes	154
Psychoeducational interventions compared to educational interventions for type 2 diabetes	155
Miscellaneous (non-psychological, non-psychoeducational) interventions for diabetes distress	156
Automated insulin delivery systems compared to no use of automated insulin delivery systems for type 1 diabetes	156
Continuous glucose monitoring compared to capillary glucose monitoring for type 1 diabetes	157
Continuous Glucose Monitoring compared to capillary glucose monitoring for type 2 diabetes	158
Educational interventions compared to usual care for type 2 diabetes	159
Peer support interventions compared to usual care for type 2 diabetes	160
Educational interventions compared to peer support interventions for type 2 diabetes	161

Psychological interventions for diabetes distress

Psychological interventions compared to usual care for type 1 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
16	randomised trials	serious ^a	not serious ^b	not serious ^c	serious ^d	none	643	700	-	SMD 0.21 SD lower (0.34 lower to 0.08 lower)	⊕⊕○○ Low ^{a,b,c,d}	CRITICAL

CI: confidence interval; **SMD:** standardised mean difference

Explanations

- a. None at low risk of bias. Most studies with some concerns
- b. I2 = 38%
- c. Variations in the type of interventions not considered important to downgrade.
- d. CI crosses MCID and does not cross null effect

Psychological interventions compared to educational interventions for type 1 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 9 months to 15 months; assessed with: DDS-PAID)

2	randomised trials	very serious ^a	very serious ^b	very serious ^c	serious ^d	none	242	240	-	SMD 0.11 SD lower (0.44 lower to 0.23 higher)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL
---	-------------------	---------------------------	---------------------------	---------------------------	----------------------	------	-----	-----	---	--	-------------------------------------	----------

CI: confidence interval; **SMD:** standardised mean difference

Explanations

- a. One study at high ROB and one with some concerns. p-interaction for ROB = 0.0687
- b. I2 = 69.8% and effect not large (very serious limitations)
- c. Different types of comparators
- d. CI crosses both -0.3 and null but not +0.3

Psychological interventions compared to usual care for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	usual care	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 1.7 months to 24 months; assessed with: DDS-PAID)

21	randomised trials	very serious ^a	very serious ^b	not serious ^c	serious ^d	none	2249	2301	-	SMD 0.31 SD lower (0.5 lower to 0.13 lower)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL
----	-------------------	---------------------------	---------------------------	--------------------------	----------------------	------	------	------	---	--	-------------------------------------	----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. ROB: Many studies at high risk
- b. inconsistency: I² 83.1%
- c. different types of psychological interventions, however not considered a reason to downgrade
- d. Imprecision: CI crosses MCID (0.3) and does not cross null effect

Psychological interventions compared to educational interventions for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychological interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 2.8 months to 15 months; assessed with: DDS-PAID)

10	randomised trials	very serious ^a	very serious ^b	serious ^c	very serious ^d	none	1306	998	-	SMD 0.29 SD lower (0.98 lower to 0.39 higher)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL
----	-------------------	---------------------------	---------------------------	----------------------	---------------------------	------	------	-----	---	--	-------------------------------------	----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. Most at high risk of bias
- b. Very high I2 = 94.5%
- c. different comparators, subgroup effect among outcome scales,
- d. CI crosses MCID for benefit (-0.5) and for harm (0.5)

Psychoeducational interventions for diabetes distress

Psychoeducational interventions compared to usual care for type 1 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	usual care	Relative (95% CI)	Absolute (95% CI)		
2	randomised trials	serious ^a	serious ^b	serious ^c	serious ^d	none	62	71	-	SMD 0.17 SD lower (0.62 lower to 0.28 higher)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. Some concerns in both studies
- b. I2 42.1% with no large effect (serious)
- c. some variations in psychoeducational interventions
- d. CI crosses -MCID and null but not +MCID

Psychoeducational interventions compared to educational interventions for type 1 diabetes

Certainty assessment							Nº of participants		Effect		Certain ty	Importan ce
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 6 months to 12 months; assessed with: DDS-PAID)

3	randomised trials	very serious ^a	not serious ^b	not serious ^c	not serious ^d	none	165	162	-	SMD 0.02 SD lower (0.23 lower to 0.2 higher)	⊕⊕○○ Low ^{a,b,c,d}	CRITICAL
---	-------------------	---------------------------	--------------------------	--------------------------	--------------------------	------	-----	-----	---	---	--------------------------------	----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. most studies at high rob
- b. i2 = 0
- c. different comparators.
- d. CI crosses null but not MCID

Psychoeducational interventions compared to usual care for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	usual care	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID T2D overall (follow-up: range 1.4 months to 36 months; assessed with: SMD DDS-PAID)

23	randomised trials	very serious ^a	very serious ^b	serious ^c	serious ^d	none	1936	1811	-	SMD 0.19 SD lower (0.40 lower to 0.02 higher)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL
----	-------------------	---------------------------	---------------------------	----------------------	----------------------	------	------	------	---	--	-------------------------------------	----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. almost half studies at high rob
- b. i2 = 78.7%
- c. heterogenous interventions
- d. CI crosses MCID and does not cross null effect

Psychoeducational interventions compared to educational interventions for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychoeducational interventions	educational interventions	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 1.8 months to 16 months; assessed with: SMD DDS-PAID)

13	randomised trials	very serious ^a	very serious ^b	serious ^c	not serious ^d	none	881	876	-	SMD 0.15 SD lower (0.34 lower to 0.03 higher)	⊕○○○ Very low ^{a,b,c,d}	CRITICAL
----	-------------------	---------------------------	---------------------------	----------------------	--------------------------	------	-----	-----	---	---	-------------------------------------	----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. almost half studies at high rob
- b. i2 = 72.2%
- c. different comparators and interventions
- d. CI crosses null but not MCID

Miscellaneous (non-psychological, non-psychoeducational) interventions for diabetes distress

Automated insulin delivery systems compared to no use of automated insulin delivery systems for type 1 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Automated insulin delivery systems	no use of automated insulin delivery systems	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 6 months to 6 months; assessed with: DDS-PAID)

5	randomised trials	serious ^a	not serious ^b	not serious ^c	not serious ^d	none	387	228	-	SMD 0.15 SD lower (0.33 lower to 0.02 higher)	⊕⊕⊕○ Moderate ^{a,b,c,d}	IMPORTANT
---	-------------------	----------------------	--------------------------	--------------------------	--------------------------	------	-----	-----	---	--	-------------------------------------	-----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. some concerns, no interaction by ROB
- b. I2 = 0.0%
- c. check detailed assessment
- d. CI crosses MCID and null effect.

Continuous glucose monitoring compared to capillary glucose monitoring for type 1 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Continuous glucose monitoring	Self-monitoring of blood glucose (SMBG)	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 2.8 months to 6 months; assessed with: DDS-PAID)

6	randomised trials	not serious ^a	not serious ^b	not serious ^c	serious ^d	none	425	348	-	SMD 0.26 SD lower (0.41 lower to 0.11 higher)	⊕⊕⊕○ Moderate ^{a,b,c,d}	IMPORTANT
---	-------------------	--------------------------	--------------------------	--------------------------	----------------------	------	-----	-----	---	--	-------------------------------------	-----------

CI: confidence interval; **SMD:** standardised mean difference

Explanations

a. Most trials with some concerns

b. I2 = 0%

c. check detailed assessment

d. CI crosses -MCID but not null effect

Continuous Glucose Monitoring compared to capillary glucose monitoring for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Continuous Glucose Monitoring	Self-monitoring of blood glucose (SMBG)	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 6 months to 12 months; assessed with: DDS-PAID)

3	randomised trials	serious ^a	very serious ^b	not serious ^c	serious ^d	none	345	266	-	SMD 0.35 SD lower (0.98 lower to 0.28 higher)	⊕○○○ Very low ^{a,b,c,d}	IMPORTANT
---	-------------------	----------------------	---------------------------	--------------------------	----------------------	------	-----	-----	---	--	-------------------------------------	-----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. 1 high, 2 some concerns
- b. I2 = 92.3%
- c. check detailed assessment
- d. CI crosses MCID and null effect

Educational interventions compared to usual care for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	educational interventions	usual care	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 3 months to 6 months; assessed with: DDS-PAID)

3	randomised trials	serious ^a	not serious ^b	not serious ^c	serious ^d	none	138	179	-	SMD 0.34 SD lower (0.56 lower to 0.11 lower)	⊕⊕○○ Low ^{a,b,c,d}	IMPORTANT
---	-------------------	----------------------	--------------------------	--------------------------	----------------------	------	-----	-----	---	--	--------------------------------	-----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. 1 high, 2 some concerns
- b. I2 = 0%
- c. check details
- d. CI crosses MCID and does not cross null effect

Peer support interventions compared to usual care for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	peer support interventions	usual care	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 6 months to 12 months; assessed with: DDS-PAID)

4	randomised trials	very serious ^a	not serious ^b	not serious ^c	not serious ^d	none	410	405	-	SMD 0.03 SD lower (0.19 lower to 0.13 higher)	⊕⊕○○ Low ^{a,b,c,d}	IMPORTANT
---	-------------------	---------------------------	--------------------------	--------------------------	--------------------------	------	-----	-----	---	--	--------------------------------	-----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. most trials at high rob
- b. I2 = 0.0%
- c. check details
- d. CI crosses null but not MCID, meaning neither benefit nor harm

Educational interventions compared to peer support interventions for type 2 diabetes

Certainty assessment							Nº of participants		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	educational interventions	peer support interventions	Relative (95% CI)	Absolute (95% CI)		

SMD DDS-PAID (follow-up: range 3 months to 12 months; assessed with: DDS-PAID)

3	randomised trials	serious ^a	not serious ^b	serious ^c	not serious ^d	none	241	235	-	SMD 0.10 SD lower (0.28 lower to 0.08 higher)	⊕⊕○○ Low ^{a,b,c,d}	IMPORTANT
---	-------------------	----------------------	--------------------------	----------------------	--------------------------	------	-----	-----	---	--	--------------------------------	-----------

CI: confidence interval; SMD: standardised mean difference

Explanations

- a. 1 high, 2 some concerns
- b. I2 = 0%
- c. check details
- d. CI crosses null but not MCID, meaning neither benefit nor harm

Electronic Supplementary Material 7: GRADE evidence to decision (EtD) frameworks for the management clinical questions

Table of contents

Psychological interventions for diabetes distress	164
Should psychological interventions vs. usual care be used for type 1 diabetes?	164
Recommendation	179
Should psychological interventions vs. educational interventions be used for type 1 diabetes?	180
Recommendation	191
Should psychological interventions vs. usual care be used for type 2 diabetes?	192
Recommendation	208
Should psychological interventions vs. educational interventions be used for type 2 diabetes?	209
Recommendation	221
Psychoeducational interventions for diabetes distress	223
Should psychoeducational interventions vs. usual care be used for type 1 diabetes?	223
Recommendation	237
Should psychoeducational interventions vs. educational interventions be used for type 1 diabetes?	238
Recommendation	250
Should psychoeducational interventions vs. usual care be used for type 2 diabetes?	252
Recommendation	268
Should psychoeducational interventions vs. educational interventions be used for type 2 diabetes?	270
Recommendation	282
Miscellaneous (non-psychological, non-psychoeducational) interventions for diabetes distress	284

<u>Should Automated insulin delivery systems vs. no use of automated insulin delivery systems be used for type 1 diabetes to reduce diabetes distress?</u>	284
<u>Recommendation</u>	299
<u>Should Continuous glucose monitoring vs. capillary glucose monitoring be used for type 1 diabetes to reduce diabetes distress?</u>	300
<u>Recommendation</u>	314
<u>Should Continuous Glucose Monitoring vs. capillary glucose monitoring be used for type 2 diabetes to reduce diabetes distress?</u>	315
<u>Recommendation</u>	330
<u>Should educational interventions vs. usual care be used for type 2 diabetes?</u>	332
<u>Recommendation</u>	348
<u>Should peer support interventions vs. usual care be used for type 2 diabetes?</u>	349
<u>Recommendation</u>	364
<u>Should educational interventions vs. peer support interventions be used for type 2 diabetes?</u>	366
<u>Recommendation</u>	380

Psychological interventions for diabetes distress

QUESTION

Should psychological interventions vs. usual care be used for type 1 diabetes?	
POPULATION:	type 1 diabetes
INTERVENTION:	psychological interventions
COMPARISON:	usual care
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes distress is highly prevalent among adults with type 1 diabetes (Dennick 2015). In the DAWN study (Peyrot 2005), which surveyed 5,104 adults with diabetes across 13 countries, 41% reported poor psychological well-being, and emotional concerns related to diabetes were common; however, the results were not stratified by diabetes type. The subsequent DAWN2 study (Nicolucci 2013) included 8,596 adults with diabetes from 17 countries, of whom 1,368 had type 1 diabetes. In this cohort, 45% of participants reported elevated diabetes distress. The prevalence varied substantially between countries, with the highest rates found in Algeria, Russia, and Turkey; and the lowest in the Netherlands, Denmark, and the USA. The DAWN2 dataset also showed that young adults (<30 years old) with type 1 diabetes reported higher levels of diabetes-specific distress than older adults (Vallis 2018). National studies have also provided estimates for adults with type 1 diabetes. In the United States, the prevalence of elevated diabetes distress was estimated at 42%, with a 9-month incidence of 54% in a sample of 224 adults (Fisher 2016). In Croatia, a cross-sectional survey of 100 adults with type 1 diabetes found that 36% had high diabetes-related distress, defined by a PAID score of ≥ 40 (Grulovic 2022). In Norway, a nationwide population-based registry study including over 10,000 adults with	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	type 1 diabetes reported that 22% experienced high levels of distress. Common concerns included fear of complications and emotional exhaustion related to self-management demands (Hernar 2024). A consistent body of evidence links higher diabetes distress with poorer glycaemic outcomes, suboptimal self-management behaviours, and deteriorated mental health. In a cross-sectional study using continuous glucose monitoring (CGM), adults with higher distress spent more time above the target glucose range and less time in range than those with lower distress (Kelly 2024). Similar findings were observed in a 17-day ecological momentary assessment study, where daily distress ratings were positively associated with hyperglycaemia and higher mean glucose levels. Time spent with distress also predicted HbA1c at three-month follow-up (Ehrmann 2022). Longitudinal studies have shown that greater baseline distress is associated with more frequent missed insulin boluses and higher HbA1c over time, while reductions in distress coincide with improved glycaemic outcomes (Hessler 2017). The bi-directional relationship between diabetes distress and mental health outcomes has been demonstrated in studies including individuals with both type 1 diabetes and type 2 diabetes. In one study, baseline diabetes distress was associated with a more than twofold increase in the likelihood of developing or maintaining depressive symptoms over six months, while depressive symptoms also increased the likelihood of sustained diabetes distress (Ehrmann 2015). Similarly, in a trial of psychosocial intervention, a clinically meaningful reduction in diabetes distress was associated with a fourfold increase in the likelihood of improved depressive symptoms (Reimer 2017). References · Dennick K, Sturt J, Hessler D, Purssell E, Hunter B, Oliver J, Fisher L. High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis. International Diabetes Nursing, 2015; 12(3), pp. 93-107. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. Diabet Med. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ehrmann D, Schmitt A, Priesterroth L, Kulzer B, Haak T, Hermanns N. Time With Diabetes Distress and Glycemia-Specific Distress: New Patient-Reported Outcome Measures for the Psychosocial	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Burden of Diabetes Using Ecological Momentary Assessment in an Observational Study. Diabetes Care. 2022 Jul 7;45(7):1522-1531. · Fisher L, Hessler D, Polonsky W, Strycker L, Masharani U, Peters A. Diabetes distress in adults with type 1 diabetes: Prevalence, incidence and change over time. J Diabetes Complications. 2016 Aug;30(6):1123-8. doi: 10.1016/j.jdiacomp.2016.03.032. · Grulovic N, Rojnic Kuzman M, Baretic M. Prevalence and predictors of diabetes-related distress in adults with type 1 diabetes. Sci Rep. 2022 Sep 21;12(1):15758. doi: 10.1038/s41598-022-19961-4. · Hernar I, Cooper JG, Nilsen RM, Skinner TC, Strandberg RB, Iversen MM, Graue M, Ernes T, Løvaas KF, Madsen TV, Lie SS, Richards DA, Ueland GÅ, Haugstvedt A. Diabetes Distress and Associations With Demographic and Clinical Variables: A Nationwide Population-Based Registry Study of 10,186 Adults With Type 1 Diabetes in Norway. Diabetes Care. 2024 Jan 1;47(1):126-131. doi: 10.2337/dc23-1001. · Hessler DM, Fisher L, Polonsky WH, Masharani U, Strycker LA, Peters AL, Blumer I, Bowyer V. Diabetes distress is linked with worsening diabetes management over time in adults with Type 1 diabetes. Diabet Med. 2017 Sep;34(9):1228-1234. doi: 10.1111/dme.13381. · Kelly CS, Nguyen H, Chapman KS, Wolf WA. The emotional burden of type 1 diabetes: A cross-sectional study to understand associations between diabetes distress and glucose metrics in adulthood. Diabet Med. 2024 Nov;41(11):e15425. doi: 10.1111/dme.15425. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Vallis M, Willaing I, Holt RIG. Emerging adulthood and Type 1 diabetes: insights from the DAWN2 Study. Diabet Med. 2018 Feb;35(2):203-213. doi: 10.1111/dme.13554.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ● Small ○ Moderate ○ Large ○ Varies ○ Don't know	Diabetes distress reduction: SMD = -0.22 suggesting small benefit Desirable effects on other outcomes: A 2022 systematic review and meta-analysis synthesised findings from 20 randomised controlled trials investigating the impact of psychological interventions on outcomes other than diabetes distress in people with type 1 diabetes (Efthymiadis 2022). These interventions included cognitive-behavioural therapy, coping skills training, mindfulness, and emotional or motivational approaches, delivered individually or in groups. The meta-analysis found a statistically significant improvement in quality of life following psychological interventions, with a SMD of 0.27 (95% confidence interval: 0.11 to 0.42). This finding, based on five studies, was assessed as moderate-quality evidence. Improvements were observed in areas such as diabetes-related worry, impact on daily life, and overall life satisfaction. The review also reported a reduction in HbA1c (mean difference: -0.26% [3 mmol/mol], 95% confidence interval: -0.51 to -0.01 [5 to 0.1 mmol/mol]) across 16 studies. A prespecified subgroup analysis showed that interventions incorporating cognitive-behavioural components resulted in a mean difference of -0.23% (2 mmol/mol; 95% CI: -0.44 to -0.02 [4 to 0.2 mmol/mol]) with minimal heterogeneity. These results suggest that psychological interventions, particularly those grounded in cognitive-behavioural techniques, may contribute to improved glycaemic outcomes in this population. In contrast, effects on depressive symptoms and anxiety were not statistically significant, although the trend was in a favourable direction.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect In addition to the primary outcome, potential benefits on secondary outcomes such as health-related quality of life or glycaemic levels were supplementarily considered

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Overall, the evidence indicates that psychological interventions may yield meaningful benefits beyond distress reduction, particularly in enhancing quality of life and supporting glycaemic management among adults with type 1 diabetes. The most consistent effects were observed for interventions based on cognitive-behavioural principles. References · Efthymiadis A, Boursaki M, Bastounis A. The effectiveness of psychological interventions on mental health and quality of life in people living with type 1 diabetes: a systematic review and meta-analysis. <i>Diabetol Int.</i> 2022 Jan 28;13(3):513-521. doi: 10.1007/s13340-021-00564-9.	based on findings from previously published systematic reviews.

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	A 2022 systematic review and meta-analysis of 20 randomised controlled trials evaluating psychological interventions for adults with type 1 diabetes found no evidence of undesirable effects (Efthymiadis 2022). However, adverse events were not prespecified as outcomes in this systematic review. Among the outcomes that were assessed, such as depressive symptoms, anxiety, glycaemic levels, and quality of life, none worsened, and most either improved or remained unchanged following psychological intervention. References · Efthymiadis A, Boursaki M, Bastounis A. The effectiveness of psychological interventions on mental health and quality of life in people living with type 1 diabetes: a systematic review and meta-analysis. <i>Diabetol Int.</i> 2022 Jan 28;13(3):513-521. doi: 10.1007/s13340-021-00564-9. A 2022 systematic review and meta-	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress, the primary outcome, this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	analysis of 20 randomized controlled trials evaluating psychological interventions for adults with type 1 diabetes found no evidence of undesirable effects (Efthymiadis et al. 2022). However, no specific adverse events were not prespecified as outcomes in this systematic review. Outcomes that were assessed, such as depressive symptoms, anxiety, glycaemic control, and quality of life either improved or remained unchanged with psychological intervention.	guideline development panel (GDP) concluded, based on collective clinical and research experience, that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty	Various sources support that diabetes distress is consistently regarded as a meaningful and important outcome by adults with type 1 diabetes, healthcare professionals, and other stakeholders. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised insights from 19 studies, several of which included adults with type 1 diabetes. Although findings were not disaggregated by diabetes type, central themes, such as perceived helplessness, loss of autonomy, and the invisibility of emotional burden in healthcare encounters, are highly applicable to people	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
or variability	with type 1 diabetes given the intensive nature of daily self-management. The authors concluded that diabetes distress should be proactively acknowledged and addressed in clinical care. An international Delphi consensus process involving over 300 stakeholders (Porth 2024), including 40% of participants living with type 1 diabetes, found that 85% of people with diabetes and 71% of healthcare professionals rated diabetes distress as highly important (≥ 7 out of 10) for inclusion in routine diabetes care. Subgroup analysis showed no meaningful difference in ratings between people with type 1 diabetes and type 2 diabetes, suggesting broad and consistent valuation across the diabetes community. In Denmark, a national participatory initiative (Skovlund 2021) developed a person-centred core outcome set through interviews and expert consensus. Diabetes distress was explicitly identified by people with type 1 diabetes and type 2 diabetes and adopted by a multi-stakeholder working group as one of the most important outcome domains for routine use in diabetes care. An international Delphi study specifically targeting young adults with type 1 diabetes (Byrne 2017) identified diabetes-related stress as one of only eight core outcomes achieving consensus ($\geq 70\%$ endorsement) among people with diabetes, clinicians, and researchers. The study underscored that young adults view diabetes distress as a critical emotional experience, closely tied to identity, autonomy, and developmental transitions. Finally, a comparative qualitative study (Orben 2022) reported that adults with type 1 diabetes experience a high emotional burden associated with long-term disease management and stigma. While some noted greater acknowledgement of distress by healthcare professionals compared to those with type 2 diabetes, they emphasised that diabetes distress remained a significant and under-supported concern. In summary, diabetes distress is consistently recognised as a highly valued and relevant outcome by adults with type 1 diabetes, clinicians, researchers, and health system stakeholders (Hamilton 2023). These findings support the prioritisation of distress in routine care, outcome measurement, and intervention development across all stakeholder groups. References · Byrne M, O'Connell A, Egan AM, Dinneen SF, Hynes L, O'Hara MC, Holt RIG, Willaing I, Vallis M, Hendrieckx C, Coyne I. A core outcomes set for clinical trials of interventions for young adults with	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	type 1 diabetes: an international, multi-perspective Delphi consensus study. <i>Trials</i>. 2017 Dec 19;18(1):602. doi: 10.1186/s13063-017-2364-y. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Saltik AZO, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. <i>Patient Educ Couns</i>. 2023 Nov;116:107933. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben K, Ritholz MD, McCalla M, Beverly EA. Differences and similarities in the experience of living with diabetes distress: A qualitative study of adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022 Oct;39(10):e14919. doi: 10.1111/dme.14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on judgements for domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● No included studies		approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	A cross-sectional registry study in Denmark found that adults with high diabetes distress had significantly more healthcare visits compared to those with lower distress levels, but no substantial increase in total healthcare costs was observed (Schmidt 2025). Similarly, a German cohort study concluded that depressive symptoms, but not diabetes distress, were associated with increased healthcare expenditures and lost productivity (Sommer 2024). These findings suggest that diabetes distress may contribute to greater healthcare engagement but not necessarily to higher costs. Only one randomised controlled trial has directly evaluated the cost-effectiveness of psychological interventions in adults with type 1 diabetes. The UK-based ADaPT study (Ismail 2010) compared cognitive behavioural therapy (CBT), motivational enhancement therapy (MET), and their combination against usual care in adults with persistent hyperglycaemia. Although the combined MET+CBT group demonstrated a statistically significant reduction in HbA1c compared to usual care, the economic evaluation was inconclusive. Both interventions were associated with higher healthcare costs, and cost-effectiveness varied depending on the instrument used to calculate QALYs (EQ-5D vs SF-36) and the method for imputing missing data. Two systematic reviews offer supplementary context. A 2013 review of psychological interventions for co-morbid depression in people with diabetes identified four U.S.-based economic evaluations of collaborative care models. All were found to be cost-effective or cost-saving, with ICERs ranging from \$267 to \$4,317 per QALY gained, though none reported findings specific to type 1 diabetes (Jeeva 2013).	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	In summary, while some psychological interventions show clinical promise for adults with type 1 diabetes, the existing cost-effectiveness evidence is limited and inconsistent. More rigorous economic evaluations are needed to support implementation in routine care. References · Ismail K, Maissi E, Thomas S, Chalder T, Schmidt U, Bartlett J, Patel A, Dickens C, Creed F, Treasure J. A randomised controlled trial of cognitive behaviour therapy and motivational interviewing for people with Type 1 diabetes mellitus with persistent sub-optimal glycaemic control: a Diabetes and Psychological Therapies (ADaPT) study. Health Technol Assess. 2010 May;14(22):1-101, iii-iv. doi: 10.3310/hta14220. · Jeeva F, Dickens C, Coventry P, Bundy C, Davies L. Is treatment of depression cost-effective in people with diabetes? A systematic review of the economic evidence. Int J Technol Assess Health Care. 2013 Oct;29(4):384-91. doi: 10.1017/S0266462313000445. · Schmidt CB, Keijsper E, Bosmans JE, van Loon BJP, Snoek FJ, Honig A. Medical costs and health care utilization in Dutch diabetes patients with high levels of diabetes-distress. J Diabetes Complications. 2025 May 21;39(8):109086. doi: 10.1016/j.jdiacomp.2025.109086. · Sommer J, Linnenkamp U, Gontscharuk V, Andrich S, Brüne M, Schmitz-Losem I, Kruse J, Evers SMAA, Hiligsmann M, Hoffmann B, Icks A. Prospective health care costs and lost work days associated with diabetes-related distress and depression symptoms among 1488 individuals with diabetes. Sci Rep. 2024 Feb 13;14(1):3621. doi: 10.1038/s41598-024-52361-4.	context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	Evidence directly assessing equity-related aspects of diabetes distress in adults with type 1 diabetes is limited. However, findings from mixed-population studies suggest that diabetes distress may be influenced by ethnic and socioeconomic factors, with possible implications for people with type 1 diabetes. In the U.S. subset of the DAWN2 study (Peyrot et al. 2014), which included 16.3% of participants with type 1 diabetes, ethnic differences in psychological outcomes were examined among adults with diabetes. While overall well-being and quality of life were sometimes more favourable in ethnic minority groups, levels of diabetes distress were consistently higher among African American, Hispanic, and Chinese American participants compared to White non-Hispanics. A cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care in U.S. safety-net clinics. Although only a small proportion of the sample had type 1 diabetes, the study found that diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with suboptimal medication taking and worse glycaemic levels. A mixed-methods study (Silver 2025) conducted among Black and Hispanic adults with diabetes in a large safety-net health system also reported high levels of diabetes distress. Participants described how financial strain, inadequate nutrition education, and systemic barriers undermined their capacity to self-manage their condition. Although most participants likely had type 2 diabetes, the identified themes, such as limited access to support and exacerbation of distress by social determinants, are relevant to individuals with type 1 diabetes as well. In summary, while direct evidence for equity impacts in type 1 diabetes is limited, findings from diverse and underserved populations suggest that socioeconomic and ethnic disparities may contribute to higher levels of diabetes distress. This highlights the importance of equitable delivery of interventions to reduce distress, which may help address disparities in emotional burden and self-management support among people with type 1 diabetes. References · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	patients with diabetes. J Epidemiol Community Health. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063. · Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. Curr Med Res Opin. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. Sci Diabetes Self Manag Care. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In a pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. Most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully	

	reflected in attrition rates from controlled trials. Conversely, when interventions, such as education, psychoeducation, efforts to reduce treatment complexity, or the introduction of diabetes technologies, are integrated into routine diabetes care, attrition rates may be lower compared to interventions that require referral to external providers (e.g., psychotherapists). However, further research is clearly needed to confirm this. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5	
--	---	--

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☐	Conditional recommendation for the intervention ☒	Strong recommendation for the intervention ☐
---	--	---	---	---

CONCLUSIONS

Recommendation

We suggest using psychological interventions in addition to usual care, rather than usual care alone, to reduce diabetes distress among adults with type 1 diabetes. (Conditional recommendation based on low certainty of evidence).

