

Supplementary Appendix for:

Efficacy of the digital therapeutic glucura combined with CGM in the treatment of type 2 diabetes: a randomised controlled trial over 6 months

This supplementary document provides supporting information and results to complement the main manuscript and to enhance transparency and reproducibility.

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Supplementary Tables

ESM Table 1. Baseline characteristics – medical data (ITT)

Group	Statistics	Age (years)	Body height (m)	Body weight (kg)	BMI (kg/m ²)	Waist circumfer- ence (cm)	Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)
Total	<i>n</i> *	320	320	320	320	309	283	283
	Mean	58.18	1.73	99.08	33.14	114.12	135.68	83.40
	Standard deviation	11.26	0.09	18.98	5.93	13.80	15.60	10.21
	Minimum	19	1.50	62	24.19	60	94	51
	1. Quartile	52	1.67	86	28.62	105	125	78
	Median	59	1.72	96	32	114	134	83
	3. Quartile	65	1.80	110	36.83	122	143	90
	Maximum	85	1.98	190	54.88	160	187	116
Intervention Group	<i>n</i> *	158	158	158	158	152	136	136
	Mean	58.18	1.73	100.41	33.53	114.77	137.15	83.77
	Standard deviation	11.06	0.10	20.21	5.72	14.34	15.68	9.85
	Minimum	23	1.50	63	24.19	60	94	57
	1. Quartile	52	1.65	87	29.39	105	130	80
	Median	59	1.73	97	32.41	114	135	83
	3. Quartile	66	1.82	110	36.85	123	147	90
	Maximum	85	1.98	190	54.88	158	181	110
Control Group	<i>n</i> *	162	162	162	162	157	147	147
	Mean	58.19	1.73	97.78	32.76	113.49	134.31	83.05
	Standard deviation	11.49	0.09	17.67	6.13	13.27	15.46	10.55
	Minimum	19	1.50	62	25.01	81	96	51
	1. Quartile	52	1.68	84	28.01	104	122	77

Group	Statistics	Age (years)	Body height (m)	Body weight (kg)	BMI (kg/m ²)	Waist circumfer- ence (cm)	Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)
	Median	60	1.72	96	31.17	113	131	83
	3. Quartile	65	1.79	110	36.51	122	140	90
	Maximum	81	1.94	151	53.32	160	187	116
n: number of individuals. n*: number of individuals with non-missing values. BMI: Body-Mass-Index								

ESM Table 2. Baseline characteristics - laboratory parameters (ITT)

Group	Statistics	HbA _{1c} (mmol/mol (%))	Total cholesterol (mmol/l (mg/dl))	LDL-C (mg/dl)	HDL-C (mg/dl)	Triglycerides (mg/dl)	eGFR (ml/min/1.73m ²)
Total	<i>n</i> *	320	105	139	97	120	163
	Mean	61.86 (7.81)	4.72 (182.14)	101.84	48.32	223.09	82.44
	Standard deviation	8.63 (0.79)	1.21 (46.62)	38.94	15.20	137.01	19.94
	Minimum	53.01 (7.0)	2.22 (86)	24	27	54	30
	1. Quartile	55.19 (7.2)	3.85 (149)	74	38	128	70
	Median	59.56 (7.6)	4.78 (185)	99	46	184	83
	3. Quartile	66.12 (8.2)	5.46 (211)	132	54	294	95
	Maximum	95.63 (10.9)	8.15 (315)	219	130	801	153
Intervention Group	<i>n</i> *	158	56	72	49	65	86
	Mean	61.42 (7.77)	4.78 (184.89)	106.46	43.3	254.24	81.22
	Standard deviation	8.09 (0.74)	1.12 (43.31)	37.83	9.28	152.10	21.45
	Minimum	53.01 (7.0)	2.22 (86)	30	27	69	30
	1. Quartile	55.19 (7.2)	3.96 (153)	76.5	37	139	70
	Median	58.47 (7.5)	4.89 (189)	101.65	43.3	212	83
	3. Quartile	66.12 (8.2)	5.52 (213.5)	135.5	48	320	92
	Maximum	89.07 (10.3)	7.14 (276)	214	72	801	153
Control Group	<i>n</i> *	162	49	67	48	55	77
	Mean	62.30 (7.85)	4.63 (179.00)	96.88	53.44	186.28	83.79
	Standard deviation	9.18 (0.84)	1.30 (50.42)	39.79	18.2	106.77	18.14
	Minimum	53.01 (7.0)	2.53 (98)	24	31	54	33