Justification

We suggest psychological interventions in addition to usual care due to their moderate beneficial effect on reducing diabetes distress and minimal associated harms. Although the certainty of evidence is low, the intervention can be acceptable to adults with type 1 diabetes, may support equity, and aligns with stakeholder values prioritising emotional well-being.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress.

Implementation considerations

Implementation may require additional training for health professionals and integration into routine diabetes care. Delivery through trained non-diabetes or non-psychology specialists, or digital formats may improve feasibility in varied healthcare settings. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs) in questionnaires such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Further research should focus on real-world studies evaluating psychological interventions for diabetes distress in diverse clinical settings. Additional cost-effectiveness analyses specific to type 1 diabetes populations are also needed.

QUESTION

Should psychological interventions vs. educational interventions be used for type 1 diabetes?	
POPULATION:	type 1 diabetes
INTERVENTION:	psychological interventions
COMPARISON:	educational interventions
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is highly prevalent among adults with type 1 diabetes (Dennick 2015). In the DAWN study (Peyrot 2005), which surveyed 5,104 adults with diabetes across 13 countries, 41% reported poor psychological well-being, and emotional concerns related to diabetes were common; however, the results were not stratified by diabetes type. The subsequent DAWN2 study (Nicolucci 2013) included 8,596 adults with diabetes from 17 countries, of whom 1,368 had type 1 diabetes. In this cohort, 45% of participants reported elevated diabetes distress. The prevalence varied substantially between countries, with the highest rates found in Algeria, Russia, and Turkey; and the lowest in the Netherlands, Denmark, and the USA. The DAWN2 dataset also showed that young adults (<30 years old) with type 1 diabetes reported higher levels of diabetes-specific distress than older adults (Vallis 2018). National studies have also provided estimates for adults with type 1 diabetes. In the United States, the prevalence of elevated diabetes distress was estimated at 42%, with a 9-month incidence of 54% in a sample of 224 adults (Fisher 2016). In Croatia, a cross-sectional survey of 100 adults with type 1 diabetes found that 36% had high diabetes-related distress, defined by a PAID score of ≥ 40 (Grulovic 2022). In Norway, a nationwide population-based registry study including over 10,000 adults with type 1 diabetes reported that 22% experienced high levels of distress. Common concerns included fear of complications and emotional exhaustion related to self-management demands (Hernar 2024).	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A consistent body of evidence links higher diabetes distress with poorer glycaemic outcomes, suboptimal self-management behaviours, and deteriorated mental health. In a cross-sectional study using continuous glucose monitoring (CGM), adults with higher distress spent more time above the target glucose range and less time in range than those with lower distress (Kelly 2024). Similar findings were observed in a 17-day ecological momentary assessment study, where daily distress ratings were positively associated with hyperglycaemia and higher mean glucose levels. Time spent with distress also predicted HbA1c at three-month follow-up (Ehrmann 2022). Longitudinal studies have shown that greater baseline distress is associated with more frequent missed insulin boluses and higher HbA1c over time, while reductions in distress coincide with improved glycaemic outcomes (Hessler 2017). The bi-directional relationship between diabetes distress and mental health outcomes has been demonstrated in studies including individuals with both type 1 diabetes and type 2 diabetes. In one study, baseline diabetes distress was associated with a more than twofold increase in the likelihood of developing or maintaining depressive symptoms over six months, while depressive symptoms also increased the likelihood of sustained diabetes distress (Ehrmann 2015). Similarly, in a trial of psychosocial intervention, a clinically meaningful reduction in diabetes distress was associated with a fourfold increase in the likelihood of improved depressive symptoms (Reimer 2017). References · Dennick K, Sturt J, Hessler D, Purssell E, Hunter B, Oliver J, Fisher L. High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis. <i>International Diabetes Nursing</i>, 2015; 12(3), pp. 93-107. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ehrmann D, Schmitt A, Priesterroth L, Kulzer B, Haak T, Hermanns N. Time With Diabetes Distress and Glycemia-Specific Distress: New Patient-Reported Outcome Measures for the Psychosocial Burden of Diabetes Using Ecological Momentary Assessment in an Observational Study. <i>Diabetes Care</i>. 2022 Jul 7;45(7):1522-1531. · Fisher L, Hessler D, Polonsky W, Strycker L, Masharani U, Peters A. Diabetes distress in adults with type 1 diabetes: Prevalence, incidence and change over time. <i>J Diabetes Complications</i>. 2016 Aug;30(6):1123-8. doi: 10.1016/j.jdiacomp.2016.03.032.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Grulovic N, Rojnic Kuzman M, Baretic M. Prevalence and predictors of diabetes-related distress in adults with type 1 diabetes. Sci Rep. 2022 Sep 21;12(1):15758. doi: 10.1038/s41598-022-19961-4. · Hernar I, Cooper JG, Nilsen RM, Skinner TC, Strandberg RB, Iversen MM, Graue M, Ernes T, Løvaas KF, Madsen TV, Lie SS, Richards DA, Ueland GÅ, Haugstvedt A. Diabetes Distress and Associations With Demographic and Clinical Variables: A Nationwide Population-Based Registry Study of 10,186 Adults With Type 1 Diabetes in Norway. Diabetes Care. 2024 Jan 1;47(1):126-131. doi: 10.2337/dc23-1001. · Hessler DM, Fisher L, Polonsky WH, Masharani U, Strycker LA, Peters AL, Blumer I, Bowyer V. Diabetes distress is linked with worsening diabetes management over time in adults with Type 1 diabetes. Diabet Med. 2017 Sep;34(9):1228-1234. doi: 10.1111/dme.13381. · Kelly CS, Nguyen H, Chapman KS, Wolf WA. The emotional burden of type 1 diabetes: A cross-sectional study to understand associations between diabetes distress and glucose metrics in adulthood. Diabet Med. 2024 Nov;41(11):e15425. doi: 10.1111/dme.15425. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Vallis M, Willaing I, Holt RIG. Emerging adulthood and Type 1 diabetes: insights from the DAWN2 Study. Diabet Med. 2018 Feb;35(2):203-213. doi: 10.1111/dme.13554.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	Meta-analysis found a non-significant difference in diabetes distress for psychological versus educational interventions.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Meta-analysis found a non-significant difference in diabetes distress for psychological versus educational interventions.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded, based on collective clinical and research experience, that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Various sources support that diabetes distress is consistently regarded as a meaningful and important outcome by adults with type 1 diabetes, healthcare professionals, and other stakeholders. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised insights from 19 studies, several of which included adults with type 1 diabetes. Although findings were not disaggregated by diabetes type, central themes, such as perceived helplessness, loss of autonomy, and the invisibility of emotional burden in healthcare encounters, are highly applicable to people with type 1 diabetes given the intensive nature of daily self-management. The authors concluded that diabetes distress should be proactively acknowledged and addressed in clinical care. An international Delphi consensus process involving over 300 stakeholders (Porth 2024), including 40% of participants living with type 1 diabetes, found that 85% of people with diabetes and 71% of healthcare professionals rated diabetes distress as highly important (≥ 7 out of 10) for inclusion in routine diabetes care. Subgroup analysis showed no meaningful difference in ratings between people with type 1 diabetes and type 2 diabetes, suggesting broad and consistent valuation across the diabetes community. In Denmark, a national participatory initiative (Skovlund 2021) developed a person-centred core outcome set through interviews and expert consensus. Diabetes distress was explicitly identified by people with type 1 diabetes and type 2 diabetes and adopted by a multi-stakeholder working group as one of the most important outcome domains for routine use in diabetes care. An international Delphi study specifically targeting young adults with type 1 diabetes (Byrne 2017) identified diabetes-related stress as one of only eight core outcomes achieving consensus ($\geq 70\%$ endorsement) among	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	people with diabetes, clinicians, and researchers. The study underscored that young adults view diabetes distress as a critical emotional experience, closely tied to identity, autonomy, and developmental transitions. Finally, a comparative qualitative study (Orben 2022) reported that adults with type 1 diabetes experience a high emotional burden associated with long-term disease management and stigma. While some noted greater acknowledgement of distress by healthcare professionals compared to those with type 2 diabetes, they emphasised that diabetes distress remained a significant and under-supported concern. In summary, diabetes distress is consistently recognised as a highly valued and relevant outcome by adults with type 1 diabetes, clinicians, researchers, and health system stakeholders. These findings support the prioritisation of distress in routine care, outcome measurement, and intervention development across all stakeholder groups. References · Byrne M, O'Connell A, Egan AM, Dinneen SF, Hynes L, O'Hara MC, Holt RIG, Willaing I, Vallis M, Hendrieckx C, Coyne I. A core outcomes set for clinical trials of interventions for young adults with type 1 diabetes: an international, multi-perspective Delphi consensus study. <i>Trials</i>. 2017 Dec 19;18(1):602. doi: 10.1186/s13063-017-2364-y. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben K, Ritholz MD, McCalla M, Beverly EA. Differences and similarities in the experience of living with diabetes distress: A qualitative study of adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022 Oct;39(10):e14919. doi: 10.1111/dme.14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on judgements for domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
		approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	No evidence on cost-effectiveness comparing psychological to educational interventions. Data on the cost-effectiveness of either type of interventions vs usual care are also limited and variable across different healthcare settings and countries.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ● Don't know	Psychological interventions have the potential to reduce diabetes distress among adults with type 1 diabetes, provided they are delivered equitably, particularly in socioeconomically disadvantaged populations where distress is more prevalent. It is uncertain whether psychological interventions could offer a greater advantage in reducing disparities compared to educational interventions. As such, no conclusions can be drawn regarding their relative impact on health equity.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In a pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g. psychologists, diabetes specialist nurses), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☒	Conditional recommendation for the intervention ☐	Strong recommendation for the intervention ☐
---	--	--	--	---

CONCLUSIONS

Recommendation

We do not suggest using psychological interventions instead of educational interventions or vice versa to reduce diabetes distress among adults with type 1 diabetes. (Conditional recommendation based on very low certainty of evidence)

Justification

We issue a conditional recommendation not to prefer one intervention over the other. Meta-analysis of two trials found no difference in effect on diabetes distress between psychological and educational interventions. No important differences are expected in undesirable effects, acceptability, feasibility, or cost-effectiveness, which are likely to vary depending on context and implementation.

Subgroup considerations

Subgroup analyses not performed as there were only two studies.

Implementation considerations

Implementation may require additional training for health professionals and integration into routine diabetes care. Delivery through trained non-diabetes or non-psychology specialists or digital formats may improve feasibility in varied healthcare settings. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Future studies, including non-inferiority trials, should directly compare psychological and educational interventions in adults with type 1 diabetes, evaluating their relative effects on diabetes distress. Such trials would help clarify comparative benefits and inform more targeted recommendations.

QUESTION

Should psychological interventions vs. usual care be used for type 2 diabetes?	
POPULATION:	type 2 diabetes
INTERVENTION:	psychological interventions
COMPARISON:	usual care
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy, though no	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	associations were found with retinopathy or nephropathy (Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017). Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007). A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017). References · Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. <i>Diabetes Care</i>. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181. · Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. <i>J Behav Med</i>. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x. · Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. <i>Diabet Med</i>. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933. · Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. Diabetologia. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● Moderate ○ Large ○ Varies ○ Don't know	Diabetes distress reduction: SMD = -0.31 in favour of the intervention, which suggest a moderate effect in reducing diabetes distress. A 2017 Cochrane systematic review of 30 randomised controlled trials (n = 9,177) evaluated psychological interventions, including emotion-focused, cognition-focused, and mixed approaches, for adults with type 2 diabetes (Chew 2017). The review found small improvements in two outcomes. Psychological interventions improved self-efficacy compared to usual care, with a standardised mean difference of 0.15 (95% confidence interval: 0.00 to 0.30), based on six trials (n = 2,675; low-quality evidence). Second, interventions modestly reduced HbA1c levels, with a mean difference of -0.14% (1 mmol/mol; 95% confidence interval: -0.27 to 0.00 [3 to 0 mmol/mol]), based on 11 trials (n = 3,165; low-quality evidence). No clinically meaningful effects were observed on diabetes-related distress, quality of life, blood pressure, or mortality. The quality of evidence across all outcomes was judged to be low, primarily due to risk of bias, imprecision, and inconsistency across studies. References · Chew BH, Vos RC, Metzendorf MI, Scholten RJ, Rutten GE. Psychological interventions for diabetes-related distress in adults with type 2 diabetes mellitus. Cochrane Database Syst Rev. 2017 Sep 27;9(9):CD011469. doi: 10.1002/14651858.CD011469.pub2.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect In addition to the primary outcome, potential benefits on secondary outcomes such as health-related quality of life or glycaemic levels were supplementarily considered based on findings from previously published systematic reviews.

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	A 2017 Cochrane systematic review of 30 randomised controlled trials evaluated the safety of psychological interventions in adults with type 2 diabetes (Chew 2017). Only three of the included trials (n = 438) reported adverse events. The pooled risk ratio for adverse events was 2.40 (95% confidence interval: 0.78 to 7.39), based on low-quality evidence. However, the trials did not detail the nature or severity of the adverse events, and no serious or intervention-related harms were identified. The review noted that adverse events were rarely prespecified or systematically assessed, limiting the strength of conclusions regarding potential harms. Despite these limitations, there was no evidence to suggest that psychological interventions are associated with substantial undesirable effects in this population. References · Chew BH, Vos RC, Metzendorf MI, Scholten RJPM, Rutten GEHM. Psychological interventions for diabetes-related distress in adults with type 2 diabetes mellitus. Cochrane Database Syst Rev. 2017;(9):CD011469. doi:10.1002/14651858.CD011469.pub2	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded, based on collective clinical and research experience, that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care. In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016). Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks. References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an Audit of 4 Australian Specialist Diabetes Clinics. <i>Can J Diabetes</i>. 2020 Aug;44(6):473-480. doi: 10.1016/j.jcjd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. <i>Diabetes Educ</i>. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022;39(10):e14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7. · Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. <i>J Diabetes Complications</i>. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	A cross-sectional registry study in Denmark found that adults with high diabetes distress had significantly more healthcare visits compared to those with lower distress levels, but no substantial increase in total healthcare costs was observed (Schmidt 2025). Similarly, a German cohort study concluded that depressive symptoms, but not diabetes distress, were associated with increased healthcare expenditures and lost productivity (Sommer 2024). These findings suggest that diabetes distress may contribute to greater healthcare engagement but not necessarily to higher costs. A systematic review of economic evaluations of psychological therapies in physical health conditions (Nicklas 2022) synthesized findings from 46 studies, including a subset focused on diabetes. The authors found that many psychological interventions across chronic diseases appeared to be cost-effective, particularly when delivered digitally or remotely. However, only three studies addressed diabetes, and the review did not distinguish findings for type 1 diabetes versus type 2 diabetes. Therefore, while the results offer indirect support for the value of psychological therapies in type 2 diabetes, they do not provide conclusive, diabetes-specific economic estimates. A separate systematic review of economic evidence (Jeeva 2013) focused specifically on psychological interventions for individuals with diabetes and comorbid depression. It included four U.S.-based studies evaluating collaborative care models incorporating psychological therapy. All studies involved adults with diabetes (mainly type 2 diabetes) and reported cost-effectiveness or cost-saving results. ICERs ranged from US\$267 to US\$4,317 per quality-adjusted life year (QALY) gained. However, study quality was variable, and no formal subgroup analyses by diabetes type were provided. The authors concluded that collaborative psychological care in diabetes is likely to be cost-effective but highlighted the need for stronger evidence tailored to diabetes subtypes. Together, these findings suggest that psychological interventions may be economically favourable in type 2 diabetes, especially when implemented through scalable models such as telehealth or collaborative primary care. However, direct, high-quality cost-effectiveness data specific to type 2 diabetes populations remain limited and should be a priority for future research.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	References · Jeeva F, Dickens C, Coventry P, Bundy C, Davies L. Is treatment of depression cost-effective in people with diabetes? A systematic review of the economic evidence. <i>Int J Technol Assess Health Care</i>. 2013 Oct;29(4):384-91. doi: 10.1017/S0266462313000445. · Nicklas L, Albiston M, Dunbar M, Gillies A, Hislop J, Moffat H, Thomson J. A systematic review of economic analyses of psychological interventions and therapies in health-related settings. <i>BMC Health Serv Res</i>. 2022 Sep 7;22(1):1131. doi: 10.1186/s12913-022-08158-0. · Schmidt CB, Keijsper E, Bosmans JE, van Loon BJP, Snoek FJ, Honig A. Medical costs and health care utilization in Dutch diabetes patients with high levels of diabetes-distress. <i>J Diabetes Complications</i>. 2025 May 21;39(8):109086. doi: 10.1016/j.jdiacomp.2025.109086. · Sommer J, Linnenkamp U, Gontscharuk V, Andrich S, Brüne M, Schmitz-Losem I, Kruse J, Evers SMAA, Hilgsmann M, Hoffmann B, Icks A. Prospective health care costs and lost work days associated with diabetes-related distress and depression symptoms among 1488 individuals with diabetes. <i>Sci Rep</i>. 2024 Feb 13;14(1):3621. doi: 10.1038/s41598-024-52361-4.	

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	A substantial body of evidence indicates that diabetes distress is more prevalent and more severe among adults with type 2 diabetes who are socioeconomically disadvantaged or belong to racially and ethnically minoritized groups. These disparities appear to be driven by both structural and psychosocial factors. In the U.S. subset of the DAWN2 study (Peyrot 2014), diabetes distress scores were higher among African American, Hispanic, and Chinese American adults with diabetes compared to White non-Hispanic participants. These differences were associated with modifiable diabetes-specific factors such as healthcare access, perceived burden of disease, and social support. Although the sample included both diabetes types, over 80% of participants had type 2 diabetes, making the findings highly relevant. A mixed-methods study (Levy 2022) focused exclusively on people with insulin-dependent type 2 diabetes receiving care in a safety-net clinic. Nearly four out of five participants reported at least moderate distress,	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	and 92% experienced barriers in at least one social determinant of health domain. Interviews revealed that job-related stress, limited provider access, and difficulties navigating the health system contributed to emotional burden. A large cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care at U.S. safety-net clinics, the majority of whom had type 2 diabetes. Diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with lower medication taking, higher HbA1c, and worse cardiovascular risk profiles, suggesting a link between socioeconomic disadvantage, emotional burden, and suboptimal diabetes outcomes. Another study (Silver 2025) reported high diabetes distress among Black and Hispanic adults with diabetes in a safety-net setting. Participants described the compounding effects of financial stress, inadequate access to self-management education, and discrimination on their emotional well-being. In a survey of older adults with type 2 diabetes (Williams 2020), perceived discrimination and low physician trust partially explained higher diabetes distress scores among African American participants compared to their White American counterparts. Among Latino adults with type 2 diabetes, racial or ethnic discrimination was found to be associated with increased diabetes distress and depressive symptoms (LeBrón 2019). In the Dutch Diabetes Pearl cohort, ethnic minority groups had significantly higher rates of diabetes distress than White participants, even after adjustment for a wide range of metabolic, cardiovascular, and lifestyle factors (Özcan 2018). Taken together, the evidence indicates that diabetes distress is both more common and potentially more harmful among people with type 2 diabetes who face socioeconomic disadvantage or systemic inequities. Addressing diabetes distress in these populations, particularly through equitable access to supportive interventions, may help reduce disparities in emotional burden and improve diabetes care outcomes. References · LeBrón AMW, Spencer M, Kieffer E, Sinco B, Palmisano G. Racial/Ethnic Discrimination and Diabetes-Related Outcomes Among Latinos with Type 2 Diabetes. J Immigr Minor Health. 2019 Feb;21(1):105-114. doi: 10.1007/s10903-018-0710-0. · Levy NK, Park A, Solis D, Hu L, Langford AT, Wang B, Rogers ES. Social Determinants of Health and Diabetes-Related Distress in Patients With Insulin-Dependent Type 2 Diabetes: Cross-sectional, Mixed Methods Approach. JMIR Form Res. 2022 Oct 12;6(10):e40164. doi: 10.2196/40164.	populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Özcan B, Rutters F, Snoek FJ, Roosendaal M, Sijbrands EJ, Elders PJM, Holleman F, Pijl H, Tack CJ, Abbink EJ, de Valk HW, Wolffenbuttel BHR, Stehouwer CDA, Schaper NC, Dekker JM, Schram MT; Diabetes Pearl from the Parelsnoer Initiative. High Diabetes Distress Among Ethnic Minorities Is Not Explained by Metabolic, Cardiovascular, or Lifestyle Factors: Findings From the Dutch Diabetes Pearl Cohort. <i>Diabetes Care</i>. 2018 Sep;41(9):1854-1861. doi: 10.2337/dc17-2181. · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. <i>J Epidemiol Community Health</i>. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063. · Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. <i>Curr Med Res Opin</i>. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. · Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. <i>Sci Diabetes Self Manag Care</i>. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085. Williams IC, Clay OJ, Ovalle F, Atkinson D, Crowe M. The Role of Perceived Discrimination and Other Psychosocial Factors in Explaining Diabetes Distress Among Older African American and White Adults. <i>J Appl Gerontol</i>. 2020 Jan;39(1):99-104. doi: 10.1177/0733464817750273.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies	In one pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023).	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Don't know	Another pilot randomised controlled trial evaluated a five-session programme combining acceptance and commitment therapy principles with diabetes education for adults with type 2 diabetes and moderate diabetes distress. The intervention was well accepted, with a high completion rate and positive qualitative feedback (Ngan 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Ngan HY, Chong YY, Loo KM, Chien WT. Preliminary efficacy of an acceptance-based diabetes education (ACT-DE) programme for people with type 2 diabetes on diabetes distress and self-care behaviours: A pilot randomised controlled trial. J Contextual Behav Sci. Volume 30. 2023. Pages 50-60. https://doi.org/10.1016/j.jcbs.2023.09.002. · Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5.	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☐	Conditional recommendation for the intervention ☒	Strong recommendation for the intervention ☐
---	--	---	---	---

CONCLUSIONS

Recommendation

We suggest using psychological interventions in addition to usual care, rather than usual care alone, to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on very low certainty of evidence)

Justification

We suggest psychological interventions in addition to usual care due to their moderate beneficial effect on reducing diabetes distress and minimal associated harms. Although the certainty of evidence is very low, the intervention can be acceptable to adults with type 2 diabetes, may support equity, and aligns with stakeholder values prioritising emotional well-being.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress.

Implementation considerations

Implementation may require additional training for health professionals and integration into routine diabetes care. Delivery through trained non-specialists or digital formats may improve feasibility in varied healthcare settings. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Further research should focus on real-world studies evaluating psychological interventions for diabetes distress in diverse clinical settings. Additional cost-effectiveness analyses specific to type 2 diabetes populations are also needed.

QUESTION

Should psychological interventions vs. educational interventions be used for type 2 diabetes?	
POPULATION:	type 2 diabetes
INTERVENTION:	psychological interventions
COMPARISON:	educational interventions
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy, though no	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	associations were found with retinopathy or nephropathy (Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017). Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007). The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017). References · Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. <i>Diabetes Care</i>. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181. · Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. <i>J Behav Med</i>. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x. · Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. <i>Diabet Med</i>. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. <i>Diabetologia</i>. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large	A non-significant difference in diabetes distress for psychological versus	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit:

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
• Varies ○ Don't know	educational interventions. Both types of interventions were effective in reducing diabetes distress in respective analyses vs. usual care.	· $SMD \leq -0.5$: large effect · $SMD > -0.5$ and ≤ -0.3: moderate effect · $SMD > -0.3$ and ≤ -0.2: small effect · $SMD > -0.2$: trivial or no effect In addition to the primary outcome, potential benefits on secondary outcomes such as health-related quality of life or glycaemic levels were supplementarily considered based on findings from previously published systematic reviews.

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies • Don't know	Available evidence for either psychological or educational interventions against usual care suggests that no serious or intervention-related harms were identified. However, adverse events were infrequently and inconsistently assessed, and no trials directly compared the two interventions. Therefore, no conclusions can be drawn about the relative undesirable effects of psychological versus educational interventions.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · $SMD \geq +0.5$: large undesirable effect · $SMD \geq +0.3$ and $< +0.5$: moderate undesirable effect · $SMD \geq +0.2$ and $< +0.3$: small undesirable effect · $SMD < +0.2$: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of psychological and psychoeducational interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded—based on collective clinical and research experience—that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care. In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016). Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks. References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an Audit of 4 Australian Specialist Diabetes Clinics. <i>Can J Diabetes</i>. 2020 Aug;44(6):473-480. doi: 10.1016/j.jcjd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. <i>Diabetes Educ</i>. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022;39(10):e14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7. · Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. <i>J Diabetes Complications</i>. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
		approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	No evidence on cost-effectiveness comparing psychological to educational interventions. Data on the cost-effectiveness of either type of interventions vs usual care are also limited and variable across different healthcare settings and countries.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ● Don't know	Both psychological and educational interventions have the potential to reduce diabetes distress among adults with type 2 diabetes, provided they are delivered equitably, particularly in socioeconomically disadvantaged populations where distress is more prevalent. However, given the lack of direct comparative data, it is uncertain whether either intervention offers a greater advantage in reducing disparities, and no conclusions can be drawn regarding their relative impact on health equity.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In one pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). Another pilot randomised controlled trial evaluated a five-session programme combining acceptance and commitment therapy principles with diabetes education for adults with type 2 diabetes and moderate diabetes distress. The intervention was well accepted, with a high completion rate and positive qualitative feedback (Ngan 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Ngan HY, Chong YY, Loo KM, Chien WT. Preliminary efficacy of an acceptance-based diabetes education (ACT-DE) programme for people with type 2 diabetes on diabetes distress and self-care behaviours: A pilot randomised controlled trial. J Contextual Behav Sci. Volume 30. 2023. Pages 50-60. https://doi.org/10.1016/j.jcbs.2023.09.002.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5.	

Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☒	Conditional recommendation for the intervention ☐	Strong recommendation for the intervention ☐
---	--	--	--	---

CONCLUSIONS

Recommendation

We suggest using either psychological or educational interventions to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on very low certainty of evidence)

Justification

Both interventions showed beneficial effects on diabetes distress in separate comparisons with usual care. The relative effects, acceptability, feasibility, and cost-effectiveness of the two interventions remain uncertain due to limited and indirect evidence. Given this, either intervention may be a suitable option depending on local context and preferences.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on duration of study, delivery mode of the intervention (individual or group intervention), or level of diabetes distress at baseline.

Implementation considerations

Implementation may depend on resource availability, service structure, and health professional training. Programmes should be tailored to fit within existing care pathways and capacities, with appropriate support and supervision. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Further research should focus on real-world studies evaluating psychological interventions versus educational interventions for diabetes distress in diverse clinical settings. Additional cost-effectiveness analyses specific to type 2 diabetes populations are also needed. Since the effect size difference between psychological interventions and psychosocial education is minimal and both are active interventions, it is worth considering whether psychosocial education may be non-inferior to psychological interventions. This question is particularly relevant given that psychosocial education can be more readily implemented within routine healthcare settings. Future research should explicitly test this through well-designed non-inferiority studies.

Psychoeducational interventions for diabetes distress

QUESTION

Should psychoeducational interventions vs. usual care be used for type 1 diabetes?	
POPULATION:	type 1 diabetes
INTERVENTION:	psychoeducational interventions
COMPARISON:	usual care
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is highly prevalent among adults with type 1 diabetes (Dennick 2015). In the DAWN study (Peyrot 2005), which surveyed 5,104 adults with diabetes across 13 countries, 41% reported poor psychological well-being, and emotional concerns related to diabetes were common; however, the results were not stratified by diabetes type. The subsequent DAWN2 study (Nicolucci 2013) included 8,596 adults with diabetes from 17 countries, of whom 1,368 had type 1 diabetes. In this cohort, 45% of participants reported elevated diabetes distress. The prevalence varied substantially between countries, with the highest rates found in Algeria, Russia, and Turkey; and the lowest in the Netherlands, Denmark, and the USA. The DAWN2 dataset also showed that young adults (<30 years old) with type 1 diabetes reported higher levels of diabetes-specific distress than older adults (Vallis 2018). National studies have also provided estimates for adults with type 1 diabetes. In the United States, the prevalence of elevated diabetes distress was estimated at 42%, with a 9-month incidence of 54% in a sample of 224 adults (Fisher 2016). In Croatia, a cross-sectional survey of 100 adults with type 1 diabetes found that 36% had high diabetes-related distress, defined by a PAID score of ≥ 40 (Grulovic 2022). In Norway, a nationwide population-based registry study including over 10,000 adults with type 1 diabetes reported that 22%	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	experienced high levels of distress. Common concerns included fear of complications and emotional exhaustion related to self-management demands (Hernar 2024). A consistent body of evidence links higher diabetes distress with poorer glycaemic outcomes, sub-optimal self-management behaviours, and deteriorated mental health. In a cross-sectional study using continuous glucose monitoring (CGM), adults with higher distress spent more time above the target glucose range and less time in range than those with lower distress (Kelly 2024). Similar findings were observed in a 17-day ecological momentary assessment study, where daily distress ratings were positively associated with hyperglycaemia and higher mean glucose levels. Time spent with distress also predicted HbA1c at three-month follow-up (Ehrmann 2022). Longitudinal studies have shown that greater baseline distress is associated with more frequent missed insulin boluses and higher HbA1c over time, while reductions in distress coincide with improved glycaemic outcomes (Hessler 2017). The bi-directional relationship between diabetes distress and mental health outcomes has been demonstrated in studies including individuals with both type 1 diabetes and type 2 diabetes. In one study, baseline diabetes distress was associated with a more than twofold increase in the likelihood of developing or maintaining depressive symptoms over six months, while depressive symptoms also increased the likelihood of sustained diabetes distress (Ehrmann 2015). Similarly, in a trial of psychosocial intervention, a clinically meaningful reduction in diabetes distress was associated with a fourfold increase in the likelihood of improved depressive symptoms (Reimer 2017). References · Dennick K, Sturt J, Hessler D, Purssell E, Hunter B, Oliver J, Fisher L. High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis. <i>International Diabetes Nursing</i>, 2015; 12(3), pp. 93-107. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ehrmann D, Schmitt A, Priesterroth L, Kulzer B, Haak T, Hermanns N. Time With Diabetes Distress and Glycemia-Specific Distress: New Patient-Reported Outcome Measures for the Psychosocial Burden of Diabetes Using Ecological Momentary Assessment in an Observational Study. <i>Diabetes Care</i>. 2022 Jul 7;45(7):1522-1531.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Fisher L, Hessler D, Polonsky W, Strycker L, Masharani U, Peters A. Diabetes distress in adults with type 1 diabetes: Prevalence, incidence and change over time. J Diabetes Complications. 2016 Aug;30(6):1123-8. doi: 10.1016/j.jdiacomp.2016.03.032. · Grulovic N, Rojnic Kuzman M, Baretic M. Prevalence and predictors of diabetes-related distress in adults with type 1 diabetes. Sci Rep. 2022 Sep 21;12(1):15758. doi: 10.1038/s41598-022-19961-4. · Hernar I, Cooper JG, Nilsen RM, Skinner TC, Strandberg RB, Iversen MM, Graue M, Ernes T, Løvaas KF, Madsen TV, Lie SS, Richards DA, Ueland GÅ, Haugstvedt A. Diabetes Distress and Associations With Demographic and Clinical Variables: A Nationwide Population-Based Registry Study of 10,186 Adults With Type 1 Diabetes in Norway. Diabetes Care. 2024 Jan 1;47(1):126-131. doi: 10.2337/dc23-1001. · Hessler DM, Fisher L, Polonsky WH, Masharani U, Strycker LA, Peters AL, Blumer I, Bowyer V. Diabetes distress is linked with worsening diabetes management over time in adults with Type 1 diabetes. Diabet Med. 2017 Sep;34(9):1228-1234. doi: 10.1111/dme.13381. · Kelly CS, Nguyen H, Chapman KS, Wolf WA. The emotional burden of type 1 diabetes: A cross-sectional study to understand associations between diabetes distress and glucose metrics in adulthood. Diabet Med. 2024 Nov;41(11):e15425. doi: 10.1111/dme.15425. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Vallis M, Willaing I, Holt RIG. Emerging adulthood and Type 1 diabetes: insights from the DAWN2 Study. Diabet Med. 2018 Feb;35(2):203-213. doi: 10.1111/dme.13554.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	There was no effect of the intervention in reducing diabetes distress compared to usual care, based on data from two trials.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · $\text{SMD} \leq -0.5$: large effect · $\text{SMD} > -0.5$ and ≤ -0.3: moderate effect · $\text{SMD} > -0.3$ and ≤ -0.2: small effect · $\text{SMD} > -0.2$: trivial or no effect

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	There was no effect of the intervention in reducing diabetes distress compared to usual care, based on data from two trials.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress, the primary outcome, this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect The single available trial did not identify any specific undesirable effects. Based on collective clinical and research experience, the guideline development panel concluded that if undesirable effects do occur, they are most likely minimal or trivial. This judgment reflects the nature of psychoeducational interventions and the consistent absence of documented harms in the available evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important	Various sources support that diabetes distress is consistently regarded as a meaningful and important outcome by adults with type 1 diabetes, healthcare professionals, and other stakeholders.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
uncertainty or variability • Probably no important uncertainty or variability o No important uncertainty or variability	A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised insights from 19 studies, several of which included adults with type 1 diabetes. Although findings were not disaggregated by diabetes type, central themes, such as perceived helplessness, loss of autonomy, and the invisibility of emotional burden in healthcare encounters, are highly applicable to people with type 1 diabetes given the intensive nature of daily self-management. The authors concluded that diabetes distress should be proactively acknowledged and addressed in clinical care. An international Delphi consensus process involving over 300 stakeholders (Porth 2024), including 40% of participants living with type 1 diabetes, found that 85% of people with diabetes and 71% of healthcare professionals rated diabetes distress as highly important (≥ 7 out of 10) for inclusion in routine diabetes care. Subgroup analysis showed no meaningful difference in ratings between people with type 1 diabetes and type 2 diabetes, suggesting broad and consistent valuation across the diabetes community. In Denmark, a national participatory initiative (Skovlund 2021) developed a person-centred core outcome set through interviews and expert consensus. Diabetes distress was explicitly identified by people with type 1 diabetes and type 2 diabetes and adopted by a multi-stakeholder working group as one of the most important outcome domains for routine use in diabetes care. An international Delphi study specifically targeting young adults with type 1 diabetes (Byrne 2017) identified diabetes-related stress as one of only eight core outcomes achieving consensus ($\geq 70\%$ endorsement) among people with diabetes, clinicians, and researchers. The study underscored that young adults view diabetes distress as a critical emotional experience, closely tied to identity, autonomy, and developmental transitions. Finally, a comparative qualitative study (Orben 2022) reported that adults with type 1 diabetes experience a high emotional burden associated with long-term disease management and stigma. While some noted greater acknowledgement of distress by healthcare professionals compared to those with type 2 diabetes, they emphasised that diabetes distress remained a significant and under-supported concern. In summary, diabetes distress is consistently recognised as a highly valued and relevant outcome by adults with type 1 diabetes, clinicians, researchers, and health system stakeholders. These findings support the prioritisation of distress in routine care, outcome measurement, and intervention development across all stakeholder groups.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	References · Byrne M, O'Connell A, Egan AM, Dinneen SF, Hynes L, O'Hara MC, Holt RIG, Willaing I, Vallis M, Hendrieckx C, Coyne I. A core outcomes set for clinical trials of interventions for young adults with type 1 diabetes: an international, multi-perspective Delphi consensus study. <i>Trials</i>. 2017 Dec 19;18(1):602. doi: 10.1186/s13063-017-2364-y. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben K, Ritholz MD, McCalla M, Beverly EA. Differences and similarities in the experience of living with diabetes distress: A qualitative study of adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022 Oct;39(10):e14919. doi: 10.1111/dme.14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on judgements for domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	A cross-sectional registry study in Denmark found that adults with high diabetes distress had significantly more healthcare visits compared to those with lower distress levels, but no substantial increase in total healthcare costs was observed (Schmidt 2025). Similarly, a German cohort study concluded that depressive symptoms, but not diabetes distress, were associated with increased healthcare expenditures and lost productivity (Sommer 2024). These findings suggest that diabetes distress may contribute to greater healthcare engagement but not necessarily to higher costs. A Dutch cost-effectiveness study (de Wit 2017) evaluated the HypoAware programme, a psychoeducational intervention combining group and online components, for adults with type 1 diabetes or insulin-treated type 2 diabetes experiencing problematic hypoglycaemia. From a societal perspective, the intervention had an incremental cost-effectiveness ratio (ICER) of €2,233 per severe hypoglycaemic event prevented. However, no gain in quality-adjusted life years (QALYs) was observed, and the probability of cost-effectiveness was modest (approximately 54–55%) in both societal and healthcare perspectives. A subgroup analysis restricted to people with type 1 diabetes found similar results, although separate ICERs were not reported. In the T1-REDEEM trial, a U.S.-based study (Shumway 2019) examined the costs of implementing two group interventions targeting diabetes distress: OnTrack (psychoeducational) and KnowIt (educational control). Both reduced distress, with OnTrack showing superior short-term effects. OnTrack was more expensive to deliver (USD 799 vs USD 497 per participant), and no formal cost-effectiveness analysis was performed. The authors	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
	noted that both interventions were within the lower cost range of previously studied self-management programmes. A 2020 systematic review (Siegel 2020) assessed the cost-effectiveness of diabetes-related interventions broadly, including multicomponent programmes integrating behavioural, pharmacological, and educational strategies. These were generally very cost-effective, with an estimated cost of USD 2,315 per QALY gained. While these findings provide indirect support for psychoeducational models, they are not stratified by diabetes type or by the psychological components of the intervention. In summary, current evidence suggests that psychoeducational interventions in type 1 diabetes may involve moderate implementation costs and limited cost-effectiveness when assessed via QALYs. More diabetes distress-specific economic evaluations are needed to inform routine implementation. References · Schmidt CB, Keijsper E, Bosmans JE, van Loon BJP, Snoek FJ, Honig A. Medical costs and health care utilization in Dutch diabetes patients with high levels of diabetes-distress. J Diabetes Complications. 2025 May 21;39(8):109086. doi: 10.1016/j.jdiacomp.2025.109086. · Shumway M, Fisher L, Hessler D, Bowyer V, Polonsky WH, Masharani U. Economic costs of implementing group interventions to reduce diabetes distress in adults with type 1 diabetes mellitus in the T1-REDEEM trial. J Diabetes Complications. 2019 Nov;33(11):107416. doi: 10.1016/j.jdiacomp.2019.107416. · Siegel KR, Ali MK, Zhou X, Ng BP, Jawanda S, Proia K, Zhang X, Gregg EW, Albright AL, Zhang P. Cost-effectiveness of Interventions to Manage Diabetes: Has the Evidence Changed Since 2008? Diabetes Care. 2020 Jul;43(7):1557-1592. doi: 10.2337/dci20-0017. · Sommer J, Linnenkamp U, Gontscharuk V, Andrich S, Brüne M, Schmitz-Losem I, Kruse J, Evers SMAA, Hiligsmann M, Hoffmann B, Icks A. Prospective health care costs and lost work days associated with diabetes-related distress and depression symptoms among 1488 individuals with diabetes. Sci Rep. 2024 Feb 13;14(1):3621. doi: 10.1038/s41598-024-52361-4. · de Wit M, Rondags SMPA, van Tulder MW, Snoek FJ, Bosmans JE. Cost-effectiveness of the psycho-educational blended (group and online) intervention HypoAware compared with usual care for people with Type 1 and insulin-treated Type 2 diabetes with problematic hypoglycaemia: analyses of a cluster-randomized controlled trial. Diabet Med. 2018 Feb;35(2):214-222. doi: 10.1111/dme.13548.	diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	Evidence directly assessing equity-related aspects of diabetes distress in adults with type 1 diabetes is limited. However, findings from mixed-population studies suggest that diabetes distress may be influenced by ethnic and socioeconomic factors, with possible implications for people with type 1 diabetes. In the U.S. subset of the DAWN2 study (Peyrot et al. 2014), which included 16.3% of participants with type 1 diabetes, ethnic differences in psychological outcomes were examined among adults with diabetes. While overall well-being and quality of life were sometimes more favourable in ethnic minority groups, levels of diabetes distress were consistently higher among African American, Hispanic, and Chinese American participants compared to White non-Hispanics. A cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care in U.S. safety-net clinics. Although only a small proportion of the sample had type 1 diabetes, the study found that diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with suboptimal medication taking and worse glycaemic levels. A mixed-methods study (Silver 2025) conducted among Black and Hispanic adults with diabetes in a large safety-net health system also reported high levels of diabetes distress. Participants described how financial strain, inadequate nutrition education, and systemic barriers undermined their capacity to self-manage their condition. Although most participants likely had type 2 diabetes, the identified themes, such as limited access to support and exacerbation of distress by social determinants, are relevant to individuals with type 1 diabetes as well. In summary, while direct evidence for equity impacts in type 1 diabetes is limited, findings from diverse and underserved populations suggest that socioeconomic and ethnic disparities may contribute to higher levels of diabetes distress. This highlights the importance of equitable delivery of interventions to reduce distress, which may help address disparities in emotional burden and self-management support among people with type 1 diabetes. References · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. J Epidemiol Community Health. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063.	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. Curr Med Res Opin. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. Sci Diabetes Self Manag Care. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In a pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials.	

	References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5	
--	--	--

Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☒	Conditional recommendation for the intervention ☐	Strong recommendation for the intervention ☐
---	--	--	--	---

CONCLUSIONS

Recommendation

We do not suggest using psychoeducational interventions in addition to usual care, rather than usual care alone, to reduce diabetes distress among adults with type 1 diabetes. (Conditional recommendation based on very low certainty of evidence)

Justification

We issue a conditional recommendation against routinely using psychoeducational interventions in preference to usual care to reduce diabetes distress in adults with type 1 diabetes based on very low certainty of evidence. The two available trials showed no benefit on diabetes distress. While undesirable effects are likely minimal, the overall balance of effects does not favour the intervention.

Subgroup considerations

Not applicable

Implementation considerations

Implementation may require additional training for health professionals and integration into routine diabetes care. Delivery through trained non-specialists or digital formats may improve feasibility in varied healthcare settings. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Future trials are needed to evaluate the effects of psychoeducational interventions compared with usual care in adults with type 1 diabetes, with a focus on diabetes distress. Additional evidence would strengthen the certainty of effect estimates and support more definitive recommendations.

QUESTION

Should psychoeducational interventions vs. educational interventions be used for type 1 diabetes?	
POPULATION:	type 1 diabetes
INTERVENTION:	psychoeducational interventions
COMPARISON:	educational interventions
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is highly prevalent among adults with type 1 diabetes (Dennick 2015). In the DAWN study (Peyrot 2005), which surveyed 5,104 adults with diabetes across 13 countries, 41% reported poor psychological well-being, and emotional concerns related to diabetes were common; however, the results were not stratified by diabetes type. The subsequent DAWN2 study (Nicolucci 2013) included 8,596 adults with diabetes from 17 countries, of whom 1,368 had type 1 diabetes. In this cohort, 45% of participants reported elevated diabetes distress. The prevalence varied substantially between countries, with the highest rates found in Algeria, Russia, and Turkey; and the lowest in the Netherlands, Denmark, and the USA. The DAWN2 dataset also showed that young adults (<30 years old) with type 1 diabetes reported higher levels of diabetes-specific distress than older adults (Vallis 2018). National studies have also provided estimates for adults with type 1 diabetes. In the United States, the prevalence of elevated diabetes distress was estimated at 42%, with a 9-month incidence of 54% in a sample of 224 adults (Fisher 2016). In Croatia, a cross-sectional survey of 100 adults with type 1 diabetes found that 36% had high diabetes-related distress, defined by a PAID score of ≥ 40 (Grulovic 2022). In Norway, a nationwide population-based registry study including over 10,000 adults with type 1 diabetes reported that 22% experienced high levels of distress. Common concerns included fear of complications and emotional exhaustion related to self-management demands (Hernar 2024).	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A consistent body of evidence links higher diabetes distress with poorer glycaemic outcomes, suboptimal self-management behaviours, and deteriorated mental health. In a cross-sectional study using continuous glucose monitoring (CGM), adults with higher distress spent more time above the target glucose range and less time in range than those with lower distress (Kelly 2024). Similar findings were observed in a 17-day ecological momentary assessment study, where daily distress ratings were positively associated with hyperglycaemia and higher mean glucose levels. Time spent with distress also predicted HbA1c at three-month follow-up (Ehrmann 2022). Longitudinal studies have shown that greater baseline distress is associated with more frequent missed insulin boluses and higher HbA1c over time, while reductions in distress coincide with improved glycaemic outcomes (Hessler 2017). The bi-directional relationship between diabetes distress and mental health outcomes has been demonstrated in studies including individuals with both type 1 diabetes and type 2 diabetes. In one study, baseline diabetes distress was associated with a more than twofold increase in the likelihood of developing or maintaining depressive symptoms over six months, while depressive symptoms also increased the likelihood of sustained diabetes distress (Ehrmann 2015). Similarly, in a trial of psychosocial intervention, a clinically meaningful reduction in diabetes distress was associated with a fourfold increase in the likelihood of improved depressive symptoms (Reimer 2017). References · Dennick K, Sturt J, Hessler D, Purssell E, Hunter B, Oliver J, Fisher L. High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis. <i>International Diabetes Nursing</i>, 2015; 12(3), pp. 93-107. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ehrmann D, Schmitt A, Priesterroth L, Kulzer B, Haak T, Hermanns N. Time With Diabetes Distress and Glycemia-Specific Distress: New Patient-Reported Outcome Measures for the Psychosocial Burden of Diabetes Using Ecological Momentary Assessment in an Observational Study. <i>Diabetes Care</i>. 2022 Jul 7;45(7):1522-1531. · Fisher L, Hessler D, Polonsky W, Strycker L, Masharani U, Peters A. Diabetes distress in adults with type 1 diabetes: Prevalence, incidence and change over time. <i>J Diabetes Complications</i>. 2016 Aug;30(6):1123-8. doi: 10.1016/j.jdiacomp.2016.03.032. · Grulovic N, Rojnic Kuzman M, Baretic M. Prevalence and predictors of diabetes-related distress in adults with type 1 diabetes. <i>Sci Rep</i>. 2022 Sep 21;12(1):15758. doi: 10.1038/s41598-022-19961-4.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Hernar I, Cooper JG, Nilsen RM, Skinner TC, Strandberg RB, Iversen MM, Graue M, Ernes T, Løvaas KF, Madsen TV, Lie SS, Richards DA, Ueland GÅ, Haugstvedt A. Diabetes Distress and Associations With Demographic and Clinical Variables: A Nationwide Population-Based Registry Study of 10,186 Adults With Type 1 Diabetes in Norway. <i>Diabetes Care</i>. 2024 Jan 1;47(1):126-131. doi: 10.2337/dc23-1001. · Hessler DM, Fisher L, Polonsky WH, Masharani U, Strycker LA, Peters AL, Blumer I, Bowyer V. Diabetes distress is linked with worsening diabetes management over time in adults with Type 1 diabetes. <i>Diabet Med</i>. 2017 Sep;34(9):1228-1234. doi: 10.1111/dme.13381. · Kelly CS, Nguyen H, Chapman KS, Wolf WA. The emotional burden of type 1 diabetes: A cross-sectional study to understand associations between diabetes distress and glucose metrics in adulthood. <i>Diabet Med</i>. 2024 Nov;41(11):e15425. doi: 10.1111/dme.15425. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. <i>Diabet Med</i>. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. <i>Diabet Med</i>. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. <i>PLoS One</i>. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Vallis M, Willaing I, Holt RIG. Emerging adulthood and Type 1 diabetes: insights from the DAWN2 Study. <i>Diabet Med</i>. 2018 Feb;35(2):203-213. doi: 10.1111/dme.13554.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	Meta-analysis found a non-significant difference in diabetes distress for psychoeducational versus educational interventions.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Meta-analysis found a non-significant difference in diabetes distress for psychoeducational versus educational interventions.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress, the primary outcome, this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect Given the lack of evidence suggesting potential undesirable effects of the intervention or comparator on other outcomes, the guideline development panel (GDP) concluded—based on collective clinical and research experience—that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude.