Group	Statistics	HbA _{1c} (mmol/mol (%))	Total cholesterol (mmol/l (mg/dl))	LDL-C (mg/dl)	HDL-C (mg/dl)	Triglycerides (mg/dl)	eGFR (ml/min/1.73m ²)
	1. Quartile	55.19 (7.2)	3.78 (146)	69	41.38	111	71
	Median	59.56 (7.6)	4.50 (174)	95	50	168	84
	3. Quartile	65.36 (8.13)	5.35 (207)	129	62	223	99
	Maximum	95.63 (10.9)	8.15 (315)	219	130	561	120
n: number of individuals. n*: number of individuals with non-missing values. HbA _{1c} : N-(1-deoxy)-fructosyl-hemoglobin. LDL-C: low-density lipoprotein-cholesterol. HDL-C: high-density lipoprotein-cholesterol. eGFR: estimated glomerular filtration rate							

ESM Table 3. Baseline characteristics - demographics/medical history [ITT]

	Total		Intervention Group		Control Group	
	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *
Disease duration						
	320	320	158	158	162	162
	9.82 (6.85)		9.42 (6.47)		10.20 (7.29)	
	9 (5 - 14)		8 (5 - 13)		9 (5 - 14)	
Time since entry into DMP type 2 diabetes mellitus or other comparable treatment according to national guidelines						
	320	320	158	158	162	162
	6.78 (5.33)		6.27 (5.06)		7.27 (5.55)	
	5 (3 - 10)		5 (2 - 10)		6 (3 - 10)	
	<i>n</i> (%)	<i>n</i> *	<i>n</i> (%)	<i>n</i> *	<i>n</i> (%)	<i>n</i> *
Sex:						
female	135 (42.2%)	320	64 (40.5%)	158	71 (43.8%)	162
male	185 (57.8%)		94 (59.5%)		91 (56.2%)	
diverse	0 (0.0%)		0 (0.0%)		0 (0.0%)	
not specified	0 (0.0%)		0 (0.0%)		0 (0.0%)	
Services used during standard treatment in past 3 months						
Personal coaching by certified diabetes assistant	35 (10.9%)	320	18 (11.4%)	158	17 (10.5%)	162
Patient training on lifestyle changes	25 (7.8%)	320	11 (7.0%)	158	14 (8.6%)	162
Patient training on diabetes management	16 (5.0%)	320	6 (3.8%)	158	10 (6.2%)	162
None	261 (81.6%)	320	130 (82.3%)	158	131 (80.9%)	162
Comorbidities (modified MedDRA SOC):						
Cardiovascular disorders	237 (80.9%)	293	116 (80.0%)	145	121 (81.8%)	148
Metabolism and nutrition disorders	205 (70.0%)		94 (64.8%)		111 (75.0%)	
Nervous system disorders	80 (27.3%)		30 (20.7%)		50 (33.8%)	