Certainty of evidence		
What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Various sources support that diabetes distress is consistently regarded as a meaningful and important outcome by adults with type 1 diabetes, healthcare professionals, and other stakeholders. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised insights from 19 studies, several of which included adults with type 1 diabetes. Although findings were not disaggregated by diabetes type, central themes, such as perceived helplessness, loss of autonomy, and the invisibility of emotional burden in healthcare encounters, are highly applicable to people with type 1 diabetes given the intensive nature of daily self-management. The authors concluded that diabetes distress should be proactively acknowledged and addressed in clinical care. An international Delphi consensus process involving over 300 stakeholders (Porth 2024), including 40% of participants living with type 1 diabetes, found that 85% of people with diabetes and 71% of healthcare professionals rated diabetes distress as highly important (≥7 out of 10) for inclusion in routine diabetes care. Subgroup analysis showed no meaningful difference in ratings between people with type 1 diabetes and type 2 diabetes, suggesting broad and consistent valuation across the diabetes community. In Denmark, a national participatory initiative (Skovlund 2021) developed a person-centred core outcome set through interviews and expert consensus. Diabetes distress was explicitly identified by people with type 1 diabetes and type 2 diabetes and adopted by a multi-stakeholder working group as one of the most important outcome domains for routine use in diabetes care.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	An international Delphi study specifically targeting young adults with type 1 diabetes (Byrne 2017) identified diabetes-related stress as one of only eight core outcomes achieving consensus ($\geq 70\%$ endorsement) among people with diabetes, clinicians, and researchers. The study underscored that young adults view diabetes distress as a critical emotional experience, closely tied to identity, autonomy, and developmental transitions. Finally, a comparative qualitative study (Orben 2022) reported that adults with type 1 diabetes experience a high emotional burden associated with long-term disease management and stigma. While some noted greater acknowledgement of distress by healthcare professionals compared to those with type 2 diabetes, they emphasised that diabetes distress remained a significant and under-supported concern. In summary, diabetes distress is consistently recognised as a highly valued and relevant outcome by adults with type 1 diabetes, clinicians, researchers, and health system stakeholders. These findings support the prioritisation of distress in routine care, outcome measurement, and intervention development across all stakeholder groups. References · Byrne M, O'Connell A, Egan AM, Dinneen SF, Hynes L, O'Hara MC, Holt RIG, Willaing I, Vallis M, Hendrieckx C, Coyne I. A core outcomes set for clinical trials of interventions for young adults with type 1 diabetes: an international, multi-perspective Delphi consensus study. <i>Trials</i>. 2017 Dec 19;18(1):602. doi: 10.1186/s13063-017-2364-y. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben K, Ritholz MD, McCalla M, Beverly EA. Differences and similarities in the experience of living with diabetes distress: A qualitative study of adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022 Oct;39(10):e14919. doi: 10.1111/dme.14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on judgements for domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	A U.S.-based randomized trial (Shumway et al. 2019) compared two manualized group interventions in adults with type 1 diabetes and elevated diabetes distress: OnTrack (a psychoeducational intervention targeting emotional coping, led by a psychologist) versus KnowIt (an educational control condition). While both interventions reduced diabetes distress, OnTrack showed greater short-term improvements. Implementation costs were higher for OnTrack (USD 799 per participant vs USD 497 for KnowIt). The study did not include a formal cost-effectiveness analysis, but did report resource use by intervention arm, highlighting the higher delivery cost of psychologically oriented programs. The authors concluded: "This is the first study to examine the costs of implementing interventions targeting diabetes distress in the context of type 1 diabetes. Both interventions had per participant implementation costs in the lower end of the range of previously examined diabetes self-management interventions (\$219 to \$5,390)." (Shumway et al. 2019). However, the cost-effectiveness of either type of interventions can vary considerably across different healthcare settings and countries. References Shumway M, Griffith K, Anderson J, et al. A randomized trial comparing psychoeducational and educational group interventions for adults with type 1 diabetes	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	and elevated diabetes distress. J Diabetes Complications. 2019;33(10):107419. doi:10.1016/j.jdiacomp.2019.107419	approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ● Don't know	All interventions that can reduce diabetes distress, if equitably delivered, may contribute to reducing disparities in emotional burden and support among people with type 1 diabetes. However, It is uncertain whether psychoeducational interventions could offer a greater advantage in reducing disparities compared to educational interventions. As such, no conclusions can be drawn regarding their relative impact on health equity.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In a pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016).	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☒	Conditional recommendation for the intervention ☐	Strong recommendation for the intervention ☐
---	--	--	--	---

CONCLUSIONS

Recommendation

We do not suggest psychoeducational interventions instead of educational interventions or vice versa to reduce diabetes distress among adults with type 1 diabetes. (Conditional recommendation based on low certainty of evidence)

Justification

We issue a conditional recommendation not to prefer one intervention over the other. Meta-analysis of three trials found no difference in effect on diabetes distress between psychoeducational and educational interventions. No important differences are expected in undesirable effects, acceptability, feasibility, or cost-effectiveness, which are likely to vary depending on context and implementation.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), baseline level of diabetes distress, or risk of bias.

Implementation considerations

Implementation may require additional training for health professionals and integration into routine diabetes care. Delivery through trained non-specialists or digital formats may improve feasibility in varied healthcare settings. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Future studies should directly compare psychoeducational and educational interventions in adults with type 1 diabetes, evaluating their relative effects on diabetes distress. Such trials would help clarify comparative benefits and inform more targeted recommendations. Moreover, the definitional distinction between psychoeducational and educational interventions is often unclear. This overlap complicates interpretation and comparison of findings and should be more clearly addressed in future research.

QUESTION

Should psychoeducational interventions vs. usual care be used for type 2 diabetes?	
POPULATION:	type 2 diabetes
INTERVENTION:	psychoeducational interventions
COMPARISON:	usual care
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy, though no	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	associations were found with retinopathy or nephropathy (Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017). Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007). The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017). References · Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. <i>Diabetes Care</i>. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181. · Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. <i>J Behav Med</i>. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x. · Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. <i>Diabet Med</i>. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. <i>Diabetologia</i>. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large	Diabetes distress reduction: SMD = -0.19 in favour of the intervention, which suggest a trivial effect in reducing diabetes distress.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Varies ○ Don't know	A 2019 systematic review and meta-analysis assessed the effectiveness of psychoeducational interventions in adults with type 2 diabetes, focusing in part on glycaemic outcomes (Perrin 2019). Across 23 randomised controlled trials (n = 3,818) that reported HbA1c data, psychoeducational interventions were associated with a reduction in HbA1c compared to control conditions. The pooled weighted mean difference was -0.28% (3 mmol/mol; 95% confidence interval: -0.48 to -0.08 [-5 to 1 mmol/mol]). This finding suggests a modest improvement in glycaemic levels. However, overall heterogeneity was high, and most interventions were not specifically designed to target diabetes distress, which may have influenced the magnitude and consistency of the effect. References · Perrin N, Bodicoat DH, Davies MJ, Robertson N, Snoek FJ, Khunti K. Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: A systematic review and meta-analysis. Prim Care Diabetes. 2019 Dec;13(6):556-567. doi: 10.1016/j.pcd.2019.04.001.	standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect In addition to the primary outcome, potential benefits on secondary outcomes such as health-related quality of life or glycaemic levels were supplementarily considered based on findings from previously published systematic reviews.

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	A 2019 systematic review and meta-analysis of 32 randomized controlled trials evaluated psychoeducational interventions for adults with type 2 diabetes (Perrin 2019), but did not assess adverse events or harms. References · Perrin N, Bodicoat DH, Davies MJ, Robertson N, Snoek FJ, Khunti K.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: a systematic review and meta-analysis. Prim Care Diabetes. 2019;13(6):556–567. doi:10.1016/j.pcd.2019.04.001	In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded—based on collective clinical and research experience—that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
important uncertainty or variability o No important uncertainty or variability	In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management. A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016). Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecq L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933. · Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an Audit of 4 Australian Specialist Diabetes Clinics. Can J Diabetes. 2020 Aug;44(6):473-480. doi: 10.1016/j.cjcd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. Diabetes Educ. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. J Diabetes Res. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. Diabet Med. 2022;39(10):e14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. BMJ Ment Health. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. Res Involv Engagem. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. J Diabetes Complications. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	A cross-sectional registry study in Denmark found that adults with high diabetes distress had significantly more healthcare visits compared to those with lower distress levels, but no substantial increase in total healthcare costs was observed (Schmidt 2025). Similarly, a German cohort study concluded that depressive symptoms, but not diabetes distress, were associated with increased healthcare expenditures and lost productivity (Sommer 2024). These findings suggest that diabetes distress may contribute to greater healthcare engagement but not necessarily to higher costs. A Spanish cluster randomized trial (García-Pérez 2022) evaluated a patient-targeted intervention (PTI) in 2,334 adults with type 2 diabetes across 32 primary care practices. The PTI included group-based educational workshops, tailored motivational SMS messages over 2 years, and access to an interactive educational website. Although the intervention did not include formal psychological therapy, its combination of structured education, motivational content, and behavioural self-management support aligns it conceptually with psychoeducational models. The economic evaluation, conducted from the Spanish healthcare system perspective, found that the PTI had an incremental cost-effectiveness ratio (ICER) of €38,486 per quality-adjusted life year (QALY) gained compared to usual care. In a predefined subgroup of individuals with suboptimal glycaemic levels, the PTI was dominant—yielding higher QALYs at lower cost than	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	the control arm. The PTI was also less costly and more effective than professional- or combined-targeted interventions tested in the same trial. A Dutch cost-effectiveness study (de Wit 2018) evaluated the HypoAware programme, a psychoeducational blended intervention combining group sessions and an online module, in 137 adults with type 1 diabetes or insulin-treated type 2 diabetes who experienced problematic hypoglycaemia. From a societal perspective, the ICER was €2,233 per severe hypoglycaemic event prevented. However, no QALY gains were observed, and the probability of cost-effectiveness was approximately 54–55% depending on the analytical perspective. Although results were not stratified separately for type 2 diabetes, a portion of the cohort consisted of people with insulin-treated type 2 diabetes, making the findings partially relevant. A systematic review of 122 economic evaluations (Siegel 2020) reported that multicomponent interventions incorporating behaviour change, structured education, and medication support were typically cost-effective or cost-saving in adults with type 2 diabetes. Among the subset of studies reporting ICERs, the median value was US\$2,315 per QALY gained. While the review did not isolate psychoeducational elements specifically, most included studies were conducted in type 2 diabetes populations and provide indirect support for the economic value of such interventions. References · García-Pérez L, Ramallo-Fariña Y, Vallejo-Torres L, Rodríguez-Rodríguez L, González-Pacheco H, Santos-Hernández B, García-Bello MA, Wägner AM, Carmona M, Serrano-Aguilar PG; INDICA team. Cost-effectiveness of multicomponent interventions in type 2 diabetes mellitus in a cluster randomised controlled trial: the INDICA study. <i>BMJ Open</i>. 2022 Apr 8;12(4):e058049. doi: 10.1136/bmjopen-2021-058049. · Schmidt CB, Keijsper E, Bosmans JE, van Loon BJP, Snoek FJ, Honig A. Medical costs and health care utilization in Dutch diabetes patients with high levels of diabetes-distress. <i>J Diabetes Complications</i>. 2025 May 21;39(8):109086. doi: 10.1016/j.jdiacomp.2025.109086. · Siegel KR, Ali MK, Zhou X, Ng BP, Jawanda S, Proia K, Zhang X, Gregg EW, Albright AL, Zhang P. Cost-effectiveness of Interventions to Manage Diabetes: Has the Evidence Changed Since 2008? <i>Diabetes Care</i>. 2020 Jul;43(7):1557-1592. doi: 10.2337/dci20-0017.	diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Sommer J, Linnenkamp U, Gontscharuk V, Andrich S, Brüne M, Schmitz-Losem I, Kruse J, Evers SMAA, Hiligsmann M, Hoffmann B, Icks A. Prospective health care costs and lost work days associated with diabetes-related distress and depression symptoms among 1488 individuals with diabetes. Sci Rep. 2024 Feb 13;14(1):3621. doi: 10.1038/s41598-024-52361-4. · de Wit M, Rondags SMPA, van Tulder MW, Snoek FJ, Bosmans JE. Cost-effectiveness of the psycho-educational blended (group and online) intervention HypoAware compared with usual care for people with Type 1 and insulin-treated Type 2 diabetes with problematic hypoglycaemia: analyses of a cluster-randomized controlled trial. Diabet Med. 2018 Feb;35(2):214-222. doi: 10.1111/dme.13548.	

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	A substantial body of evidence indicates that diabetes distress is more prevalent and more severe among adults with type 2 diabetes who are socioeconomically disadvantaged or belong to racially and ethnically minoritized groups. These disparities appear to be driven by both structural and psychosocial factors. In the U.S. subset of the DAWN2 study (Peyrot 2014), diabetes distress scores were higher among African American, Hispanic, and Chinese American adults with diabetes compared to White non-Hispanic participants. These differences were associated with modifiable diabetes-specific factors such as healthcare access, perceived burden of disease, and social support. Although the sample included both diabetes types, over 80% of participants had type 2 diabetes, making the findings highly relevant. A mixed-methods study (Levy 2022) focused exclusively on people with insulin-dependent type 2 diabetes receiving care in a safety-net clinic. Nearly four out of five participants reported at least moderate distress, and 92% experienced barriers in at least one social determinant of health domain. Interviews revealed that job-related stress, limited provider access, and difficulties navigating the health system contributed to emotional burden. A large cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care at U.S. safety-net clinics, the majority of whom had type 2 diabetes. Diabetes distress was more common among	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	younger individuals, women, and those with low income. High distress was independently associated with lower medication taking, higher HbA1c, and worse cardiovascular risk profiles, suggesting a link between socioeconomic disadvantage, emotional burden, and suboptimal diabetes outcomes. Another study (Silver 2025) reported high diabetes distress among Black and Hispanic adults with diabetes in a safety-net setting. Participants described the compounding effects of financial stress, inadequate access to self-management education, and discrimination on their emotional well-being. In a survey of older adults with type 2 diabetes (Williams 2020), perceived discrimination and low physician trust partially explained higher diabetes distress scores among African American participants compared to their White counterparts. Among Latino adults with type 2 diabetes, racial or ethnic discrimination was found to be associated with increased diabetes distress and depressive symptoms (LeBrón 2019). In the Dutch Diabetes Pearl cohort, ethnic minority groups had significantly higher rates of diabetes distress than Caucasian participants, even after adjustment for a wide range of metabolic, cardiovascular, and lifestyle factors (Özcan 2018). Taken together, the evidence indicates that diabetes distress is both more common and potentially more harmful among people with type 2 diabetes who face socioeconomic disadvantage or systemic inequities. Addressing diabetes distress in these populations, particularly through equitable access to supportive interventions, may help reduce disparities in emotional burden and improve diabetes care outcomes. References · LeBrón AMW, Spencer M, Kieffer E, Sinco B, Palmisano G. Racial/Ethnic Discrimination and Diabetes-Related Outcomes Among Latinos with Type 2 Diabetes. <i>J Immigr Minor Health</i>. 2019 Feb;21(1):105-114. doi: 10.1007/s10903-018-0710-0. · Levy NK, Park A, Solis D, Hu L, Langford AT, Wang B, Rogers ES. Social Determinants of Health and Diabetes-Related Distress in Patients With Insulin-Dependent Type 2 Diabetes: Cross-sectional, Mixed Methods Approach. <i>JMIR Form Res</i>. 2022 Oct 12;6(10):e40164. doi: 10.2196/40164. · Özcan B, Rutters F, Snoek FJ, Roosendaal M, Sijbrands EJ, Elders PJM, Holleman F, Pijl H, Tack CJ, Abbink EJ, de Valk HW, Wolffenbuttel BHR, Stehouwer CDA, Schaper NC, Dekker JM, Schram MT; Diabetes Pearl from the Parelnoer Initiative. High Diabetes Distress Among Ethnic Minorities Is Not Explained by Metabolic, Cardiovascular, or Lifestyle Factors: Findings From the Dutch Diabetes Pearl Cohort. <i>Diabetes Care</i>. 2018 Sep;41(9):1854-1861. doi: 10.2337/dc17-2181.	existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. J Epidemiol Community Health. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063. · Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. Curr Med Res Opin. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. · Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. Sci Diabetes Self Manag Care. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085. Williams IC, Clay OJ, Ovalle F, Atkinson D, Crowe M. The Role of Perceived Discrimination and Other Psychosocial Factors in Explaining Diabetes Distress Among Older African American and White Adults. J Appl Gerontol. 2020 Jan;39(1):99-104. doi: 10.1177/0733464817750273.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In one pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). Another pilot randomised controlled trial evaluated a five-session programme combining acceptance and commitment therapy principles with diabetes education for adults with type 2 diabetes and moderate diabetes distress. The intervention was well accepted, with a high completion rate and positive qualitative feedback (Ngan 2023).	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Ngan HY, Chong YY, Loo KM, Chien WT. Preliminary efficacy of an acceptance-based diabetes education (ACT-DE) programme for people with type 2 diabetes on diabetes distress and self-care behaviours: A pilot randomised controlled trial. J Contextual Behav Sci. Volume 30. 2023. Pages 50-60. https://doi.org/10.1016/j.jcbs.2023.09.002. · Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5.	

Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☐	Conditional recommendation for the intervention ☒	Strong recommendation for the intervention ☐
---	--	---	---	---

CONCLUSIONS

Recommendation

We suggest using psychoeducational interventions in addition to usual care, rather than usual care alone, to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on very low certainty of evidence)

Justification

We issue a conditional recommendation for psychoeducational interventions based on very low certainty of evidence. The effect on diabetes distress was trivial, and undesirable effects were judged to be absent or negligible. Although cost-effectiveness varies depending on setting and implementation, psychoeducational interventions can be acceptable and feasible when integrated into routine care.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress.

Implementation considerations

Implementation may require additional training for health professionals and integration into routine diabetes care. Delivery through trained non-specialists or digital formats may improve feasibility in varied healthcare settings. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Further research should prioritise real-world implementation studies of psychoeducational interventions in diverse health systems. As many of the intervention studies were primarily powered to detect changes in other outcomes, such as HbA1c, diabetes knowledge, medication taking, or weight loss, rather than diabetes distress specifically, further research is needed that is specifically powered to detect changes in diabetes distress in order to address this question more conclusively, complemented by economic evaluations to inform cost-effectiveness, especially in resource-constrained settings.

QUESTION

Should psychoeducational interventions vs. educational interventions be used for type 2 diabetes?	
POPULATION:	type 2 diabetes
INTERVENTION:	psychoeducational interventions
COMPARISON:	educational interventions
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy, though no	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	associations were found with retinopathy or nephropathy (Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017). Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007). The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017). References · Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. <i>Diabetes Care</i>. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181. · Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. <i>J Behav Med</i>. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x. · Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. <i>Diabet Med</i>. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. <i>Diabetologia</i>. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Diabetes distress reduction: marginally non-significant SMD = -0.15 in favour of psychoeducational interventions vs. educational interventions.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD $\leq$ -0.5: large effect · SMD $>$ -0.5 and $\leq$ -0.3: moderate effect · SMD $>$ -0.3 and $\leq$ -0.2: small effect · SMD $>$ -0.2: trivial or no effect In addition to the primary outcome, potential benefits on secondary outcomes such as health-related quality of life or glycaemic levels were supplementarily considered based on findings from previously published systematic reviews.

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ● Don't know	Available evidence for either psychoeducational or educational interventions against usual care suggests that no serious or intervention-related harms were identified. However, adverse events were infrequently and inconsistently assessed, and no trials directly compared the two interventions. Therefore, no conclusions can be drawn about the relative undesirable effects of psychoeducational versus educational interventions.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) $\geq$ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq$ +0.5: large undesirable effect · SMD $\geq$ +0.3 and $<$ +0.5: moderate undesirable effect · SMD $\geq$ +0.2 and $<$ +0.3: small undesirable effect · SMD $<$ +0.2: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded—based on collective clinical and research experience—that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care. In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management. A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016). Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks. References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. <i>J Prim Care Community Health</i>. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecq L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. <i>Patient Educ Couns</i>. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933. · Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Audit of 4 Australian Specialist Diabetes Clinics. Can J Diabetes. 2020 Aug;44(6):473-480. doi: 10.1016/j.jcjd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. Diabetes Educ. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. J Diabetes Res. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553.Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. Diabet Med. 2022;39(10):e14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. BMJ Ment Health. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. Res Involv Engagem. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7. Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. J Diabetes Complications. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
		approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	Data on the cost-effectiveness of either type of interventions vs. usual care are limited and variable across different healthcare settings and countries.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	Both psychoeducational and educational interventions have the potential to reduce diabetes distress among adults with type 2 diabetes, particularly when delivered in socioeconomically disadvantaged populations where distress is more prevalent. Given that psychoeducational interventions may have a trivial, favourable effect on diabetes distress compared to educational interventions, they may offer a slight advantage in addressing disparities, particularly if distress reduction is more impactful in underserved groups.	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In one pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). Another pilot randomised controlled trial evaluated a five-session programme combining acceptance and commitment therapy principles with diabetes education for adults with type 2 diabetes and moderate diabetes distress. The intervention was well accepted, with a high completion rate and positive qualitative feedback (Ngan 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Ngan HY, Chong YY, Loo KM, Chien WT. Preliminary efficacy of an acceptance-based diabetes education (ACT-DE) programme for people with type 2 diabetes on diabetes distress and self-care behaviours: A pilot randomised controlled trial. J Contextual Behav Sci. Volume 30. 2023. Pages 50-60. https://doi.org/10.1016/j.jcbs.2023.09.002.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5.	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☒	Conditional recommendation for the intervention ☐	Strong recommendation for the intervention ☐
---	--	--	--	---

CONCLUSIONS

Recommendation

We suggest using either psychoeducational or educational interventions to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on very low certainty of evidence)

Justification

This conditional recommendation is based on very low certainty evidence showing a small, marginally non-significant difference between psychoeducational and educational interventions, with substantial uncertainty around the magnitude and clinical importance of any effect. As both intervention types have demonstrated benefit compared with usual care and no important undesirable effects were identified, the panel did not favour one approach over the other.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on duration of study, delivery mode of the intervention (individual or group intervention), or level of diabetes distress at baseline.

Implementation considerations

Implementation may depend on resource availability, service structure, and health professional training. Programmes should be tailored to fit within existing care pathways and capacities, with appropriate support and supervision. Integrating peer support into care or management pathways could help expand access to diabetes-specific support.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Further research is needed to evaluate the comparative effectiveness of psychoeducational versus educational interventions in adults with type 2 diabetes, with a focus on diabetes distress as the primary outcome. Economic evaluations and real-world implementation studies are also warranted to inform scale-up

in diverse healthcare settings. In addition, the definitional overlap between psychoeducational and educational interventions adds complexity, as distinctions between these categories are often unclear. Future research should aim to establish clearer classification frameworks for intervention types

Miscellaneous (non-psychological, non-psychoeducational) interventions for diabetes distress

QUESTION

Should Automated insulin delivery systems vs. no use of automated insulin delivery systems be used for type 1 diabetes to reduce diabetes distress?	
POPULATION:	type 1 diabetes
INTERVENTION:	Automated insulin delivery systems
COMPARISON:	no use of automated insulin delivery systems
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is highly prevalent among adults with type 1 diabetes (Dennick 2015). In the DAWN study (Peyrot 2005), which surveyed 5,104 adults with diabetes across 13 countries, 41% reported poor psychological well-being, and emotional concerns related to diabetes were common; however, the results were not stratified by diabetes type. The subsequent DAWN2 study (Nicolucci 2013) included 8,596 adults with diabetes from 17 countries, of whom 1,368 had type 1 diabetes. In this cohort, 45% of participants reported elevated diabetes distress. The prevalence varied substantially between countries, with the highest rates found in Algeria, Russia, and Turkey; and the lowest in the Netherlands, Denmark, and the USA. The DAWN2 dataset also showed that young adults (<30 years old) with type 1 diabetes reported higher levels of diabetes-specific distress than older adults (Vallis 2018). National studies have also provided estimates for adults with type 1 diabetes. In the United States, the prevalence of elevated diabetes distress was estimated at 42%, with a 9-month incidence of 54% in a sample of 224 adults (Fisher 2016). In Croatia, a cross-sectional survey of 100 adults with type 1 diabetes found that 36% had high diabetes-related distress, defined by a PAID score of ≥ 40 (Grulovic 2022). In Norway, a nationwide population-based registry study including over 10,000 adults with type 1 diabetes reported that 22% experienced high levels of distress. Common concerns included fear of complications and emotional exhaustion related to self-management demands (Hernar 2024).	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A consistent body of evidence links higher diabetes distress with poorer glycaemic outcomes, suboptimal self-management behaviours, and deteriorated mental health. In a cross-sectional study using continuous glucose monitoring (CGM), adults with higher distress spent more time above the target glucose range and less time in range than those with lower distress (Kelly 2024). Similar findings were observed in a 17-day ecological momentary assessment study, where daily distress ratings were positively associated with hyperglycaemia and higher mean glucose levels. Time spent with distress also predicted HbA1c at three-month follow-up (Ehrmann 2022). Longitudinal studies have shown that greater baseline distress is associated with more frequent missed insulin boluses and higher HbA1c over time, while reductions in distress coincide with improved glycaemic outcomes (Hessler 2017). The bi-directional relationship between diabetes distress and mental health outcomes has been demonstrated in studies including individuals with both type 1 diabetes and type 2 diabetes. In one study, baseline diabetes distress was associated with a more than twofold increase in the likelihood of developing or maintaining depressive symptoms over six months, while depressive symptoms also increased the likelihood of sustained diabetes distress (Ehrmann 2015). Similarly, in a trial of psychosocial intervention, a clinically meaningful reduction in diabetes distress was associated with a fourfold increase in the likelihood of improved depressive symptoms (Reimer 2017). References · Dennick K, Sturt J, Hessler D, Purssell E, Hunter B, Oliver J, Fisher L. High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis. <i>International Diabetes Nursing</i>, 2015; 12(3), pp. 93-107. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ehrmann D, Schmitt A, Priesterroth L, Kulzer B, Haak T, Hermanns N. Time With Diabetes Distress and Glycemia-Specific Distress: New Patient-Reported Outcome Measures for the Psychosocial Burden of Diabetes Using Ecological Momentary Assessment in an Observational Study. <i>Diabetes Care</i>. 2022 Jul 7;45(7):1522-1531. · Fisher L, Hessler D, Polonsky W, Strycker L, Masharani U, Peters A. Diabetes distress in adults with type 1 diabetes: Prevalence, incidence and change over time. <i>J Diabetes Complications</i>. 2016 Aug;30(6):1123-8. doi: 10.1016/j.jdiacomp.2016.03.032.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Grulovic N, Rojnic Kuzman M, Baretic M. Prevalence and predictors of diabetes-related distress in adults with type 1 diabetes. Sci Rep. 2022 Sep 21;12(1):15758. doi: 10.1038/s41598-022-19961-4. · Hernar I, Cooper JG, Nilsen RM, Skinner TC, Strandberg RB, Iversen MM, Graue M, Ernes T, Løvaas KF, Madsen TV, Lie SS, Richards DA, Ueland GÅ, Haugstvedt A. Diabetes Distress and Associations With Demographic and Clinical Variables: A Nationwide Population-Based Registry Study of 10,186 Adults With Type 1 Diabetes in Norway. Diabetes Care. 2024 Jan 1;47(1):126-131. doi: 10.2337/dc23-1001. · Hessler DM, Fisher L, Polonsky WH, Masharani U, Strycker LA, Peters AL, Blumer I, Bowyer V. Diabetes distress is linked with worsening diabetes management over time in adults with Type 1 diabetes. Diabet Med. 2017 Sep;34(9):1228-1234. doi: 10.1111/dme.13381. · Kelly CS, Nguyen H, Chapman KS, Wolf WA. The emotional burden of type 1 diabetes: A cross-sectional study to understand associations between diabetes distress and glucose metrics in adulthood. Diabet Med. 2024 Nov;41(11):e15425. doi: 10.1111/dme.15425. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Vallis M, Willaing I, Holt RIG. Emerging adulthood and Type 1 diabetes: insights from the DAWN2 Study. Diabet Med. 2018 Feb;35(2):203-213. doi: 10.1111/dme.13554.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ● Small ○ Moderate ○ Large ○ Varies ○ Don't know	Use of automated insulin delivery (AID) was associated with a small reduction in diabetes distress compared with no use of AID (pooled SMD -0.15, 95% CI -0.33 to 0.02), with a consistent direction of effect favouring AID across trials, although statistical significance was not reached. The GDP noted that a subsequent sub-study analysis (Halliday 2024) of one of the trials included in the meta-analysis (McAuley 2020) found a reduction in diabetes distress with HCL, after adjusting for multiple covariates, as opposed to the main findings, which were based on unadjusted analysis. While suggestive of benefit, this finding requires corroboration in future trials. The GDP also noted that a recent meta-analysis reported a positive impact of automated insulin delivery (AID) system use on person-reported outcomes (Roos 2024). This analysis included 62 studies ($n = 9,253$), comprising 27 randomized controlled trials (RCTs), 25 observational studies, and 10 qualitative studies. Meta-analyses of RCTs showed a significant reduction in diabetes distress (standardized mean difference [SMD] -0.159, 95% CI $[-0.309, -0.010]$; $I^2 = 23.0\%$). Observational meta-analyses supported these findings, also showing reduced diabetes distress (SMD -0.217, 95% CI $[-0.403, -0.031]$; $I^2 = 68.5\%$). However, this meta-analysis was broad in scope, including children and adolescents as well as real-world evidence. Based on this broader dataset, the impact of AID use on diabetes distress ranged from trivial (in RCTs) to small (in observational studies). Further research is clearly needed to better understand the effects of AID systems on diabetes distress, particularly in more diverse and inclusive populations. A recent systematic review and meta-analysis focused on fully automated systems found that these technologies significantly increased time in range (TIR) by nearly 10% compared to various insulin delivery methods, including multiple daily injections, insulin pumps, and even hybrid AID systems (Fan 2025). This improvement was particularly marked in younger individuals and those with a shorter duration of diabetes. Additionally, users reported greater treatment satisfaction, suggesting a favourable impact on quality of life. However, fully AID systems performed less effectively than hybrid AID when directly compared, indicating the current limitations of full automation and the potential need for algorithm refinement and multi-hormonal integration in future models (Fan 2025). Another recent large-scale network meta-analysis assessed the efficacy of various AID systems across 46 randomised controlled trials involving over 4,000 participants (Stahl-Pehe 2025). All AID systems—hybrid, advanced hybrid, and fully closed-loop—outperformed standard pump therapy in terms of increasing TIR. Advanced hybrid and fully closed-loop systems showed the greatest improvement, with TIR increases of 24.1% and 25.5%, respectively, supported by moderate to high certainty of evidence. Additionally, time spent in hyperglycaemia was	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	significantly reduced with these systems. However, the effects on hypoglycaemia (time below 3.9 or 3.0 mmol/l [70 or 54 mg/dL]) and HbA1c were inconclusive due to very low or uncertain certainty of evidence. Overall, AID systems are associated with clinical desirable effects including improved glycaemic levels and increased patient satisfaction. Yet, there remain limitations, particularly around hypoglycaemia management, HbA1c outcomes, and the technological maturity of fully automated systems. References: · Fan W et al. Fully automated insulin delivery systems in type 1 diabetes: A systematic review and meta-analysis. Diabetes Obes Metab. 2025 May 28. doi: 10.1111/dom.16499. · Halliday JA et. al. Six months of hybrid closed-loop therapy improves diabetes-specific positive well-being, and reduces diabetes distress and fear of hypoglycemia: secondary analysis of a randomized controlled trial. BMJ Open Diabetes Res Care. 2024 Dec 22;12(6):e004428. doi: 10.1136/bmjdr-2024-004428. · McAuley SA et. al. Six Months of Hybrid Closed-Loop Versus Manual Insulin Delivery With Fingerprick Blood Glucose Monitoring in Adults With Type 1 Diabetes: A Randomized, Controlled Trial. Diabetes Care. 2020 Dec;43(12):3024-3033. doi: 10.2337/dc20-1447. · Roos T, Hermanns N, Gross C, Kulzer B, Haak T, Ehrmann D (2024) Effect of automated insulin delivery systems on person-reported outcomes in people with diabetes: a systematic review and meta-analysis. EClinicalMedicine 76: 102852. 10.1016/j.eclinm.2024.102852) · Stahl-Pehe A et al. Efficacy of automated insulin delivery systems in people with type 1 diabetes: a systematic review and network meta-analysis of outpatient randomised controlled trials. EClinicalMedicine. 2025 Apr 11;82:103190.	

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	Automated insulin delivery (AID) systems improve the management of type 1 diabetes by enhancing glycaemic levels and reducing self-care burden. Users often report improved quality of life, emotional relief, and better interpersonal relationships (Nefs 2022, Adams 2018, Wang 2021). However, not all experiences are positive. Discontinuation rates remain significant, with up to one-third of users ceasing algorithm use within six months (Nefs 2022): factors include reimbursement barriers, technical frustrations, device discomfort, and unmet expectations. Physical burdens such as wearing multiple devices, discomfort, and visibility contribute to dissatisfaction (Tanenbaum 2017), affecting self-image, social interactions, and relationship intimacy (Garza 2020). Dependence on AID may also result in deskilling, reducing competence in essential management tasks like carbohydrate counting or problem-solving during system errors (Nefs 2022). To optimise benefits, psychological support is needed, addressing expectations, emotional responses, and trust. Current person-reported outcome tools may not fully capture the psychological nuances of AID use and require updating (Weissberg-Benchell 2019). Healthcare professionals must approach AID candidacy with awareness of bias and individual needs, using dialogue to support effective and sustained technology use (Kubjak 2020). References · Adams RN et al. Psychosocial and Human Factors During a Trial of a Hybrid Closed Loop System for Type 1 Diabetes Management. <i>Diabetes Technol Ther</i> 2018 20(10):648–53. · Garza KP et al. You, Me, and Diabetes: Intimacy and Technology Among Adults With T1D and Their Partners. <i>Fam Syst Health</i> (2020) 38(4):418–27. · Kubiak T et al. Psychosocial Aspects of Diabetes Technology. <i>Diabetes Med</i> (2020) 37(3):448–54. · Nefs G. The Psychological Implications of Automated Insulin Delivery Systems in Type 1 Diabetes Care. <i>Front Clin Diabetes Healthc.</i> 2022 May 3;3:846162. · Tanenbaum ML et al. Diabetes Device Use in Adults With Type 1 Diabetes: Barriers to Uptake and Potential Intervention Targets. <i>Diabetes Care</i> (2017) 40(2):181–7. · Wang LR et al. Real-World Patient Experience of Long-Term Hybrid Closed-Loop Insulin Pump Use. <i>Can. J Diabetes</i> 2021. 45(8):750–6.e3. doi: 10.1016/j.jcjd.2021.02.006 · Weissberg-Benchell J et al. Assessing Patient-Reported Outcomes for Automated Insulin Delivery Systems: The Psychometric Properties of the INSPIRE Measures. <i>Diabetes Med</i> (2019) 36(5):644–52.	

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Various sources support that diabetes distress is consistently regarded as a meaningful and important outcome by adults with type 1 diabetes, healthcare professionals, and other stakeholders. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised insights from 19 studies, several of which included adults with type 1 diabetes. Although findings were not disaggregated by diabetes type, central themes, such as perceived helplessness, loss of autonomy, and the invisibility of emotional burden in healthcare encounters, are highly applicable to people with type 1 diabetes given the intensive nature of daily self-management. The authors concluded that diabetes distress should be proactively acknowledged and addressed in clinical care. An international Delphi consensus process involving over 300 stakeholders (Porth 2024), including 40% of participants living with type 1 diabetes, found that 85% of people with diabetes and 71% of healthcare professionals rated diabetes distress as highly important (≥ 7 out of 10) for inclusion in routine diabetes care. Subgroup analysis showed no meaningful difference in ratings between people with type 1 diabetes and type 2 diabetes, suggesting broad and consistent valuation across the diabetes community. In Denmark, a national participatory initiative (Skovlund 2021) developed a person-centred core outcome set through interviews and expert consensus. Diabetes distress was explicitly identified by people with type 1 diabetes and type 2 diabetes and adopted by a multi-stakeholder working group as one of the most important outcome domains for routine use in diabetes care. An international Delphi study specifically targeting young adults with type 1 diabetes (Byrne 2017) identified diabetes-related stress as one of only eight core outcomes achieving consensus ($\geq 70\%$ endorsement) among	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	people with diabetes, clinicians, and researchers. The study underscored that young adults view diabetes distress as a critical emotional experience, closely tied to identity, autonomy, and developmental transitions. Finally, a comparative qualitative study (Orben 2022) reported that adults with type 1 diabetes experience a high emotional burden associated with long-term disease management and stigma. While some noted greater acknowledgement of distress by healthcare professionals compared to those with type 2 diabetes, they emphasised that diabetes distress remained a significant and under-supported concern. In summary, diabetes distress is consistently recognised as a highly valued and relevant outcome by adults with type 1 diabetes, clinicians, researchers, and health system stakeholders. These findings support the prioritisation of distress in routine care, outcome measurement, and intervention development across all stakeholder groups. References · Byrne M, O'Connell A, Egan AM, Dinneen SF, Hynes L, O'Hara MC, Holt RIG, Willaing I, Vallis M, Hendrieckx C, Coyne I. A core outcomes set for clinical trials of interventions for young adults with type 1 diabetes: an international, multi-perspective Delphi consensus study. <i>Trials</i>. 2017 Dec 19;18(1):602. doi: 10.1186/s13063-017-2364-y. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben K, Ritholz MD, McCalla M, Beverly EA. Differences and similarities in the experience of living with diabetes distress: A qualitative study of adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022 Oct;39(10):e14919. doi: 10.1111/dme.14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
		approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	Cost-effectiveness is likely to vary considerably depending on the healthcare setting, country, analytical perspective, and the economic model used. While we did not find specific evidence on the cost-effectiveness of AID in the context of diabetes distress, in a systematic review including six RCTs in people with type 1 diabetes who had difficulty in managing their condition despite other technologies (e.g., CGM, pump), Asgharzadeh et al. found that hybrid closed-loop systems cost about £1,500–£2,000 more annually than CSII + CGM (Asgharzadeh 2024). While they reduce HbA1c by an average of 3 mmol/mol (0.29%), there was no evidence of reduced hypoglycaemia. The estimated gain is 0.160 QALYs at a net cost of £28,628, resulting in a high cost-effectiveness ratio of £179,000 per QALY, which is well above the typical UK thresholds. The cost-effectiveness has been further observed in another review by Mathieu et al.; in all 18 studies, AID systems were associated with an incremental QALYs gain ranging from +0.03 to +3.72 (Mathieu 2024). References · Asgharzadeh A et al. Hybrid closed-loop systems for managing blood glucose levels in type 1 diabetes: a systematic review and economic modelling. Health Technol Assess. 2024 Dec;28(80):1-190. · Mathieu C. The Health Economics of Automated Insulin Delivery Systems and the Potential Use of Time in Range in Diabetes Modeling: A Narrative Review. Diabetes Technol Ther. 2024 Mar;26(S3):66-75.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	Evidence directly assessing equity-related aspects of diabetes distress in adults with type 1 diabetes is limited. However, findings from mixed-population studies suggest that diabetes distress may be influenced by ethnic and socioeconomic factors, with possible implications for people with type 1 diabetes. In the U.S. subset of the DAWN2 study (Peyrot 2014), which included 16.3% of participants with type 1 diabetes, ethnic differences in psychological outcomes were examined among adults with diabetes. While overall well-being and quality of life were sometimes more favourable in ethnic minority groups, levels of diabetes distress were consistently higher among African American, Hispanic, and Chinese American participants compared to White non-Hispanics. A cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care in U.S. safety-net clinics. Although only a small proportion of the sample had type 1 diabetes, the study found that diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with poorer medication taking and worse glycaemic levels. A mixed-methods study (Silver 2025) conducted among Black and Hispanic adults with diabetes in a large safety-net health system also reported high levels of diabetes distress. Participants described how financial strain, inadequate nutrition education, and systemic barriers undermined their capacity to self-manage their condition. Although most participants likely had type 2 diabetes, the identified themes, such as limited access to support and exacerbation of distress by social determinants, are relevant to individuals with type 1 diabetes as well. In summary, while direct evidence for equity impacts in type 1 diabetes is limited, findings from diverse and underserved populations suggest that socioeconomic and ethnic disparities may contribute to higher levels of diabetes distress. This highlights the importance of equitable delivery of interventions to reduce distress, which may help address disparities in emotional burden and self-management support among people with type 1 diabetes. References · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. J Epidemiol Community Health. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063. · Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Diabetes Attitudes, Wishes, and Needs (DAWN2) study. Curr Med Res Opin. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. · Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. Sci Diabetes Self Manag Care. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	Several studies report high overall acceptability and satisfaction among adult users. In a prospective study of the Omnipod 5 system, (Polonsky 2022) authors evaluated 115 adults over three months and found significant improvements in diabetes-specific psychosocial outcomes. Participants reported reduced diabetes distress, increased hypoglycemia confidence, higher insulin delivery satisfaction, and improved overall treatment satisfaction. Notably, general well-being and sleep quality did not show statistically significant changes, suggesting that automated insulin delivery (AID) systems may primarily alleviate disease-specific burdens rather than broader quality-of-life factors. Despite these benefits, some adults discontinue use. A study (Donaldson 2024) found a 13% discontinuation rate in a real-world study of 94 adult users after a median of 13 months. Common reasons for discontinuation included CGM-related difficulties, frustration with glucose management, frequent system alarms, and high costs. These findings suggest that while many users benefit from AID systems, practical and psychological barriers can hinder long-term use. Trust in AID technology also plays a critical role in acceptability. A review (Nefs 2022) noted that some users initially experience anxiety or scepticism about relinquishing control to an automated system. This can result in “override” behaviours, such as manual bolus or deactivating the system during exercise or mealtimes, until users develop confidence in its reliability. To enhance early adoption and sustained engagement, recent implementation studies have emphasised the value of user support tools, demonstrating the safety and acceptability of a digital onboarding toolkit and	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	clinician decision-support tool designed for individuals starting advanced hybrid closed-loop (AHCL) therapy (Sehgal 2024). Participants maintained glycemic levels with low hypoglycemia risk, and both users and providers reported high satisfaction with the intervention. In summary, while AID systems are generally well accepted among adults with type 1 diabetes, offering meaningful improvements in treatment satisfaction and diabetes-specific psychosocial outcomes, barriers such as cost, system trust, and technical challenges remain. References · Donaldson LE et al. Automated insulin delivery among adults with type 1 diabetes for up to 2 years: a real-world, multicentre study. Intern Med J. 2024 Jan;54(1):121-128. · Nefs G. The Psychological Implications of Automated Insulin Delivery Systems in Type 1 Diabetes Care. Front Clin Diabetes Healthc. 2022 May 3;3:846162. · Polonsky WH et al. How introduction of automated insulin delivery systems may influence psychosocial outcomes in adults with type 1 diabetes: Findings from the first investigation with the Omnipod® 5 System. Diabetes Res Clin Pract. 2022 Aug;190:109998. · Sehgal S et al. Use of a decision support tool and quick start onboarding tool in individuals with type 1 diabetes using advanced automated insulin delivery: a single-arm multi-phase intervention study. BMC Endocr Disord. 2024 Aug 30;24(1):167.	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	Technological advances are making systems more user-friendly and less invasive. The development of low-cost, open-source AID platforms may increase adoption in resource-constrained settings (Payne 2024). Usability and real-world functionality are also central to feasibility. Despite the complex underlying technology, users generally report good acceptance once initial setup and training are completed (Rodbard 2016). References	

	· Payne M et al. Single-arm, first-in-human feasibility study results for an ultra-low-cost insulin pump. BMC Endocr Disord. 2024;24(1):12. · Rodbard D. Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities. Diabetes Technol Ther. 2016 Feb;18 Suppl 2(Suppl 2):S3-S13.	
--	--	--

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☐	Conditional recommendation for the intervention ☒	Strong recommendation for the intervention ☐
---	--	---	---	---

CONCLUSIONS

Recommendation

We suggest using automated insulin delivery (AID) systems, rather than no use of AID, to reduce diabetes distress among adults with type 1 diabetes.
(Conditional recommendation based on moderate certainty of evidence)

Justification

This conditional recommendation is based on moderate certainty evidence showing a small reduction in diabetes distress with AID systems compared with no AID, with the direction of effect consistently favouring AID across trials. Although the pooled effect did not reach conventional statistical significance, the overall pattern of evidence supports a modest benefit on diabetes distress, and no important undesirable effects were identified; this recommendation applies only to diabetes distress and does not reflect other established clinical benefits of AID systems.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress, or risk of bias.

Implementation considerations

Implementation of AID should be guided by person-centred approaches, addressing expectations, training needs, and technological literacy. System access and support structures (e.g., financial coverage, technical support) may influence success and acceptability.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Future studies with AID systems should pre-specify psychosocial outcomes and conduct adequately powered analyses to assess the impact of AID systems on diabetes distress, including covariate-adjusted models.

QUESTION

Should Continuous glucose monitoring vs. capillary glucose monitoring be used for type 1 diabetes to reduce diabetes distress?	
POPULATION:	type 1 diabetes
INTERVENTION:	Continuous glucose monitoring
COMPARISON:	capillary glucose monitoring
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is highly prevalent among adults with type 1 diabetes (Dennick 2015). In the DAWN study (Peyrot 2005), which surveyed 5,104 adults with diabetes across 13 countries, 41% reported poor psychological well-being, and emotional concerns related to diabetes were common; however, the results were not stratified by diabetes type. The subsequent DAWN2 study (Nicolucci 2013) included 8,596 adults with diabetes from 17 countries, of whom 1,368 had type 1 diabetes. In this cohort, 45% of participants reported elevated diabetes distress. The prevalence varied substantially between countries, with the highest rates found in Algeria, Russia, and Turkey; and the lowest in the Netherlands, Denmark, and the USA. The DAWN2 dataset also showed that young adults (<30 years old) with type 1 diabetes reported higher levels of diabetes-specific distress than older adults (Vallis 2018). National studies have also provided estimates for adults with type 1 diabetes. In the United States, the prevalence of elevated diabetes distress was estimated at 42%, with a 9-month incidence of 54% in a sample of 224 adults (Fisher 2016). In Croatia, a cross-sectional survey of 100 adults with type 1 diabetes found that 36% had high diabetes-related distress, defined by a PAID score of ≥ 40 (Grulovic 2022). In Norway, a nationwide population-based registry study including over 10,000 adults with type 1 diabetes reported that 22% experienced high levels of distress. Common concerns included fear of complications and emotional exhaustion related to self-management demands (Hernar 2024).	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A consistent body of evidence links higher diabetes distress with poorer glycaemic outcomes, suboptimal self-management behaviours, and deteriorated mental health. In a cross-sectional study using continuous glucose monitoring (CGM), adults with higher distress spent more time above the target glucose range and less time in range than those with lower distress (Kelly 2024). Similar findings were observed in a 17-day ecological momentary assessment study, where daily distress ratings were positively associated with hyperglycaemia and higher mean glucose levels. Time spent with distress also predicted HbA1c at three-month follow-up (Ehrmann 2022). Longitudinal studies have shown that greater baseline distress is associated with more frequent missed insulin boluses and higher HbA1c over time, while reductions in distress coincide with improved glycaemic outcomes (Hessler 2017). The bi-directional relationship between diabetes distress and mental health outcomes has been demonstrated in studies including individuals with both type 1 diabetes and type 2 diabetes. In one study, baseline diabetes distress was associated with a more than twofold increase in the likelihood of developing or maintaining depressive symptoms over six months, while depressive symptoms also increased the likelihood of sustained diabetes distress (Ehrmann 2015). Similarly, in a trial of psychosocial intervention, a clinically meaningful reduction in diabetes distress was associated with a fourfold increase in the likelihood of improved depressive symptoms (Reimer 2017). References · Dennick K, Sturt J, Hessler D, Purssell E, Hunter B, Oliver J, Fisher L. High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis. <i>International Diabetes Nursing</i>, 2015; 12(3), pp. 93-107. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ehrmann D, Schmitt A, Priesterroth L, Kulzer B, Haak T, Hermanns N. Time With Diabetes Distress and Glycemia-Specific Distress: New Patient-Reported Outcome Measures for the Psychosocial Burden of Diabetes Using Ecological Momentary Assessment in an Observational Study. <i>Diabetes Care</i>. 2022 Jul 7;45(7):1522-1531. · Fisher L, Hessler D, Polonsky W, Strycker L, Masharani U, Peters A. Diabetes distress in adults with type 1 diabetes: Prevalence, incidence and change over time. <i>J Diabetes Complications</i>. 2016 Aug;30(6):1123-8. doi: 10.1016/j.jdiacomp.2016.03.032.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Grulovic N, Rojnic Kuzman M, Baretic M. Prevalence and predictors of diabetes-related distress in adults with type 1 diabetes. Sci Rep. 2022 Sep 21;12(1):15758. doi: 10.1038/s41598-022-19961-4. · Hernar I, Cooper JG, Nilsen RM, Skinner TC, Strandberg RB, Iversen MM, Graue M, Ernes T, Løvaas KF, Madsen TV, Lie SS, Richards DA, Ueland GÅ, Haugstvedt A. Diabetes Distress and Associations With Demographic and Clinical Variables: A Nationwide Population-Based Registry Study of 10,186 Adults With Type 1 Diabetes in Norway. Diabetes Care. 2024 Jan 1;47(1):126-131. doi: 10.2337/dc23-1001. · Hessler DM, Fisher L, Polonsky WH, Masharani U, Strycker LA, Peters AL, Blumer I, Bowyer V. Diabetes distress is linked with worsening diabetes management over time in adults with Type 1 diabetes. Diabet Med. 2017 Sep;34(9):1228-1234. doi: 10.1111/dme.13381. · Kelly CS, Nguyen H, Chapman KS, Wolf WA. The emotional burden of type 1 diabetes: A cross-sectional study to understand associations between diabetes distress and glucose metrics in adulthood. Diabet Med. 2024 Nov;41(11):e15425. doi: 10.1111/dme.15425. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Vallis M, Willaing I, Holt RIG. Emerging adulthood and Type 1 diabetes: insights from the DAWN2 Study. Diabet Med. 2018 Feb;35(2):203-213. doi: 10.1111/dme.13554.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ● Large ○ Varies ○ Don't know	Continuous glucose monitoring interventions had a small effect (SMD = -0.26) in reducing diabetes distress compared to capillary glucose monitoring. CGM offers several clinical benefits in adults with type 1 diabetes, particularly in comparison to traditional capillary glucose monitoring. A 2022 systematic review and meta-analysis of 22 randomised controlled trials involving 2,188 individuals demonstrated that CGM use significantly improved glycaemic levels (Teo 2022). Specifically, CGM reduced HbA1c levels by an average of 2.46 mmol/mol (0.25%) across the overall population, with greater reductions in those individuals with poorly controlled diabetes (HbA1c >64 mmol/mol [$>8.0\%$]), in whom the authors reported an average reduction of 4.67 mmol/mol (0.5%) (1). While CGM did not significantly affect the frequency of severe hypoglycaemia or diabetic ketoacidosis in this analysis, its impact on daily glycaemic stability remains clear, particularly in outpatient settings. Based on the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) framework, the evidence was deemed to be of moderate certainty, with most included trials presenting low risk of bias (Teo 2022). References: · Teo E et al. Effectiveness of continuous glucose monitoring in maintaining glycaemic control among people with type 1 diabetes mellitus: a systematic review of randomised controlled trials and meta-analysis. <i>Diabetologia</i>. 2022 Apr;65(4):604–619.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	Limited research is available examining the psychological and behavioral reactions of CGM use in adults exclusively, as most studies examined these reactions in samples of youth and adults without reporting stratified results. In their investigation, Pickup et al. included 50 adult individuals with type 1 diabetes and 50 caregivers of children with type 1 diabetes (Pickup 2015): although the overall user or caregiver response to CGM was highly positive, the study also revealed several undesirable psychological and behavioural effects associated with its routine use. A notable concern was alarm fatigue as, while alarms were appreciated for signalling hypoglycaemia, they were also criticised for being disruptive, particularly at night. Additionally, participants reported anxiety and data-related stress, including an obsession with glucose readings and distress when confronted with poor results. Other undesirable effects included perceived sensor inaccuracy or unreliability, which, despite being tolerated by many users, contributed to psychological burden. This was compounded by limited training and support, with participants citing a lack of understanding and even misinformation about CGM among some healthcare providers. Psychological impacts also arose from the overload of data, which some users found overwhelming. Social stigma also remains a significant barrier. The visible presence of a CGM sensor can lead to feelings of embarrassment or discomfort, particularly in public or professional settings where individuals may fear judgment. These emotional responses can discourage self-management behaviours in public, further contributing to suboptimal glycaemic levels (Barnard-Kelly 2024). References · Barnard-Kelly KD et al. Identifying the deficiencies of currently available CGM to improve uptake and benefit. Diabet Med. 2024 Aug;41(8):e15338. · Pickup JC et al. Real-time continuous glucose monitoring in type 1 diabetes: a qualitative framework analysis of patient narratives. Diabetes Care. 2015;38(4):544-550.	