	Total		Intervention Group		Control Group	
	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *
Musculoskeletal disorders	75 (25.6%)		30 (20.7%)		45 (30.4%)	
Renal and urinary disorders	74 (25.3%)		32 (22.1%)		42 (28.4%)	
Hepatobiliary disorders	70 (23.9%)		37 (25.5%)		33 (22.3%)	
Endocrine disorders	64 (21.8%)		30 (20.7%)		34 (23.0%)	
Respiratory disorders	50 (17.1%)		22 (15.2%)		28 (18.9%)	
Psychiatric disorders	40 (13.7%)		17 (11.7%)		23 (15.5%)	
Gastrointestinal disorders	36 (12.3%)		16 (11.0%)		20 (13.5%)	
Eye disorders	21 (7.2%)		8 (5.5%)		13 (8.8%)	
Skin and subcutaneous tissue disorders	17 (5.8%)		9 (6.2%)		8 (5.4%)	
Reproductive system and breast disorders	11 (3.8%)		6 (4.1%)		5 (3.4%)	
Neoplasms benign. malignant and unspecified (including haematologic malignancies)	11 (3.8%)		4 (2.8%)		7 (4.7%)	
Immune system disorders	2 (0.7%)		0 (0.0%)		2 (1.4%)	
Other	50 (17.1%)		21 (14.5%)		29 (19.6%)	
Medication						
Yes. diabetes-specific	308 (96.2%)	320	152 (96.20 %)	158	156 (96.30 %)	162
Yes. not diabetes-specific	6 (1.9%)		5 (3.16 %)		1 (0.62 %)	
No	6 (1.9%)		1 (0.63 %)		5 (3.09 %)	
Diabetes-specific medication: Subclass						
Biguanides (incl. Metformin)	267 (40.9%)	308	131 (42.5%)	152	136 (39.4%)	156
SGLT-2 Inhibitors	189 (28.9%)		85 (27.6%)		104 (30.1%)	
GLP-1-Analogues	96 (14.7%)		47 (15.3%)		49 (14.2%)	
DPP-4 Inhibitors	80 (12.3%)		36 (11.7%)		44 (12.8%)	
Sulfonylureas	17 (2.6%)		7 (2.3%)		10 (2.9%)	
Meglitinides	3 (0.5%)		1 (0.3%)		2 (0.6%)	
Thiazolidinediones	1 (0.2%)		1 (0.3%)		0 (0.0%)	

	Total		Intervention Group		Control Group	
	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *
Smoking status						
Non-smoker	263 (82.2%)	320	131 (82.9%)	158	132 (81.5%)	162
Occasionally	12 (3.8%)		4 (2.5%)		8 (4.9%)	
>1 cigarette a day or >5 cigarettes a week	45 (14.1%)		23 (14.6%)		22 (13.6%)	
Highest educational degree						
Lower graduation	198 (61.9%)	320	88 (55.7%)	158	110 (67.9%)	162
General university entrance qualification ("Abitur") or equivalent	59 (18.4%)		37 (23.4%)		22 (13.6%)	
Bachelor's degree	30 (9.4%)		16 (10.1%)		14 (8.6%)	
Master's degree	32 (10.0%)		17 (10.8%)		15 (9.3%)	
Doctorate degree	1 (0.3%)		0 (0.0%)		1 (0.6%)	
n: number of individuals in each category. n*: number of individuals with non-missing values. DMP: disease management program. MedDRA: medical dictionary for regulatory activities. SGLT-2: sodium-dependent glucose transporter 2. GLP-1 glucagon-like peptide 1: DPP-4 Dipeptidylpeptidase- 4. SOC: system organ classes. mono. dual. triple. quadruple therapy refers to number of active pharmaceutical ingredients. Disease duration = Time from diagnosis until start of study Percentages for diabetes-specific medication subclasses are relative to the total number of drug class prescriptions (e.g. 267/653 = 40.9% for biguanides). so that values sum to 100% across classes.						

ESM Table 4. Baseline characteristics - demographics/medical history [PP]

	Total		Intervention Group		Control Group	
	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *
Disease duration						
	241	241	117	117	124	124
	9.75 (6.70)		9.63 (6.61)		9.85 (6.81)	
	9 (5 - 13)		9 (5 - 13)		9 (5 - 13)	
Time since entry into DMP type 2 diabetes mellitus or other comparable treatment according to national guidelines						
	241	241	117	117	124	124
	6.83 (5.32)		6.65 (5.19)		7 (5.45)	
	5 (3 - 10)		5 (3 - 10)		6 (3 - 10)	
	<i>n</i> (%)	<i>n</i> *	<i>n</i> (%)	<i>n</i> *	<i>n</i> (%)	<i>n</i> *
Sex:						
female	104 (43.2%)	241	47 (40.2%)	117	57 (46.0%)	124
male	137 (56.9%)		70 (59.8%)		67 (54.0%)	
diverse	0 (0.0%)		0 (0.0%)		0 (0.0%)	
not specified	0 (0.0%)		0 (0.0%)		0 (0.0%)	
Services used during standard treatment in past 3 months						
Personal coaching by certified diabetes assistant	27 (11.2%)	241	14 (12.0%)	117	13 (10.5%)	124
Patient training on lifestyle changes	18 (7.5%)	241	8 (6.8%)	117	10 (8.1%)	124
Patient training on diabetes management	11 (4.6%)	241	6 (5.1%)	117	5 (4.0%)	124
None	197 (81.7%)	241	96 (82.1%)	117	101 (81.5%)	124
Comorbidities (modified MedDRA SOC):						
Cardiovascular disorders	179 (81.0%)	221	89 (82.4%)	108	90 (79.7%)	113
Metabolism and nutrition disorders	156 (70.6%)		73 (67.6%)		83 (73.5%)	
Nervous system disorders	58 (26.2%)		20 (18.5%)		38 (33.6%)	
Musculoskeletal disorders	59 (26.7%)		21 (19.4%)		38 (33.6%)	