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ● Moderate ○ High ○ No included studies	Based on GRADE certainty assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Various sources support that diabetes distress is consistently regarded as a meaningful and important outcome by adults with type 1 diabetes, healthcare professionals, and other stakeholders. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised insights from 19 studies, several of which included adults with type 1 diabetes. Although findings were not disaggregated by diabetes type, central themes—such as perceived helplessness, loss of autonomy, and the invisibility of emotional burden in healthcare encounters—are highly applicable to people with type 1 diabetes given the intensive nature of daily self-management. The authors concluded that diabetes distress should be proactively acknowledged and addressed in clinical care. An international Delphi consensus process involving over 300 stakeholders (Porth 2024), including 40% of participants living with type 1 diabetes, found that 85% of people with diabetes and 71% of healthcare professionals rated diabetes distress as highly important (≥ 7 out of 10) for inclusion in routine diabetes care. Subgroup analysis showed no meaningful difference in ratings between people with type 1 diabetes and type 2 diabetes, suggesting broad and consistent valuation across the diabetes community. In Denmark, a national participatory initiative (Skovlund 2021) developed a person-centred core outcome set through interviews and expert consensus. Diabetes distress was explicitly identified by people with type 1 diabetes and type 2 diabetes and adopted by a multi-stakeholder working group as one of the most important outcome domains for routine use in diabetes care.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	An international Delphi study specifically targeting young adults with type 1 diabetes (Byrne 2017) identified diabetes-related stress as one of only eight core outcomes achieving consensus ($\geq 70\%$ endorsement) among people with diabetes, clinicians, and researchers. The study underscored that young adults view diabetes distress as a critical emotional experience, closely tied to identity, autonomy, and developmental transitions. Finally, a comparative qualitative study (Orben 2022) reported that adults with type 1 diabetes experience a high emotional burden associated with long-term disease management and stigma. While some noted greater acknowledgement of distress by healthcare professionals compared to those with type 2 diabetes, they emphasised that diabetes distress remained a significant and under-supported concern. In summary, diabetes distress is consistently recognised as a highly valued and relevant outcome by adults with type 1 diabetes, clinicians, researchers, and health system stakeholders. These findings support the prioritisation of distress in routine care, outcome measurement, and intervention development across all stakeholder groups. References · Byrne M, O'Connell A, Egan AM, Dinneen SF, Hynes L, O'Hara MC, Holt RIG, Willaing I, Vallis M, Hendrieckx C, Coyne I. A core outcomes set for clinical trials of interventions for young adults with type 1 diabetes: an international, multi-perspective Delphi consensus study. <i>Trials</i>. 2017 Dec 19;18(1):602. doi: 10.1186/s13063-017-2364-y. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben K, Ritholz MD, McCalla M, Beverly EA. Differences and similarities in the experience of living with diabetes distress: A qualitative study of adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022 Oct;39(10):e14919. doi: 10.1111/dme.14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. Res Involv Engagem. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	Jiao et al. investigated in a systematic review and meta-analysis the cost-effectiveness of CGM compared to SMBG in individuals with type 1 diabetes (Jiao 2022). Nineteen studies were included, most evaluating CGM within sensor-augmented pump systems. The reported incremental cost-effectiveness ratios (ICERs) ranged from \$18,734 to \$99,941, with quality-adjusted life years (QALY) gains between 0.76 and 2.99; 17 studies reported CGM as a cost-effective tool. Cost-effectiveness was higher in people with suboptimal glycaemic levels or high hypoglycaemia risk, and largely driven by the prevention of both short- and long-term diabetes complications. Cost-effectiveness is likely to vary considerably depending on the healthcare setting, country, analytical perspective, and the economic model used. References · Jiao Y et al. A systematic review: Cost-effectiveness of continuous glucose monitoring compared to self-monitoring of blood glucose in type 1 diabetes. Endocrinol Diabetes Metab. 2022 Nov;5(6):e369.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	Evidence directly assessing equity-related aspects of diabetes distress in adults with type 1 diabetes randomised to CGM or SMBG is limited. However, indirect evidence from mixed-population studies suggests that diabetes distress may be influenced by ethnic and socioeconomic factors, with possible implications for people with type 1 diabetes. In the U.S. subset of the DAWN2 study (Peyrot 2014), which included 16.3% of participants with type 1 diabetes, ethnic differences in psychological outcomes were examined among adults with diabetes. While overall well-being and quality of life were sometimes more favourable in ethnic minority groups, levels of diabetes distress were consistently higher among African American, Hispanic, and Chinese American participants compared to White non-Hispanics. A cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care in U.S. safety-net clinics. Although only a small proportion of the sample had type 1 diabetes, the study found that diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with poorer medication taking and worse glycaemic levels. A mixed-methods study (Silver 2025) conducted among Black and Hispanic adults with diabetes in a large safety-net health system also reported high levels of diabetes distress. Participants described how financial strain, inadequate nutrition education, and systemic barriers undermined their capacity to self-manage their condition. Although most participants likely had type 2 diabetes, the identified themes, such as limited access to support and exacerbation of distress by social determinants, are relevant to individuals with type 1 diabetes as well. In summary, while direct evidence for equity impacts in type 1 diabetes is limited, findings from diverse and underserved populations suggest that socioeconomic and ethnic disparities may contribute to higher levels of diabetes distress. This highlights the importance of equitable delivery of interventions to reduce distress, which may help address disparities in emotional burden and self-management support among people with type 1 diabetes. References · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. J Epidemiol Community Health. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063.	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. Curr Med Res Opin. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. · Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. Sci Diabetes Self Manag Care. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The acceptability of CGM among adults with type 1 diabetes has been the subject of various studies, highlighting both its benefits and challenges. CGM adoption has been associated with improved glycaemic levels, reduced hypoglycaemia, and enhanced quality of life. However, the acceptability of CGM is influenced by various factors, including user experience and perceived ease of use. A study found that while participants generally evaluated CGM positively, feelings of information overload and concerns about device accuracy were notable barriers to sustained use (Rodbard 2016). Disparities in CGM adoption exist. An evidence-based review by the National Institute for Health and Care Excellence (NICE) noted that broader access to CGM devices should reduce inequalities. However, uptake may still be lower in certain groups, such as older adults, people with disabilities, and those from lower socio-economic backgrounds, due to factors like limited access to technology and the need for additional support (NICE 2022). Further insights can be drawn from a recent study: the authors found that while many users appreciated the benefits of CGM, issues such as perceived device visibility negatively impacted sustained use. The study emphasised the importance of user experience, highlighting as current users were more likely to continue using CGM compared to former users, suggesting that familiarity and comfort with the technology play crucial roles in its acceptability (Borges 2016).	

	Another study identified several obstacles, including concerns about insurance coverage and patients' understanding of how to use the technology effectively. The study highlighted the need for targeted education and support to address these concerns and improve CGM uptake (Lanning 2020). References · Borges U Jr et al. Continuous Glucose Monitoring in Type 1 Diabetes. J Diabetes Sci Technol. 2016 May;10(3):633-639. · Lanning MS et al. Barriers to Continuous Glucose Monitoring in People With Type 1 Diabetes: Clinician Perspectives. Diabetes Spectrum. 2020;33(4):324–331. · National Institute for Health and Care Excellence (NICE). Evidence reviews for continuous glucose monitoring in adults with type 1 diabetes. NICE guideline [NG17]. 2022. · Rodbard D. Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities. Diabetes Technol Ther. 2016 Feb;18 Suppl 2(Suppl 2):S3-S13.	
--	--	--

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	From a usability standpoint, CGM devices have evolved to become more user-friendly, with smaller sensors, longer wear times, improved accuracy, and minimal calibration (Tauschmann 2018). However, barriers to consistent CGM use exist, such as alarm fatigue (Pickup 2015). Some users also find constant data monitoring overwhelming (“data overload”) or anxiety-provoking, which may lead to discontinuation; tailoring CGM use to patient preferences can improve long-term engagement (Tanenbaum 2022). Accessibility is also a critical barrier to CGM feasibility. The high cost of devices and sensors often limits insurance coverage, especially in lower-income populations and some countries: efforts to lower device costs, expand reimbursement policies, and increase awareness among healthcare providers are essential to enhance broader adoption (Tanenbaum 2022). References · Pickup JC et al. Real-time continuous glucose monitoring in type 1 diabetes: a qualitative framework analysis of patient narratives. Diabetes Care. 2015;38(4):544-550.	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Tanenbaum ML et al. Barriers and facilitators to diabetes device adoption for people with type 1 diabetes. Curr Diab Rep. 2022 Jul;22(7):291-299. · Tauschmann M et al. Technology in the management of type 1 diabetes mellitus: current status and future prospects. Nat Rev Endocrinol. 2018 Aug;14(8):464-475.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☐	Conditional recommendation for the intervention ☒	Strong recommendation for the intervention ☐
---	--	---	---	---

CONCLUSIONS

Recommendation

We suggest using continuous glucose monitoring (CGM), rather than capillary glucose monitoring (finger prick), to reduce diabetes distress among adults with type 1 diabetes. (Conditional recommendation based on moderate certainty of evidence)

Justification

We issue a conditional recommendation for continuous glucose monitoring (CGM) over capillary glucose monitoring based on moderate certainty of evidence. CGM showed a small effect in reducing diabetes distress. Although undesirable effects vary, such as alarm fatigue or information overload, they are unlikely to outweigh the benefits. Cost-effectiveness appears favourable in certain populations but remains context-dependent. CGM can be acceptable and feasible, particularly with appropriate support and access.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress.

Implementation considerations

Implementation of CGM should consider user training, addressing device-related anxiety, digital literacy, and ensuring availability of technical support. Health systems should also prepare for infrastructure needs and equitable device allocation

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Further studies should explore the psychological benefits of CGM in adults with type 1 diabetes, with a focus on diabetes distress as an outcome.

QUESTION

Should Continuous Glucose Monitoring vs. capillary glucose monitoring be used for type 2 diabetes to reduce diabetes distress?	
Population:	type 2 diabetes
Intervention:	Continuous Glucose Monitoring
Comparison:	capillary glucose monitoring
Main outcomes:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy, though no	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities

Problem: Is the problem a priority?

associations were found with retinopathy or nephropathy (Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017).

Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007).

The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017).

References

- Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. *Diabetes Care*. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181.
- Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. *J Behav Med*. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x.
- Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. *Diabet Med*. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x.
- Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. *Diabet Med*. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861.
- Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. *Diabetologia*. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3.
- Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs

Problem: Is the problem a priority?		
	second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	Intervention had no effect in reducing diabetes distress compared to SMBG. Recent systematic reviews and meta-analyses indicate that CGM provides significant benefits in managing adults living with type 2 diabetes, especially when compared to SMBG or usual care. An umbrella review of 31 systematic reviews, covering over 11,000 patients, found that CGM use led to greater reductions in HbA1c (mean decrease of 0.40%), increased time in range (TIR) by about 6%, and decreased time above range (TAR) by more than 4%. These improvements were consistent across CGM	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference

Desirable Effects: How substantial are the desirable anticipated effects?		
	modalities, insulin use, and study characteristics, though no significant benefits were seen in patient-reported outcome measures (PROMs) (Tan 2024). A meta-analysis of 12 randomized controlled trials with 1,248 adults reinforced these findings, showing that CGM use—whether real-time (rtCGM) or intermittently scanned (isCGM), reduced HbA1c by 3 mmol/mol (0.31%) (Jancey 2024). rtCGM showed a trend toward greater effectiveness than isCGM. CGM also improved TIR and reduced time spent above and below target glucose levels, as well as glycaemic variability. However, limited data on severe hypoglycaemia and vascular complications prevented firm conclusions on long-term clinical outcomes. Additionally, a systematic review analysing CGM-derived TIR as a predictor of microvascular complications found that increased TIR was associated with lower risks of diabetic retinopathy, nephropathy, and peripheral neuropathy. A 10% increase in TIR corresponded with reduced albuminuria, less severe retinopathy, and lower prevalence of neuropathy, suggesting TIR could serve as a useful predictor of microvascular outcomes in type 2 diabetes (Raj 2022). References · Jancev M et al. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. <i>Diabetologia</i>. 2024 May;67(5):798-810. · Raj R et al. Time in range, as measured by continuous glucose monitor, as a predictor of microvascular complications in type 2 diabetes: a systematic review. <i>BMJ Open Diabetes Res Care</i>. 2022 Jan;10(1):e002573. · Tan YY et al. Effectiveness of continuous glucose monitoring in patient management of Type 2 Diabetes Mellitus: an umbrella review of systematic reviews from 2011 to 2024. <i>Arch Public Health</i>. 2024 Dec 2;82(1):231.	(SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	Intervention had no effect in reducing diabetes distress compared to SMBG. One of the most frequently reported challenges with CGM is alarm fatigue (Shivers 2013). Frequent or false alerts, particularly during sleep, can cause significant frustration. Over time, users may begin to ignore these alarms or discontinue use of the device entirely, potentially undermining the clinical benefits of CGM and negatively impacting diabetes self-management. Another concern is information overload (Chen 2025). While the continuous stream of glucose data can be valuable, it may also feel overwhelming. Some users report heightened anxiety and stress from the constant need to interpret and respond to glucose trends. Social stigma also remains a significant barrier. The visible presence of a CGM sensor can lead to feelings of embarrassment or discomfort, particularly in public or professional settings where individuals may fear judgment. These emotional responses can discourage self-management behaviours in public, further contributing to suboptimal glycaemic levels (Barnard-Kelly 2024). References · Barnard-Kelly KD et al. Identifying the deficiencies of currently available CGM to improve uptake and benefit. <i>Diabet Med.</i> 2024 Aug;41(8):e15338. · Chen H-C et al. Overcoming barriers in continuous glucose monitoring: Challenges and future directions in diabetes management. <i>J Diabetes Investig.</i> 2025;16(5):769-774. · Shivers JP et al. "Turn It Off!": Diabetes Device Alarm Fatigue Considerations for the Present and the Future. <i>J Diabetes Sci Technol.</i> 2013 May 1;7(3):789–794.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Very low, based on GRADE certainty assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care. In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with type 1 diabetes and type 2 diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016). Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks. References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an Audit of 4 Australian Specialist Diabetes Clinics. <i>Can J Diabetes</i>. 2020 Aug;44(6):473-480. doi: 10.1016/j.jcjd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. <i>Diabetes Educ</i>. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. <i>J Diabetes Res</i>. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. <i>Diabet Med</i>. 2022;39(10):e14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. <i>BMJ Ment Health</i>. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. <i>Res Involv Engagem</i>. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7. · Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. <i>J Diabetes Complications</i>. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	Evidence directly assessing equity-related aspects of diabetes distress in adults with type 2 diabetes randomised to CGM or SMBG is limited. Using a large electronic health record dataset (claims and laboratory data), Sierra et al. investigated the economic benefits CGM in people with type 2 diabetes in the United States (Sierra 2018). In a propensity-score matched analysis, 5,677 patients with CGM were 1:1 matched to control users without CGM: the subgroup of people using CGM more than once per year (n = 1,242) had a -\$3,376 difference (i.e., lower for Pro CGM), as well as patients who used CGM while changing their treatment regimens (n = 3,304; -\$3,327). Combined with the improvement in HbA1c (-0.44% [4 mmol/mol] and -0.27% [3 mmol/mol] in favour of CGM), these results suggest clinical and economic benefits of using CGM more than once within a 1-year period or who used it during a change of diabetes therapy. García-Lorenzo et al. used the results of their meta-analysis of HbA1c outcomes to develop a Markov-based cost-effectiveness model with end-stage organ complications within a lifetime horizon (Garcia-Lorenzo 2018). By simulating cohorts of individuals with type 2 diabetes aged 57 years old, they estimated an incremental ICER of € 180,533 per QALY, which is significantly higher than commonly used willing-to-pay threshold of € 25,000. Cost-effectiveness is likely to vary considerably depending on the healthcare setting, country, analytical perspective, and the economic model used. References · García-Lorenzo B et al. Cost-effectiveness analysis of real-time continuous monitoring glucose compared to self-monitoring of blood glucose for diabetes mellitus in Spain. J Eval Clin Pract. 2018 Aug;24(4):772-781. · Sierra JA et al. Clinical and economic benefits of professional CGM among people with type 2 diabetes in the United States: analysis of claims and lab data. J Med Econ. 2018 Mar;21(3):225-230.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	A substantial body of evidence indicates that diabetes distress is more prevalent and more severe among adults with type 2 diabetes who are socioeconomically disadvantaged or belong to racially and ethnically minoritized groups. These disparities appear to be driven by both structural and psychosocial factors. In the U.S. subset of the DAWN2 study (Peyrot 2014), diabetes distress scores were higher among African American, Hispanic, and Chinese American adults with diabetes compared to White non-Hispanic participants. These differences were associated with modifiable diabetes-specific factors such as healthcare access, perceived burden of disease, and social support. Although the sample included both diabetes types, over 80% of participants had type 2 diabetes, making the findings highly relevant. A mixed-methods study (Levy 2022) focused exclusively on people with insulin-dependent type 2 diabetes receiving care in a safety-net clinic. Nearly four out of five participants reported at least moderate distress, and 92% experienced barriers in at least one social determinant of health domain. Interviews revealed that job-related stress, limited provider access, and difficulties navigating the health system contributed to emotional burden. A large cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care at U.S. safety-net clinics, the majority of whom had type 2 diabetes. Diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with lower medication taking, higher HbA1c, and worse cardiovascular risk profiles, suggesting a link between socioeconomic disadvantage, emotional burden, and suboptimal diabetes outcomes. Another study (Silver 2025) reported high diabetes distress among Black and Hispanic adults with diabetes in a safety-net setting. Participants described the compounding effects of financial stress, inadequate access to self-management education, and discrimination on their emotional well-being. In a survey of older adults with type 2 diabetes (Williams 2020), perceived discrimination and low physician trust partially explained higher diabetes distress scores among African American participants compared to their White counterparts. Among Latino adults with type 2 diabetes, racial or ethnic discrimination was found to be associated with increased diabetes distress and depressive symptoms (LeBrón 2019). In the Dutch Diabetes Pearl cohort, ethnic minority groups had significantly higher rates of diabetes distress than Caucasian participants, even after adjustment for a wide range of metabolic, cardiovascular, and lifestyle factors (Özcan 2018). Taken together, the evidence indicates that diabetes distress is both more common and potentially more harmful among people with type 2 diabetes who face socioeconomic disadvantage or systemic inequities.	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?

Addressing diabetes distress in these populations, particularly through equitable access to supportive interventions, may help reduce disparities in emotional burden and improve diabetes care outcomes.

References

- LeBrón AMW, Spencer M, Kieffer E, Sinco B, Palmisano G. Racial/Ethnic Discrimination and Diabetes-Related Outcomes Among Latinos with Type 2 Diabetes. *J Immigr Minor Health*. 2019 Feb;21(1):105-114. doi: 10.1007/s10903-018-0710-0.
- Levy NK, Park A, Solis D, Hu L, Langford AT, Wang B, Rogers ES. Social Determinants of Health and Diabetes-Related Distress in Patients With Insulin-Dependent Type 2 Diabetes: Cross-sectional, Mixed Methods Approach. *JMIR Form Res*. 2022 Oct 12;6(10):e40164. doi: 10.2196/40164.
- Özcan B, Rutters F, Snoek FJ, Roosendaal M, Sijbrands EJ, Elders PJM, Holleman F, Pijl H, Tack CJ, Abbink EJ, de Valk HW, Wolffenbuttel BHR, Stehouwer CDA, Schaper NC, Dekker JM, Schram MT; Diabetes Pearl from the Parelsoer Initiative. High Diabetes Distress Among Ethnic Minorities Is Not Explained by Metabolic, Cardiovascular, or Lifestyle Factors: Findings From the Dutch Diabetes Pearl Cohort. *Diabetes Care*. 2018 Sep;41(9):1854-1861. doi: 10.2337/dc17-2181.
- Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. *J Epidemiol Community Health*. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063.
- Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. *Curr Med Res Opin*. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023.
- Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. *Sci Diabetes Self Manag Care*. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085.
- Williams IC, Clay OJ, Ovalle F, Atkinson D, Crowe M. The Role of Perceived Discrimination and Other Psychosocial Factors in Explaining Diabetes Distress Among Older African American and White Adults. *J Appl Gerontol*. 2020 Jan;39(1):99-104. doi: 10.1177/0733464817750273.

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In a qualitative study involving 12 adults with type 2 diabetes on insulin therapy using semi-structured qualitative interviews revealed that participants found real-time CGM (rt-CGM) systems more acceptable and easier to engage with compared to traditional capillary blood glucose monitoring. Users reported that rt-CGM facilitated improved health behaviours, such as increased dietary awareness and physical activity. However, some challenges were noted, including technical issues like connectivity problems, sensor longevity, and skin irritation from adhesives (Sergel-Stringer 2024). A narrative review encompassing 11 studies with over 5,500 participants demonstrated that CGM use in people with type 2 diabetes led to greater reductions in HbA1c levels, body weight, and caloric intake compared to traditional self-monitoring methods. High compliance rates (>90%) with CGM wear-time and calibration were also observed. The addition of lifestyle and behavioural counselling further enhanced these outcomes, suggesting that CGM can be a powerful adjunct to comprehensive diabetes management strategies (Taylor 2018). However, the authors highlighted that the results should be interpreted with caution, given the impossibility to quantitatively assess in a meta-analysis acceptability and to derive reliable conclusions about acceptability of CGM use in type 2 diabetes. References · Sergel-Stringer OT et al. Acceptability and experiences of real-time continuous glucose monitoring in adults with type 2 diabetes using insulin: a qualitative study. J Diabetes Metab Disord. 2024 Mar 5;23(1):1163-1171. · Taylor PJ et al. Effectiveness and acceptability of continuous glucose monitoring for type 2 diabetes management: A narrative review. J Diabetes Investig. 2018 Jul;9(4):713-725.	

Feasibility: Is the intervention feasible to implement?		
Judgement	Research evidence	Additional considerations
○ No ○ Probably no ○ Probably yes ○ Yes	Further details about clinical efficacy, desirable and undesirable (including safety) effects, and cost-effectiveness, all part of feasibility of CGM in individuals with type 2 diabetes, have been reported in the specific sections. Patient engagement and acceptance also play a key role in CGM feasibility; studies show that patients appreciate the continuous feedback, which promotes healthier behaviours and better medication taking (Johnston 2022).	

Feasibility: Is the intervention feasible to implement?		
Judgement	Research evidence	Additional considerations
● Varies ○ Don't know	References · Johnston AR et al. Perceived impact of continuous glucose monitor use on quality of life and self-care for patients with type 2 diabetes. Diabetes Epidemiology and Management. Volume 6, April–June 2022, 100068.	

Summary of judgements

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

Type of recommendation

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ●	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
---	--	---	--	---

Conclusions

Recommendation

We do not suggest using continuous glucose monitoring (CGM), rather than capillary glucose monitoring (finger prick), to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on very low certainty of evidence)

Justification

Although continuous glucose monitoring can offer important glycaemic benefits, the available evidence indicates no effect on diabetes distress compared to SMBG. Therefore, the Guideline Development Panel does not suggest continuous glucose monitoring over SMBG solely for the purpose of reducing diabetes distress in people with type 2 diabetes.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress.

Implementation considerations

Continuous glucose monitoring may be beneficial for improving glycaemic levels and offers real-time feedback that can support diabetes self-management. However, given the absence of evidence for reducing distress, implementation should be tailored to individual needs and preferences, especially for patients experiencing psychological burden related to frequent monitoring or device use.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Future studies should assess the impact of continuous glucose monitoring interventions on diabetes distress, using adequately powered designs and validated distress measures. Research should also explore whether specific subgroups (e.g., newly diagnosed patients or those with high baseline distress) may benefit more in terms of emotional well-being.

QUESTION

Should educational interventions vs. usual care be used for type 2 diabetes?	
POPULATION:	type 2 diabetes
INTERVENTION:	educational interventions
COMPARISON:	usual care
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
☐ No ☐ Probably no ☐ Probably yes ☒ Yes ☐ Varies ☐ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy, though no	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	associations were found with retinopathy or nephropathy (Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017). Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007). The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017). References · Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. <i>Diabetes Care</i>. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181. · Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. <i>J Behav Med</i>. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x. · Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. <i>Diabet Med</i>. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. <i>Diabetologia</i>. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● Moderate ○ Large ○ Varies ○ Don't know	SMD = -0.34 suggesting a moderate beneficial effect on diabetes distress of educational interventions vs. usual care. A 2019 systematic review and meta-analysis assessed the effectiveness of psychoeducational interventions in adults with type 2 diabetes, focusing in part on glycaemic outcomes (Perrin 2019). Across 23 randomised controlled trials (n = 3,818) that reported HbA1c data, psychoeducational interventions were associated with a reduction in HbA1c compared to control conditions. The pooled weighted mean difference was -0.28% (3 mmol/mol; 95% confidence interval: -0.48 to -0.08 [-5 to -1 mmol/mol]). This finding suggests a modest improvement in glycaemic levels. However, overall heterogeneity was high, and these interventions included psychological components beyond education alone, so the findings may not be directly applicable to purely educational interventions. Moreover, most interventions were not specifically designed to target diabetes distress, which may have influenced the magnitude and consistency of the effect. References · Perrin N, Bodicoat DH, Davies MJ, Robertson N, Snoek FJ, Khunti K. Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: A systematic review and meta-analysis. Prim Care Diabetes. 2019 Dec;13(6):556-567. doi: 10.1016/j.pcd.2019.04.001.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect In addition to the primary outcome, potential benefits on secondary outcomes such as health-related quality of life or glycaemic levels were supplementarily considered based on findings from previously published systematic reviews.

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	A 2019 systematic review and meta-analysis of 32 randomized controlled trials evaluated psychoeducational interventions for adults with type 2 diabetes (Perrin 2019), but did not assess adverse events or harms. References · Perrin N, Bodicoat DH, Davies MJ, Robertson N, Snoek FJ, Khunti K. Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: a systematic review and meta-analysis. Prim Care Diabetes. 2019;13(6):556–567. doi:10.1016/j.pcd.2019.04.001	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded—based on collective clinical and research experience—that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care. In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management. A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016). Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks. References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933. · Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an Audit of 4 Australian Specialist Diabetes Clinics. Can J Diabetes. 2020 Aug;44(6):473-480. doi: 10.1016/j.jcjd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. Diabetes Educ. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. J Diabetes Res. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. - Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. Diabet Med. 2022;39(10):e14919.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. BMJ Ment Health. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejskjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. Res Involv Engagem. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7. - Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. J Diabetes Complications. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison	A cross-sectional registry study in Denmark found that adults with high diabetes distress had significantly more healthcare visits compared to those with lower distress levels, but no substantial increase in total healthcare costs was observed (Schmidt 2025). Similarly, a German cohort study concluded that depressive symptoms, but not diabetes distress, were associated with increased healthcare expenditures and lost productivity (Sommer	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	2024). These findings suggest that diabetes distress may contribute to greater healthcare engagement but not necessarily to higher costs. A Spanish cluster randomized trial (García-Pérez 2022) evaluated a patient-targeted intervention (PTI) in 2,334 adults with type 2 diabetes across 32 primary care practices. The PTI included group-based educational workshops, tailored motivational SMS messages over 2 years, and access to an interactive educational website. Although the intervention did not include formal psychological therapy, its combination of structured education, motivational content, and behavioural self-management support aligns it conceptually with psychoeducational models. The economic evaluation, conducted from the Spanish healthcare system perspective, found that the PTI had an incremental cost-effectiveness ratio (ICER) of €38,486 per quality-adjusted life year (QALY) gained compared to usual care. In a predefined subgroup of individuals with suboptimal glycaemic levels, the PTI was dominant—yielding higher QALYs at lower cost than the control arm. The PTI was also less costly and more effective than professional- or combined-targeted interventions tested in the same trial. A Dutch cost-effectiveness study (de Wit 2018) evaluated the HypoAware programme, a psychoeducational blended intervention combining group sessions and an online module, in 137 adults with type 1 diabetes or insulin-treated type 2 diabetes who experienced problematic hypoglycaemia. From a societal perspective, the ICER was €2,233 per severe hypoglycaemic event prevented. However, no QALY gains were observed, and the probability of cost-effectiveness was approximately 54–55% depending on the analytical perspective. Although results were not stratified separately for type 2 diabetes, a portion of the cohort consisted of people with insulin-treated type 2 diabetes, making the findings partially relevant. A systematic review of 122 economic evaluations (Siegel 2020) reported that multicomponent interventions incorporating behaviour change, structured education, and medication support were typically cost-effective or cost-saving in adults with type 2 diabetes. Among the subset of studies reporting ICERs, the median value was US\$2,315 per QALY gained. While the review did not isolate psychoeducational elements specifically, most included studies were conducted in type 2 diabetes populations and provide indirect support for the economic value of such interventions.	EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	References · García-Pérez L, Ramallo-Fariña Y, Vallejo-Torres L, Rodríguez-Rodríguez L, González-Pacheco H, Santos-Hernández B, García-Bello MA, Wägner AM, Carmona M, Serrano-Aguilar PG; INDICA team. Cost-effectiveness of multicomponent interventions in type 2 diabetes mellitus in a cluster randomised controlled trial: the INDICA study. <i>BMJ Open</i>. 2022 Apr 8;12(4):e058049. doi: 10.1136/bmjopen-2021-058049. · Schmidt CB, Keijsper E, Bosmans JE, van Loon BJP, Snoek FJ, Honig A. Medical costs and health care utilization in Dutch diabetes patients with high levels of diabetes-distress. <i>J Diabetes Complications</i>. 2025 May 21;39(8):109086. doi: 10.1016/j.jdiacomp.2025.109086. · Siegel KR, Ali MK, Zhou X, Ng BP, Jawanda S, Proia K, Zhang X, Gregg EW, Albright AL, Zhang P. Cost-effectiveness of Interventions to Manage Diabetes: Has the Evidence Changed Since 2008? <i>Diabetes Care</i>. 2020 Jul;43(7):1557-1592. doi: 10.2337/dci20-0017. · Sommer J, Linnenkamp U, Gontscharuk V, Andrich S, Brüne M, Schmitz-Losem I, Kruse J, Evers SMAA, Hiligsmann M, Hoffmann B, Icks A. Prospective health care costs and lost work days associated with diabetes-related distress and depression symptoms among 1488 individuals with diabetes. <i>Sci Rep</i>. 2024 Feb 13;14(1):3621. doi: 10.1038/s41598-024-52361-4. · de Wit M, Rondags SMPA, van Tulder MW, Snoek FJ, Bosmans JE. Cost-effectiveness of the psycho-educational blended (group and online) intervention HypoAware compared with usual care for people with Type 1 and insulin-treated Type 2 diabetes with problematic hypoglycaemia: analyses of a cluster-randomized controlled trial. <i>Diabet Med</i>. 2018 Feb;35(2):214-222. doi: 10.1111/dme.13548.	

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased	A substantial body of evidence indicates that diabetes distress is more prevalent and more severe among adults with type 2 diabetes who are socioeconomically disadvantaged or belong to racially and ethnically minoritized groups. These disparities appear to be driven by both structural and psychosocial factors. In the U.S. subset of the DAWN2 study (Peyrot 2014), diabetes distress scores were higher among African American, Hispanic, and Chinese American adults with diabetes compared to White non-Hispanic	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
- o Varies - o Don't know	participants. These differences were associated with modifiable diabetes-specific factors such as healthcare access, perceived burden of disease, and social support. Although the sample included both diabetes types, over 80% of participants had type 2 diabetes, making the findings highly relevant. A mixed-methods study (Levy 2022) focused exclusively on people with insulin-dependent type 2 diabetes receiving care in a safety-net clinic. Nearly four out of five participants reported at least moderate distress, and 92% experienced barriers in at least one social determinant of health domain. Interviews revealed that job-related stress, limited provider access, and difficulties navigating the health system contributed to emotional burden. A large cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care at U.S. safety-net clinics, the majority of whom had type 2 diabetes. Diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with lower medication taking, higher HbA1c, and worse cardiovascular risk profiles, suggesting a link between socioeconomic disadvantage, emotional burden, and suboptimal diabetes outcomes. Another study (Silver 2025) reported high diabetes distress among Black and Hispanic adults with diabetes in a safety-net setting. Participants described the compounding effects of financial stress, inadequate access to self-management education, and discrimination on their emotional well-being. In a survey of older adults with type 2 diabetes (Williams 2020), perceived discrimination and low physician trust partially explained higher diabetes distress scores among African American participants compared to their White counterparts. Among Latino adults with type 2 diabetes, racial or ethnic discrimination was found to be associated with increased diabetes distress and depressive symptoms (LeBrón 2019). In the Dutch Diabetes Pearl cohort, ethnic minority groups had significantly higher rates of diabetes distress than Caucasian participants, even after adjustment for a wide range of metabolic, cardiovascular, and lifestyle factors (Özcan 2018). Taken together, the evidence indicates that diabetes distress is both more common and potentially more harmful among people with type 2 diabetes who face socioeconomic disadvantage or systemic inequities. Addressing diabetes distress in these populations, particularly through equitable access to supportive interventions, may help reduce disparities in emotional burden and improve diabetes care outcomes.	delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	References · LeBrón AMW, Spencer M, Kieffer E, Sinco B, Palmisano G. Racial/Ethnic Discrimination and Diabetes-Related Outcomes Among Latinos with Type 2 Diabetes. J Immigr Minor Health. 2019 Feb;21(1):105-114. doi: 10.1007/s10903-018-0710-0. · Levy NK, Park A, Solis D, Hu L, Langford AT, Wang B, Rogers ES. Social Determinants of Health and Diabetes-Related Distress in Patients With Insulin-Dependent Type 2 Diabetes: Cross-sectional, Mixed Methods Approach. JMIR Form Res. 2022 Oct 12;6(10):e40164. doi: 10.2196/40164. · Özcan B, Rutters F, Snoek FJ, Roosendaal M, Sijbrands EJ, Elders PJM, Holleman F, Pijl H, Tack CJ, Abbink EJ, de Valk HW, Wolffenbuttel BHR, Stehouwer CDA, Schaper NC, Dekker JM, Schram MT; Diabetes Pearl from the Parelsnoer Initiative. High Diabetes Distress Among Ethnic Minorities Is Not Explained by Metabolic, Cardiovascular, or Lifestyle Factors: Findings From the Dutch Diabetes Pearl Cohort. Diabetes Care. 2018 Sep;41(9):1854-1861. doi: 10.2337/dc17-2181. · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. J Epidemiol Community Health. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063. · Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. Curr Med Res Opin. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. · Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. Sci Diabetes Self Manag Care. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085. - Williams IC, Clay OJ, Ovalle F, Atkinson D, Crowe M. The Role of Perceived Discrimination and Other Psychosocial Factors in Explaining Diabetes Distress Among Older African American and White Adults. J Appl Gerontol. 2020 Jan;39(1):99-104. doi: 10.1177/0733464817750273.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	In one pilot study, adults with type 1 diabetes or type 2 diabetes participated in a low-intensity mental health support programme delivered via telehealth by trained diabetes health professionals. Most participants found the number of sessions appropriate, reported feeling comfortable with the provider, and expressed satisfaction with the intervention, though some noted that the structured format limited the scope of problems that could be addressed (Holloway 2023). Another pilot randomised controlled trial evaluated a five-session programme combining acceptance and commitment therapy principles with diabetes education for adults with type 2 diabetes and moderate diabetes distress. The intervention was well accepted, with a high completion rate and positive qualitative feedback (Ngan 2023). In another feasibility study, a diabetes-specific online module was integrated into an existing e-mental health programme. Adults with type 1 diabetes and type 2 diabetes reported high satisfaction and perceived the tool as acceptable psychological support (Orman 2016). Generally, acceptability of interventions appears moderate to high in controlled trial settings, based on attrition data. In particular, most included randomised controlled trials reported completion rates between 5% and 20%, suggesting moderate acceptability, with some trials showing lower attrition. However, real-world acceptability may be lower due to factors not captured in trials, such as stigma, cultural beliefs, or service accessibility. Moreover, the GDP highlighted that stigma associated with seeking psychological care may undermine real-world acceptability, particularly for interventions involving referral to mental health professionals. This barrier may not be fully reflected in attrition rates from controlled trials. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Ngan HY, Chong YY, Loo KM, Chien WT. Preliminary efficacy of an acceptance-based diabetes education (ACT-DE) programme for people with type 2 diabetes on diabetes distress and self-care behaviours: A pilot randomised controlled trial. J Contextual Behav Sci. Volume 30. 2023. Pages 50-60. https://doi.org/10.1016/j.jcbs.2023.09.002.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Orman J, Clarke J, Whittle E, Anonuevo C, Proudfoot J. A diabetes-specific e-mental health tool: Development, acceptability and outcomes of a feasibility study. Aust Fam Physician. 2016 Aug;45(8):600-5.	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☐	Conditional recommendation for the intervention ☒	Strong recommendation for the intervention ☐
---	--	---	---	---

CONCLUSIONS

Recommendation

We suggest using educational interventions in addition to usual care, rather than usual care alone, to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on low certainty of evidence)

Justification

We issue a conditional recommendation for educational interventions based on low certainty of evidence. The effect on diabetes distress was moderate, and undesirable effects were judged to be absent or negligible. Although cost-effectiveness varies depending on setting and implementation, educational interventions can be acceptable and feasible when integrated into routine care.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress.

Implementation considerations

Implementation may require additional training for health professionals and integration into routine diabetes care. Delivery through trained non-specialists or digital formats may improve feasibility in varied healthcare settings.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Real-world studies evaluating educational interventions in adults with type 2 diabetes are needed, specifically focusing on their effectiveness in reducing diabetes distress. Further economic evaluations in diverse healthcare systems would also be valuable to understand their cost-effectiveness in routine clinical practice.

QUESTION

Should peer support interventions vs. usual care be used for type 2 diabetes?	
POPULATION:	type 2 diabetes
INTERVENTION:	peer support interventions
COMPARISON:	usual care
MAIN OUTCOMES:	SMD DDS-PAID;

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy, though no	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	associations were found with retinopathy or nephropathy (Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017). Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007). The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017). References · Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. <i>Diabetes Care</i>. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181. · Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. <i>J Behav Med</i>. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x. · Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. <i>Diabet Med</i>. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. <i>Diabetologia</i>. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3. · Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ● Varies ○ Don't know	No effect on diabetes distress of peer support interventions vs. usual care A 2021 meta-analysis of 17 randomised controlled trials involving 3,884 adults with type 2 diabetes found that peer support interventions significantly improved both self-efficacy and self-management behaviours (Liang 2021). The pooled standardised mean difference was 0.41 (95% confidence interval: 0.20 to 0.62) for self-efficacy and 1.21 (95% CI: 0.58 to 1.84) for self-management. These benefits were consistent across diverse populations, age groups, intervention formats, and durations. Peer support modalities included telephone contact, group discussions, and in-person meetings, underscoring the flexibility and broad applicability of such interventions in enhancing behavioural and psychological outcomes in type 2 diabetes. Moreover, there is strong evidence from meta-analyses that peer support interventions lead to small but statistically significant improvements in glycaemic levels, as measured by HbA1c (Qi 2016). References · Liang D, Jia R, Zhou X, Lu G, Wu Z, Yu J, Wang Z, Huang H, Guo J, Chen C. The effectiveness of peer support on self-efficacy and self-management in people with type 2 diabetes: A meta-analysis. <i>Patient Educ Couns</i>. 2021 Apr;104(4):760-769. doi: 10.1016/j.pec.2020.11.011. · Qi L, Liu Q, Qi X, Wu N, Tang W, Li J. Effectiveness of peer support for improving glycaemic control in patients with type 2 diabetes: a meta-analysis of randomized controlled trials. <i>BMC Public Health</i>. 2015;15(1):471.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect In addition to the primary outcome, potential benefits on secondary outcomes such as health-related quality of life or glycaemic levels were supplementarily considered based on findings from previously published systematic reviews.

Undesirable Effects		
How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	A 2021 meta-analysis of 17 randomized controlled trials evaluated the effects of peer support interventions for adults with type 2 diabetes (Liang 2021). The review did not assess or report any adverse events or harms associated with the interventions. References · Liang D, Jia R, Zhou X, Lu G, Wu Z, Yu J, Wang Z, Huang H, Guo J, Chen C. The effectiveness of peer support on self-efficacy and self-management in people with type 2 diabetes: A meta-analysis. Patient Educ Couns. 2021 Apr;104(4):760-769. doi: 10.1016/j.pec.2020.11.011.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded—based on collective clinical and research experience—that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care. In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management. A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016).	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks. References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933. · Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an Audit of 4 Australian Specialist Diabetes Clinics. Can J Diabetes. 2020 Aug;44(6):473-480. doi: 10.1016/j.cjcd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. Diabetes Educ. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. J Diabetes Res. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. · Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. Diabet Med. 2022;39(10):e14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	people with diabetes and healthcare professionals. BMJ Ment Health. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. Res Involv Engagem. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7. Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. J Diabetes Complications. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects		
Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	A cross-sectional registry study in Denmark found that adults with high diabetes distress had significantly more healthcare visits compared to those with lower distress levels, but no substantial increase in total healthcare costs was observed (Schmidt 2025). Similarly, a German cohort study concluded that depressive symptoms—but not diabetes distress—were associated with increased healthcare expenditures and lost productivity (Sommer 2024). These findings suggest that diabetes distress may contribute to greater healthcare engagement but not necessarily to higher costs. Few studies have evaluated diabetes peer support in terms of its cost-effectiveness. Peer support models, programmes, and interventions vary, as do the healthcare contexts in which they are implemented, making it difficult to generalise findings across settings. Nevertheless, evidence from structured peer support interventions in primary care suggests they may be either cost-neutral or cost-saving, depending on the outcomes considered (Gillespie 2012; Johansson 2016a; Johansson 2016b). References · Gillespie P, O'Shea E, Paul G, O'Dowd T, Smith SM. Cost effectiveness of peer support for type 2 diabetes. <i>Int J Technol Assess Health Care</i>. 2012;28(1):3–11. · Johansson T, Bendix M, Ahrens D, et al. Cost analysis of a peer support programme for patients with type 2 diabetes: a secondary analysis of a controlled trial. <i>Eur J Public Health</i>. 2016;27(2):256–261. · Johansson T, Keller S, Winkler H, et al. Effectiveness of a peer support programme versus usual care in disease management of diabetes mellitus type 2 regarding improvement of metabolic control: a cluster-randomised controlled trial. <i>J Diabetes Res</i>. 2016;2016:10. · Schmidt CB, Keijsper E, Bosmans JE, van Loon BJP, Snoek FJ, Honig A. Medical costs and health care utilization in Dutch diabetes patients with high levels of diabetes-distress. <i>J Diabetes Complications</i>. 2025;39(8):109086. · Sommer J, Linnenkamp U, Gontscharuk V, Andrich S, Brüne M, Schmitz-Losem I, Kruse J, Evers SMAA, Hiligsmann M, Hoffmann B, Icks A. Prospective health care costs and lost work days associated with diabetes-related distress and depression symptoms among 1488 individuals with diabetes. <i>Sci Rep</i>. 2024;14(1):3621.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	A substantial body of evidence indicates that diabetes distress is more prevalent and more severe among adults with type 2 diabetes who are socioeconomically disadvantaged or belong to racially and ethnically minoritized groups. These disparities appear to be driven by both structural and psychosocial factors. In the U.S. subset of the DAWN2 study (Peyrot 2014), diabetes distress scores were higher among African American, Hispanic, and Chinese American adults with diabetes compared to White non-Hispanic participants. These differences were associated with modifiable diabetes-specific factors such as healthcare access, perceived burden of disease, and social support. Although the sample included both diabetes types, over 80% of participants had type 2 diabetes, making the findings highly relevant. A mixed-methods study (Levy 2022) focused exclusively on people with insulin-dependent type 2 diabetes receiving care in a safety-net clinic. Nearly four out of five participants reported at least moderate distress, and 92% experienced barriers in at least one social determinant of health domain. Interviews revealed that job-related stress, limited provider access, and difficulties navigating the health system contributed to emotional burden. A large cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care at U.S. safety-net clinics, the majority of whom had type 2 diabetes. Diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with lower medication taking, higher HbA1c, and worse cardiovascular risk profiles, suggesting a link between socioeconomic disadvantage, emotional burden, and suboptimal diabetes outcomes. Another study (Silver 2025) reported high diabetes distress among Black and Hispanic adults with diabetes in a safety-net setting. Participants described the compounding effects of financial stress, inadequate access to self-management education, and discrimination on their emotional well-being. In a survey of older adults with type 2 diabetes (Williams 2020), perceived discrimination and low physician trust partially explained higher diabetes distress scores among African American participants compared to their White counterparts. Among Latino adults with type 2 diabetes, racial or ethnic discrimination was found to be associated with increased diabetes distress and depressive symptoms (LeBrón 2019). In the Dutch Diabetes Pearl cohort, ethnic minority groups had significantly	The Guideline Development Panel (GDP) noted that if interventions targeting diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	higher rates of diabetes distress than Caucasian participants, even after adjustment for a wide range of metabolic, cardiovascular, and lifestyle factors (Özcan 2018). Taken together, the evidence indicates that diabetes distress is both more common and potentially more harmful among people with type 2 diabetes who face socioeconomic disadvantage or systemic inequities. Addressing diabetes distress in these populations—particularly through equitable access to supportive interventions—may help reduce disparities in emotional burden and improve diabetes care outcomes. References · LeBrón AMW, Spencer M, Kieffer E, Sinco B, Palmisano G. Racial/Ethnic Discrimination and Diabetes-Related Outcomes Among Latinos with Type 2 Diabetes. <i>J Immigr Minor Health</i>. 2019 Feb;21(1):105-114. doi: 10.1007/s10903-018-0710-0. · Levy NK, Park A, Solis D, Hu L, Langford AT, Wang B, Rogers ES. Social Determinants of Health and Diabetes-Related Distress in Patients With Insulin-Dependent Type 2 Diabetes: Cross-sectional, Mixed Methods Approach. <i>JMIR Form Res</i>. 2022 Oct 12;6(10):e40164. doi: 10.2196/40164. · Özcan B, Rutters F, Snoek FJ, Roosendaal M, Sijbrands EJ, Elders PJM, Holleman F, Pijl H, Tack CJ, Abbink EJ, de Valk HW, Wolffenbuttel BHR, Stehouwer CDA, Schaper NC, Dekker JM, Schram MT; Diabetes Pearl from the Parelsnoer Initiative. High Diabetes Distress Among Ethnic Minorities Is Not Explained by Metabolic, Cardiovascular, or Lifestyle Factors: Findings From the Dutch Diabetes Pearl Cohort. <i>Diabetes Care</i>. 2018 Sep;41(9):1854-1861. doi: 10.2337/dc17-2181. · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. <i>J Epidemiol Community Health</i>. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063. · Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. <i>Curr Med Res Opin</i>. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023.	

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. <i>Sci Diabetes Self Manag Care</i>. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085. Williams IC, Clay OJ, Ovalle F, Atkinson D, Crowe M. The Role of Perceived Discrimination and Other Psychosocial Factors in Explaining Diabetes Distress Among Older African American and White Adults. <i>J Appl Gerontol</i>. 2020 Jan;39(1):99-104. doi: 10.1177/0733464817750273.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	Evidence suggests that peer support interventions are particularly effective and acceptable for individuals with elevated HbA1c levels, from culturally and linguistically diverse backgrounds, or experiencing social disadvantage. Such populations often report greater benefit, likely due to the relatability of peer-led support. Acceptability is enhanced when peer support includes regular contact (at least once monthly) and when peer leaders receive structured supervision (Qi 2015; Zhang 2016; Patil 2016). Moreover, individuals with lower health literacy, lower levels of formal education, and poorer engagement in diabetes self-management seem to derive more consistent value from these interventions, suggesting alignment between peer support models and the needs of underserved populations (Sokol 2016). In addition, the informal nature of peer support—typically delivered by individuals with lived experience of diabetes rather than healthcare professionals—may reduce barriers associated with stigma and cost. This format offers a less hierarchical, more relatable setting, which was viewed favourably by the GDP as likely to facilitate engagement, particularly for those reluctant to access formal mental health or medical services. References · Patil S, Ruppar T, Koopman RJ, Lindley R, Gannon M, Dobbels F. Peer Support Interventions for Adults With Diabetes: A Meta-Analysis of Hemoglobin A1c Outcomes. <i>Annals of Family Medicine</i>. 2016;14(6):540–551.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Sokol R, Fisher E. Peer Support for the Hardly Reached: A Systematic Review. American Journal of Public Health. 2016;106(7):e1–e8. · Qi L, Liu Q, Zeng Y, Li T, Li Y, Wang H. Effectiveness of peer support for improving glycaemic control in patients with type 2 diabetes: a meta-analysis of randomized controlled trials. BMC Public Health. 2015;15:471. · Zhang X, Yang S, Sun K, Wang C, Yang Z, Han Y. How to achieve better effect of peer support among adults with type 2 diabetes: A meta-analysis of randomized clinical trials. Patient Education and Counseling. 2016;99(2):186–197.	

Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☒	Conditional recommendation for the intervention ☐	Strong recommendation for the intervention ☐
---	--	--	--	---

CONCLUSIONS

Recommendation

We do not suggest using peer support interventions in addition to usual care, rather than usual care alone to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on low certainty of evidence)

Justification

We issue a conditional recommendation not to prefer peer support interventions over usual care for reducing diabetes distress in adults with type 2 diabetes. This recommendation is based on low certainty of evidence and a neutral effect on the primary outcome of diabetes distress. While peer support may offer secondary benefits, such as enhanced self-efficacy or diabetes self-management, these do not substantiate a clear advantage over usual care in terms of distress. Undesirable effects were judged to be negligible, and although cost-effectiveness varies by setting, peer support interventions may still be acceptable and feasible under certain conditions.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on study duration, mode of intervention delivery (individual vs group), or baseline level of diabetes distress.

Implementation considerations

Feasibility may be enhanced when peer support is embedded within existing diabetes education or self-management programmes. Ensuring training and supervision of peer leaders, culturally appropriate materials, and regular contact are critical components for successful implementation.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Future research should focus on real-world evaluations of peer support interventions for adults with type 2 diabetes, with diabetes distress as the primary outcome. Studies should also assess cost-effectiveness in diverse healthcare settings.