	Total		Intervention Group		Control Group	
	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *
Renal and urinary disorders	58 (26.2%)		24 (22.2%)		34 (30.1%)	
Hepatobiliary disorders	53 (24.0%)		25 (23.5%)		28 (24.8%)	
Endocrine disorders	47 (21.3%)		22 (20.4%)		25 (22.1%)	
Respiratory disorders	37 (16.7%)		16 (14.8%)		21 (18.6%)	
Psychiatric disorders	29 (13.1%)		12 (11.1%)		17 (15.0%)	
Gastrointestinal disorders	28 (12.7%)		13 (12.0%)		15 (13.3%)	
Eye disorders	16 (7.2%)		7 (6.5%)		9 (8.0%)	
Skin and subcutaneous tissue disorders	15 (6.8%)		7 (6.5%)		8 (7.1%)	
Reproductive system and breast disorders	7 (3.2%)		4 (3.7%)		3 (2.7%)	
Neoplasms benign, malignant and unspecified (including haematologic malignancies)	8 (3.6%)		3 (2.8%)		5 (4.4%)	
Immune system disorders	2 (0.9%)		0 (0.0%)		2 (1.8%)	
Other	37 (16.7%)		15 (13.9%)		22 (19.5%)	
Medication						
Yes. diabetes-specific	229 (95.0%)	241	111 (94.9%)	117	118 (95.2%)	124
Yes. not diabetes-specific	6 (2.5%)		5 (4.3%)		1 (0.9%)	
No	6 (2.5%)		1 (0.9%)		5 (4.0%)	
Diabetes-specific medication: Therapy						
Mono Therapy	59 (25.8%)	229	32 (28.8%)	111	27 (22.9%)	118
Dual Therapy	92 (40.2%)		49 (44.1%)		43 (36.4%)	
Triple Therapy	68 (29.7%)		26 (23.4%)		42 (35.6%)	
Quadruple Therapy	10 (4.4%)		4 (3.6%)		6 (5.1%)	
Diabetes-specific medication: Subclass						
Biguanides (incl. Metformin)	198 (40.7%)	229	95 (42.6%)	111	103 (39.2%)	118
SGLT-2 Inhibitors	142 (29.2%)		65 (29.2%)		77 (29.3%)	
GLP-1-Analogues	72 (14.8%)		33 (14.8%)		39 (14.8%)	

	Total		Intervention Group		Control Group	
	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *	<i>n</i> Mean (SD) Median (IQR)	<i>n</i> *
DPP-4 Inhibitors	60 (12.4%)		25 (11.21%)		35 (13.3%)	
Sulfonylureas	12 (2.5%)		5 (2.24%)		7 (2.7%)	
Meglitinides	2 (0.4%)		0 (0.00%)		2 (0.8%)	
Smoking status						
Non-smoker	199 (82.6%)	241	98 (83.8%)	117	101 (81.5%)	124
Occasionally	11 (4.6%)		4 (3.4%)		7 (5.7%)	
>1 cigarette a day or >5 cigarettes a week	31 (12.9%)		15 (12.8%)		16 (12.9%)	
Highest educational degree						
Lower graduation	146 (60.6%)	241	62 (53.0%)	117	84 (67.7%)	124
General university entrance qualification ("Abitur") or equivalent	48 (19.9%)		31 (26.5%)		17 (13.7%)	
Bachelor's degree	20 (8.3%)		9 (7.7%)		11 (8.9%)	
Master's degree	27 (11.2%)		15 (12.8%)		12 (9.7%)	
n: number of individuals in each category. n*: number of individuals with non-missing values. DMP: disease management program. MedDRA: medical dictionary for regulatory activities. SGLT-2: sodium-dependent glucose transporter 2. GLP-1 glucagon-like peptide 1: DPP-4 Dipeptidylpeptidase-4. SOC: system organ classes. mono. dual. triple. quadruple therapy refers to number of active pharmaceutical ingredients. Disease duration = Time from diagnosis until start of study						