QUESTION

Should educational interventions vs. peer support interventions be used for type 2 diabetes?	
POPULATION:	type 2 diabetes
INTERVENTION:	educational interventions
COMPARISON:	peer support interventions
MAIN OUTCOMES:	SMD DDS-PAID

ASSESSMENT

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	International and national studies have demonstrated that diabetes-related distress is prevalent among adults with type 2 diabetes. In the DAWN study, which surveyed 5,104 adults with diabetes across 13 countries, 41% of participants were classified as having poor psychological well-being, and emotional concerns related to diabetes were common; although the results were not stratified by diabetes type, the sample predominantly included people with type 2 diabetes (Peyrot 2005). In the DAWN2 study, which included 8,596 adults with diabetes from 17 countries, of whom 7,140 had type 2 diabetes, 48% of individuals treated with insulin, 38% of those treated with oral agents, and 34% of those not taking medication reported elevated diabetes-related distress, defined by a PAID-5 score of ≥ 40 (Nicolucci 2013). Global prevalence estimates are supported by meta-analyses. A systematic review of 55 studies including 36,998 individuals reported a pooled prevalence of 36% (Perrin 2017). In India, a meta-analysis of 10 studies involving 2,107 adults with type 2 diabetes found a pooled prevalence of 33% (Sinha 2024), while in China, a meta-analysis of 55 studies with 13,160 individuals found a higher pooled prevalence of 53% (Tang 2023). Observational and longitudinal studies consistently link diabetes distress in type 2 diabetes to poorer outcomes. In a primary care cohort of 253 adults, diabetes-related distress predicted future glycaemic levels and medication taking, whereas depressive symptoms were more closely associated with dietary and physical activity behaviours (Aikens 2012). In a nationwide Korean cohort of 1,862 adults, individuals with high distress (PAID-K ≥ 40) showed persistently elevated HbA1c levels over three years and significantly higher odds of diabetic neuropathy (adjusted OR 1.63), though no associations were found with retinopathy or nephropathy	The topic of diabetes distress was prioritised for guideline development by the EASD Guidelines Oversight Committee following an open call for topic suggestions launched by EASD. This reflects a recognised need for guidance in this area from both clinical and academic communities.

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	(Park 2024). However, a prospective UK cohort of 1,735 adults with newly diagnosed type 2 diabetes did not find a significant association between diabetes distress and worsening glycaemic levels or the development of complications over two years (Ismail 2017). Diabetes distress is also associated with reduced quality of life. It has been independently linked with poorer functioning in achievement-related domains, distinct from the effects of depression (Carper 2014). Distress levels are often higher among insulin-treated individuals compared to those treated with oral agents or diet alone, largely due to greater disease severity and self-management burden (Delahanty 2007). The emotional burden of diabetes distress has mental health implications. In a mixed cohort of 509 adults with type 1 diabetes and type 2 diabetes, diabetes distress was a significant predictor of the onset and persistence of depressive symptoms over six months (Ehrmann 2015). In the DIAMOS trial, participants who experienced a clinically meaningful reduction in distress were four times more likely to show improvements in depressive symptoms (Reimer 2017). References · Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. <i>Diabetes Care</i>. 2012 Dec;35(12):2472-8. doi: 10.2337/dc12-0181. · Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. <i>J Behav Med</i>. 2014 Jun;37(3):501-10. doi: 10.1007/s10865-013-9505-x. · Delahanty LM, Grant RW, Wittenberg E, Bosch JL, Wexler DJ, Cagliero E, Meigs JB. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with Type 2 diabetes. <i>Diabet Med</i>. 2007 Jan;24(1):48-54. doi: 10.1111/j.1464-5491.2007.02028.x. · Ehrmann D, Kulzer B, Haak T, Hermanns N. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. <i>Diabet Med</i>. 2015 Oct;32(10):1264-71. doi: 10.1111/dme.12861. · Ismail K, Moulton CD, Winkley K, Pickup JC, Thomas SM, Sherwood RA, Stahl D, Amiel SA. The association of depressive symptoms and diabetes distress with glycaemic control and diabetes complications over 2 years in newly diagnosed type 2 diabetes: a prospective cohort study. <i>Diabetologia</i>. 2017 Oct;60(10):2092-2102. doi: 10.1007/s00125-017-4367-3.	

Problem: Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	· Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, Kokoszka A, Pouwer F, Skovlund SE, Stuckey H, Tarkun I, Vallis M, Wens J, Peyrot M; DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med. 2013 Jul;30(7):767-77. doi: 10.1111/dme.12245. · Park HS, Cho Y, Seo DH, Ahn SH, Hong S, Suh YJ, Chon S, Woo JT, Baik SH, Lee KW, Kim SH. Impact of diabetes distress on glycemic control and diabetic complications in type 2 diabetes mellitus. Sci Rep. 2024 Mar 6;14(1):5568. doi: 10.1038/s41598-024-55901-0. · Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. Diabet Med. 2017 Nov;34(11):1508-1520. doi: 10.1111/dme.13448. · Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. Diabet Med. 2005 Oct;22(10):1379-85. doi: 10.1111/j.1464-5491.2005.01644.x. · Reimer A, Schmitt A, Ehrmann D, Kulzer B, Hermanns N. Reduction of diabetes-related distress predicts improved depressive symptoms: A secondary analysis of the DIAMOS study. PLoS One. 2017 Jul 10;12(7):e0181218. doi: 10.1371/journal.pone.0181218. · Sinha R, Priya A, Sinha A, Hifz Ur Rahman M. Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and meta-analysis. Health Psychol Behav Med. 2024 Mar 5;12(1):2324091. doi: 10.1080/21642850.2024.2324091. · Tang FY, Guo XT, Zhang L, Yuan L, Gan T, Wang M, Chen X, Feng CC, Qin Y, Li J, Yu YF. The prevalence of diabetes distress in Chinese patients with type 2 diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2023 Dec;206:110996. doi: 10.1016/j.diabres.2023.110996.	

Desirable Effects: How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Diabetes distress: no significant difference between the two types of interventions.	The primary desirable effect is a reduction in diabetes distress, which was the main outcome for each clinical question. An effect was considered clinically meaningful if the standardized mean difference (SMD) was equal to or larger than 0.3 in absolute value. The magnitude of effect was categorized as follows, with more negative values indicating greater benefit: · SMD ≤ -0.5: large effect · SMD > -0.5 and ≤ -0.3: moderate effect · SMD > -0.3 and ≤ -0.2: small effect · SMD > -0.2: trivial or no effect

Undesirable Effects: How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ● Don't know	Available evidence for either educational or peer support against usual care suggests that no serious or intervention-related harms were identified. However, adverse events were infrequently and inconsistently assessed, and no trials directly compared the two interventions. Therefore, no conclusions can be drawn about the relative undesirable effects between the two types of interventions.	If the meta-analysis demonstrated a detrimental effect of an intervention on diabetes distress—the primary outcome—this was considered an undesirable effect. A clinically meaningful increase in diabetes distress was defined as a standardized mean difference (SMD) ≥ 0.3. The magnitude of undesirable effects was categorized as follows: · SMD $\geq +0.5$: large undesirable effect · SMD $\geq +0.3$ and $< +0.5$: moderate undesirable effect · SMD $\geq +0.2$ and $< +0.3$: small undesirable effect · SMD $< +0.2$: trivial or no undesirable effect In addition, previous systematic reviews that examined harms or adverse events of relevant interventions were reviewed to supplement this assessment. Given that previous systematic reviews did not assess or identify specific adverse events or harms related to the interventions, the guideline development panel (GDP) concluded—based on collective clinical and research experience—that if any undesirable effects do occur, they are most likely to be minimal or trivial in magnitude. This judgment reflects both the nature of the interventions and the consistent absence of documented harms in the evidence base.

Certainty of evidence: What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies	Based on GRADE certainty of evidence assessment	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	Adults with type 2 diabetes and healthcare stakeholders consistently identify diabetes distress as a highly relevant outcome in both clinical care and research. A 2024 systematic review of qualitative studies (Morales-Brown 2024) synthesised evidence from 19 studies, many of which primarily involved adults with type 2 diabetes. It found that diabetes distress commonly arose from feelings of helplessness, loss of autonomy, and negative self-perception, often exacerbated by interactions with health systems. The authors concluded that acknowledging distress and promoting empowerment should be integral to diabetes care. In a multinational Delphi consensus study involving over 300 stakeholders, including people with diabetes (58% with type 2 diabetes) and healthcare professionals, diabetes distress was ranked among the top three most important psychosocial outcomes (Porth 2024). It surpassed the predefined threshold for prioritisation ($\geq 70\%$ endorsement) in both groups. Importantly, ratings were consistent across diabetes types, underscoring the cross-cutting relevance of distress in psychosocial diabetes care. In Denmark, a national participatory project (Skovlund 2021) involving people with diabetes and healthcare professionals co-developed a core outcome set for routine diabetes care. Diabetes distress was explicitly named among the key non-clinical outcomes to be routinely assessed, alongside psychological well-being and confidence in self-management.	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	A 2023 systematic review (Hamilton 2023) further confirmed that diabetes distress was among the most consistently endorsed person-reported outcomes in international studies aiming to inform core outcome sets for type 1 diabetes and type 2 diabetes. Routine care audits also reflect the salience of distress for people with type 2 diabetes. An audit in four Australian specialist clinics (Hendrieckx 2020) found that nearly half of adults with type 2 diabetes wanted to discuss their emotional experiences with healthcare professionals. Distress-related topics, such as the emotional impact of diabetes and mood, were the most frequently selected. Qualitative studies offer additional depth. In a mixed-methods study of African American adults with type 2 diabetes, participants described moderate levels of distress, particularly related to regimen and emotional burden, and expressed a desire for culturally appropriate psychosocial support (Hood 2018). Another study with rural working adults highlighted the psychological and socioeconomic barriers to self-management, including distress and insufficient coping strategies (Glenn 2022). Finally, a focus group study comparing insulin- and non-insulin-treated individuals found that those using insulin reported greater distress related to glycaemic levels, physical burden, and emotional strain, while others more often cited the burden of comorbidities (Tanenbaum 2016). Collectively, these findings affirm that diabetes distress is valued not only by people with type 2 diabetes but also by healthcare professionals and researchers. This shared recognition reinforces the importance of systematically assessing and addressing diabetes distress in care pathways, research outcomes, and policy frameworks. References · Glenn LE, Thurlow CB, Enriquez M. The "Ups and Downs" of Living With Type 2 Diabetes Among Working Adults in the Rural South. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221143715. doi: 10.1177/21501319221143715. · Hamilton K, Forde R, Due-Christensen M, Eeg-Olofson K, Nathanson D, Rossner S, Vikstrom-Greve S, Porth AK, Seidler Y, Kautzky-Willer A, Delbecque L, Ozdemir Saltik AZ, Hasler Y, Flores V, Stamm T, Hopkins D, Forbes A. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes	

Values: Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	mellitus: The European Health Outcomes Observatory (H2O) programme. Patient Educ Couns. 2023 Nov;116:107933. doi: 10.1016/j.pec.2023.107933. · Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, O'Neal D, Speight J. Adults With Diabetes Distress Often Want to Talk With Their Health Professionals About It: Findings From an Audit of 4 Australian Specialist Diabetes Clinics. Can J Diabetes. 2020 Aug;44(6):473-480. doi: 10.1016/j.jcjd.2020.02.004. · Hood S, Irby-Shasanmi A, de Groot M, Martin E, LaJoie AS. Understanding Diabetes-Related Distress Characteristics and Psychosocial Support Preferences of Urban African American Adults Living With Type 2 Diabetes: A Mixed-Methods Study. Diabetes Educ. 2018 Apr;44(2):144-157. doi: 10.1177/0145721718754325. Epub 2018 Jan 27. · Morales-Brown LA, Perez Algorta G, Salifu Y. Understanding Experiences of Diabetes Distress: A Systematic Review and Thematic Synthesis. J Diabetes Res. 2024 Nov 14;2024:3946553. doi: 10.1155/2024/3946553. Orben E, et al. The lived experience of diabetes distress: insights from adults with type 1 and type 2 diabetes. Diabet Med. 2022;39(10):e14919. · Porth AK, Seidler Y, Long PA, Stamm T, Huberts AS, Hamilton K, Kautzky-Willer A. Putting person-centred psychosocial diabetes care into practice: two psychosocial care pathways based on outcome preferences of people with diabetes and healthcare professionals. BMJ Ment Health. 2024 Aug 25;27(1):e301061. doi: 10.1136/bmjment-2024-301061. · Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejksjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. Res Involv Engagem. 2021 Sep 10;7(1):62. doi: 10.1186/s40900-021-00309-7. Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. J Diabetes Complications. 2016 Aug;30(6):1060-8. doi: 10.1016/j.jdiacomp.2016.04.023.	

Balance of effects: Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Based on domains 2, 3, 4	

Resources required		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Certainty of evidence of required resources: What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies		We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Cost effectiveness: Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ● Varies ○ No included studies	Data on the cost-effectiveness of either type of interventions vs. usual care are limited and can vary considerably across different healthcare settings and countries.	We have assessed resource use, certainty for resource evidence, and cost-effectiveness as a single domain in the EtD framework because these factors are interconnected and often share common implications in the evaluation of healthcare interventions. Additionally, due to the paucity of relevant resources/costs/cost-effectiveness data, particularly for interventions targeting diabetes distress, combining these domains allows for a more efficient approach to evaluating the economic impact of interventions. This streamlined approach helps facilitate decision-making in the context of limited evidence for individual domains.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased	Given that educational interventions may have a trivial, favourable effect on diabetes distress compared to peer support interventions, they may offer a slight advantage in addressing disparities, particularly if distress reduction is more impactful in underserved groups.	The Guideline Development Panel (GDP) noted that if interventions targeting

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Increased ○ Varies ○ Don't know	A substantial body of evidence indicates that diabetes distress is more prevalent and more severe among adults with type 2 diabetes who are socioeconomically disadvantaged or belong to racially and ethnically minoritized groups. These disparities appear to be driven by both structural and psychosocial factors. In the U.S. subset of the DAWN2 study (Peyrot 2014), diabetes distress scores were higher among African American, Hispanic, and Chinese American adults with diabetes compared to White non-Hispanic participants. These differences were associated with modifiable diabetes-specific factors such as healthcare access, perceived burden of disease, and social support. Although the sample included both diabetes types, over 80% of participants had type 2 diabetes, making the findings highly relevant. A mixed-methods study (Levy 2022) focused exclusively on people with insulin-dependent type 2 diabetes receiving care in a safety-net clinic. Nearly four out of five participants reported at least moderate distress, and 92% experienced barriers in at least one social determinant of health domain. Interviews revealed that job-related stress, limited provider access, and difficulties navigating the health system contributed to emotional burden. A large cross-sectional study (Pandit 2014) analysed data from adults with diabetes receiving care at U.S. safety-net clinics, the majority of whom had type 2 diabetes. Diabetes distress was more common among younger individuals, women, and those with low income. High distress was independently associated with lower medication taking, higher HbA1c, and worse cardiovascular risk profiles, suggesting a link between socioeconomic disadvantage, emotional burden, and suboptimal diabetes outcomes. Another study (Silver 2025) reported high diabetes distress among Black and Hispanic adults with diabetes in a safety-net setting. Participants described the compounding effects of financial stress, inadequate access to self-management education, and discrimination on their emotional well-being. In a survey of older adults with type 2 diabetes (Williams 2020), perceived discrimination and low physician trust partially explained higher diabetes distress scores among African American participants compared to their White counterparts. Among Latino adults with type 2 diabetes, racial or ethnic discrimination was found to be associated with increased diabetes distress and depressive symptoms (LeBrón 2019). In the Dutch Diabetes Pearl cohort, ethnic minority groups had significantly higher rates of diabetes distress than Caucasian participants, even after adjustment for a wide range of metabolic, cardiovascular, and lifestyle factors (Özcan 2018). Taken together, the evidence indicates that diabetes distress is both more common and potentially more harmful among people with type 2 diabetes who face socioeconomic disadvantage or systemic inequities.	diabetes distress are delivered equitably, they are likely to improve equity by addressing psychosocial needs across diverse populations. However, if access is uneven or limited to certain groups, these interventions may inadvertently exacerbate existing health inequalities.

Equity: What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
	Addressing diabetes distress in these populations—particularly through equitable access to supportive interventions—may help reduce disparities in emotional burden and improve diabetes care outcomes. References · LeBrón AMW, Spencer M, Kieffer E, Sinco B, Palmisano G. Racial/Ethnic Discrimination and Diabetes-Related Outcomes Among Latinos with Type 2 Diabetes. <i>J Immigr Minor Health</i>. 2019 Feb;21(1):105-114. doi: 10.1007/s10903-018-0710-0. · Levy NK, Park A, Solis D, Hu L, Langford AT, Wang B, Rogers ES. Social Determinants of Health and Diabetes-Related Distress in Patients With Insulin-Dependent Type 2 Diabetes: Cross-sectional, Mixed Methods Approach. <i>JMIR Form Res</i>. 2022 Oct 12;6(10):e40164. doi: 10.2196/40164. · Özcan B, Rutters F, Snoek FJ, Roosendaal M, Sijbrands EJ, Elders PJM, Holleman F, Pijl H, Tack CJ, Abbink EJ, de Valk HW, Wolffenbuttel BHR, Stehouwer CDA, Schaper NC, Dekker JM, Schram MT; Diabetes Pearl from the Parelsnoer Initiative. High Diabetes Distress Among Ethnic Minorities Is Not Explained by Metabolic, Cardiovascular, or Lifestyle Factors: Findings From the Dutch Diabetes Pearl Cohort. <i>Diabetes Care</i>. 2018 Sep;41(9):1854-1861. doi: 10.2337/dc17-2181. · Pandit AU, Bailey SC, Curtis LM, Seligman HK, Davis TC, Parker RM, Schillinger D, DeWalt D, Fleming D, Mohr DC, Wolf MS. Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. <i>J Epidemiol Community Health</i>. 2014 Jun;68(6):557-64. doi: 10.1136/jech-2013-203063. · Peyrot M, Egede LE, Campos C, Cannon AJ, Funnell MM, Hsu WC, Ruggiero L, Siminerio LM, Stuckey HL. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. <i>Curr Med Res Opin</i>. 2014 Nov;30(11):2241-54. doi: 10.1185/03007995.2014.947023. · Silver SR, Jones KC, Kim EM, Khaw-Marchetta S, Thornton S, Kremer K, Walkey A, Drainoni ML, Fantasia KL. Disparities in Diabetes Distress and Nutrition Management Among Black and Hispanic Adults: A Mixed Methods Exploration of Social Determinants. <i>Sci Diabetes Self Manag Care</i>. 2025 Feb;51(1):24-35. doi: 10.1177/26350106241311085. - Williams IC, Clay OJ, Ovalle F, Atkinson D, Crowe M. The Role of Perceived Discrimination and Other Psychosocial Factors in Explaining Diabetes Distress Among Older African American and White Adults. <i>J Appl Gerontol</i>. 2020 Jan;39(1):99-104. doi: 10.1177/0733464817750273.	

Acceptability: Is the intervention acceptable to key interest-holders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	Acceptability appears to vary for both educational and peer support interventions. Educational interventions are generally well accepted in trial settings, though real-world acceptability may be lower due to barriers like stigma or service accessibility. Peer support interventions may be more acceptable among adults from underserved or socially disadvantaged backgrounds, particularly when led by trained peers with regular contact, suggesting differential acceptability across populations and delivery formats. References · Holloway EE, Gray S, Halliday J, Harrap B, Hines C, Skinner TC, Speight J, Hendrieckx C. Feasibility and acceptability of 'low-intensity mental health support via a telehealth-enabled network' for adults with type 1 and type 2 diabetes: the LISTEN pilot study. Pilot Feasibility Stud. 2023 Jul 27;9(1):133. doi: 10.1186/s40814-023-01367-2. · Ngan HY, Chong YY, Loo KM, Chien WT. Preliminary efficacy of an acceptance-based diabetes education (ACT-DE) programme for people with type 2 diabetes on diabetes distress and self-care behaviours: A pilot randomised controlled trial. J Contextual Behav Sci. Volume 30. 2023. Pages 50-60. https://doi.org/10.1016/j.jcbs.2023.09.002. · Qi L, Liu Q, Zeng Y, Li T, Li Y, Wang H. Effectiveness of peer support for improving glycaemic control in patients with type 2 diabetes: a meta-analysis of randomized controlled trials. BMC Public Health. 2015;15:471. · Zhang X, Yang S, Sun K, Wang C, Yang Z, Han Y. How to achieve better effect of peer support among adults with type 2 diabetes: A meta-analysis of randomized clinical trials. Patient Education and Counseling. 2016;99(2):186–197. · Patil S, Ruppar T, Koopman RJ, Lindley R, Gannon M, Dobbels F. Peer Support Interventions for Adults With Diabetes: A Meta-Analysis of Hemoglobin A1c Outcomes. Annals of Family Medicine. 2016;14(6):540–551. · Sokol R, Fisher E. Peer Support for the Hardly Reached: A Systematic Review. American Journal of Public Health. 2016;106(7):e1–e8.	

Feasibility: Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	The GDP collectively considered that the feasibility of implementing diabetes distress interventions can vary substantially across regions and healthcare contexts. Key limiting factors include the availability of trained professionals (e.g., psychologists, diabetes specialist nurses, clinicians), disparities in access to diabetes care, and competing demands on health system budgets. In many settings, the scale of diabetes distress and lack of specialist workforce pose practical barriers to implementation. However, feasibility is enhanced where healthcare systems already support structured diabetes education programmes or where training of non-specialist health professionals has proven effective in delivering psychological support. Some countries have insurance frameworks or public funding models that support such interventions. Moreover, eHealth and telehealth models offer promising opportunities to increase feasibility and scalability, particularly in underserved areas. Overall, the GDP concluded that while feasibility is context-dependent and often constrained outside research settings, there are viable pathways to broader implementation in systems with supportive infrastructure.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ☐	Conditional recommendation against the intervention ☐	Conditional recommendation for either the intervention or the comparison ☒	Conditional recommendation for the intervention ☐	Strong recommendation for the intervention ☐
---	--	--	--	---

CONCLUSIONS

Recommendation

We do not suggest using educational interventions instead of peer support interventions, or vice versa, to reduce diabetes distress among adults with type 2 diabetes. (Conditional recommendation based on low certainty of evidence)

Justification

This conditional recommendation is based on low certainty evidence showing no clear or clinically meaningful difference between educational and peer support interventions in reducing diabetes distress. Although educational interventions have demonstrated benefit compared with usual care while peer support interventions have not, the available head-to-head evidence is limited and does not support a confident preference for one intervention over the other, and no important undesirable effects were identified for either approach.

Subgroup considerations

Subgroup analyses suggested that there is likely no effect modification based on duration of study, delivery mode of the intervention (individual or group intervention), or level of diabetes distress at baseline.

Implementation considerations

Educational interventions may be implemented within existing diabetes education programmes, particularly in settings that already deliver structured diabetes education. Peer support interventions may be more acceptable among adults from underserved or socially disadvantaged backgrounds, especially when peer-led support is regular and relatable.

Monitoring and evaluation

Use of validated patient-reported outcome measures (PROMs), such as the PAID or DDS scales, or structured interviews, is recommended to monitor emotional well-being and evaluate intervention effectiveness over time.

Research priorities

Further research is needed to evaluate the comparative effectiveness of educational versus peer support interventions in adults with type 2 diabetes, with a focus on diabetes distress as the primary outcome. Economic evaluations and real-world implementation studies are also warranted to inform scale-up in diverse healthcare settings.

Electronic Supplementary Material 8: Guideline Development Panel members

GDP member	Contribution	Discipline	Position, affiliation
Norbert Hermanns	GDP member	Psychology	Research Institute of the Diabetes Academy Mergentheim (FIDAM), Department of Clinical Psychology and Psychotherapy, University of Bamberg, Bamberg, Germany; member and former chair, PsychoSocial Aspects of Diabetes (PSAD) Study Group
Richard Holt	GDP Co-Chair, GOC Co-Chair	Internal medicine/diabetes	Professor of Diabetes and Endocrinology, Human Development and Health, Faculty of Medicine, University of Southampton, Southampton UK; Honorary Consultant Physician, University Hospital Southampton NHS Foundation Trust, Southampton, UK; Deputy Chair (since Feb 2026) and member, PsychoSocial Aspects of Diabetes (PSAD) Study Group
Walther Jensen	GDP member	Expert by lived experience	–
Karin Kanc	GDP member	Internal medicine/diabetes, psychotherapy	jazindiabetes (Diabetes & Me), Diabetes Centre, Ljubljana, Slovenia; Member, PsychoSocial Aspects of Diabetes (PSAD) Study Group; International Integrative Association of Psychotherapy (IIPA)
Thomas Karagiannis	GDP member, Methodologist	Evidence-based medicine, internal medicine	Assistant Professor of Internal Medicine, Clinical Research and Evidence-Based Medicine Unit, Second Medical Department, Aristotle University of Thessaloniki, Thessaloniki, Greece
Michelle Law	GDP member	Expert by lived experience	Honorary Professor, Faculty of Health and Life Sciences, University of Exeter, Exeter, UK
Andreia Mocan	GDP member	Clinical psychology, psychotherapy	Executive Committee member, PsychoSocial Aspects of Diabetes (PSAD) Study Group; Center for Diabetes, Nutrition and Metabolic Diseases, Emergency Clinical County Hospital Cluj-Napoca, Romania
Jane Speight	GDP Co-Chair	Health psychology, behavioural science	Chair, PsychoSocial Aspects of Diabetes (PSAD) Study Group; Foundation Director, The Australian Centre for Behavioural Research in Diabetes, Diabetes Victoria and Deakin University, Melbourne, Australia
Jackie Sturt	GDP member	Nursing, behavioural science	Vice Chair (until Feb 2026) and member, PsychoSocial Aspects of Diabetes (PSAD) Study Group; Professor of Behavioural Medicine in Nursing and Head of Research Division, Care in Long-term Conditions, Florence Nightingale Faculty of Nursing,

			Midwifery and Palliative Care, King's College London, UK
Francesco Zaccardi	GDP member, Methodologist	Evidence-based medicine, internal medicine	Associate Professor Clinical Epidemiology and Health Data Science, Diabetes Research Centre, University of Leicester, Leicester, UK

GDP, Guideline Development Panel; GOC, Guidelines Oversight Committee