ESM Table 5. Baseline characteristics - medical data [PP]

Group	Statistics	Age (years)	Body height (m)	Body weight (kg)	BMI (kg/m ²)	Waist circumference (cm)	Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)
Total	<i>n</i> *	241	241	241	241	233	215	215
	Mean	58.01	1.73	99.14	33.20	114.45	136.85	84.06
	Standard deviation	10.90	0.09	18.58	6.04	13.36	15.11	9.96
	Minimum	20	1.50	64	24.19	81	94	60
	1. Quartile	52	1.67	87	28.60	105	130	80
	Median	59	1.72	96	31.90	114	135	83
	3. Quartile	65	1.80	110	36.85	122	143	90
	Maximum	85	1.98	170	54.88	160	181	116
Intervention Group	<i>n</i> *	117	117	117	117	114	100	100
	Mean	58.51	1.73	99.77	33.15	114.80	138.50	84.32
	Standard deviation	10.39	0.10	19.11	5.58	12.80	15.70	9.73
	Minimum	23	1.50	64	24.19	93	94	60
	1. Quartile	54	1.65	87	29.14	106	130	80
	Median	59	1.75	97	32.25	114	136	84
	3. Quartile	65	1.82	109	36.45	122	148	90
	Maximum	85	1.98	170	54.88	158	181	110
Control Group	<i>n</i> *	124	124	124	124	119	115	115
	Mean	57.54	1.72	98.54	33.25	114.12	135.42	83.83
	Standard deviation	11.38	0.09	18.13	6.46	13.92	14.49	10.19
	Minimum	20	1.50	69	25.01	81	110	60
	1. Quartile	51	1.68	83	28.15	104	125	78
	Median	59	1.72	96	31.42	114	134	83
	3. Quartile	65	1.79	110	37.03	123	142	90

Group	Statistics	Age (years)	Body height (m)	Body weight (kg)	BMI (kg/m ²)	Waist circumfer- ence (cm)	Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)
	Maximum	80	1.94	151	53.32	160	174	116
n: number of individuals. n*: number of individuals with non-missing values. BMI: Body-Mass-Index								

ESM Table 6. Baseline characteristics - laboratory parameters [PP]

Group	Statistics	HbA _{1c} (mmol/mol (%))	Total cholesterol (mg/dl)	LDL-C (mg/dl)	HDL-C (mg/dl)	Triglyceride s (mg/dl)	eGFR (ml/min/1.7 3m ²)
Total	<i>n</i> *	241	83	109	75	93	127
	Mean	61.86 (7.77)	186.14	106.14	46.93	228.00	83.49
	Standard deviation	8.52 (0.78)	46.28	38.58	12.47	138.31	20.47
	Minimum	53.01 (7.0)	86	24	27	66	33
	1. Quartile	55.19 (7.2)	156	81	38	139	71
	Median	59.56 (7.6)	191	102	46	198	84
	3. Quartile	8.1	214	134	52	287	97
	Maximum	10.9	315	219	90	801	153
Intervention Group	<i>n</i> *	117	46	58	39	51	67
	Mean	7.72	188.04	110.66	42.96	263.12	82.51
	Standard deviation	0.71	41.89	36.86	8.86	160.28	21.96
	Minimum	7.0	86	30	27	69	34
	1. Quartile	7.2	159	85	37	139	70
	Median	7.5	192	108.5	43.3	216	84
	3. Quartile	8.0	214	139	48	335	93
	Maximum	10.3	276	214	72	801	153
Control Group	<i>n</i> *	124	37	51	36	42	60
	Mean	7.82	183.77	101.01	51.23	185.34	84.59
	Standard deviation	0.85	51.71	40.20	14.38	90.53	18.79
	Minimum	7.0	98	24	31	66	33
	1. Quartile	7.2	147	73	40.5	130	71
	Median	7.6	185	99	49	170	86
	3. Quartile	8.1	211	131	60	223	100

Group	Statistics	HbA _{1c} (mmol/mol (%))	Total cholesterol (mg/dl)	LDL-C (mg/dl)	HDL-C (mg/dl)	Triglyceride s (mg/dl)	eGFR (mL/min/1.7 3m ²)
	Maximum	10.9	315	219	90	525	120
n: number of individuals. n*: number of individuals with non-missing values. HbA _{1c} : N-(1-deoxy)-fructosyl-hemoglobin. LDL-C: low-density lipoprotein-cholesterol. HDL-C: high-density lipoprotein-cholesterol. eGFR: estimated glomerular filtration rate							

ESM Table 7. Changes from Baseline (V1) in primary and secondary endpoint variables and confirmatory (V1 vs. V3) and exploratory (V1 vs. V2) analyses of these variables [PP]

	Change from V1 to V2				Change from V1 to V3			
	IV	CO	Group difference		IV	CO	Group difference	
Measure	<i>n</i> * mean (SD) median (IQR)	<i>n</i> * mean (SD) median (IQR)	estimate [95% CI]	<i>p</i> - value	<i>n</i> * mean (SD) median (IQR)	<i>n</i> * mean (SD) median (IQR)	estimate (95% CI)	<i>p</i> -value
HbA _{1c} (%)	116 -0.4 (0.82) -0.4 (-0.9 - 0.2)	122 -0.24 (0.73) -0.2 (-0.6 - 0.2)	-0.15 (-0.35; 0.05)	0.1348	110 -0.78 (0.9) -0.8 (-1.4 - (-0.3))	117 -0.29 (0.91) -0.3 (-0.6 - 0.2)	-0.47 (-0.70; -0.24)	<0.0001
Relative change in body weight (%)	116 -1.68 (3.73) -1.24 (-3.26 - 0.49)	122 -1.08 (2.96) -0.03 (-2.25 - 0.25)	-0.63 (-1.53; 0.27)	0.1698	110 -3.99 (4.54) -3.82 (-6.41 - (-0.77))	116 -1.7 (3.84) -1.19 (-3.45 - 0.11)	-2.34 (-3.47; -1.21)	<0.0001
Severity of depression PHQ-9 (score)**	105 -0.82 (3.65) -1 (-3 - 1)	115 -0.16 (3.01) 0 (-2 - 2)	-0.72 (-1.61; 0.16)	0.1084	100 -1.47 (3.49) -1 (-3 - 0.5)	106 -0.08 (3.66) 0 (-2 - 2)	-1.25 (-2.21; -0.28)	0.0116
Self-management PAID (score)**	105 -6.11 (13.06) -6.25 (-12.50 - 1.25)	115 -2.18 (12.27) -3.75 (-8.75 - 5.00)	-4.03 (-7.37; -0.69)	0.0183	100 -7.84 (14.94) -6.25 (-15.00 - 1.25)	106 -3.55 (15.92) -3.13 (-12.50 - 2.50)	-4.65 (-8.81; -0.50)	0.0282
Mental component of quality of life MCS (score)**	107 2.33 (8.83) 1.5 (-2.61 - 5.89)	119 1.2 (10.58) 0.19 (-3.30 - 6.23)	1.34 (-1.23; 3.91)	0.3054	101 3.66 (9.74) 4.15 (-0.97 - 7.31)	111 0.75 (10.32) -0.05 (-5.66 - 6.98)	2.92 (0.20; 5.64)	0.0355

*n**. number individuals with non-missing value; **: endpoint variables sorted by *p* value - only for ITT set; ***multiple testing correction . adjusted alpha non-applicable if testing procedure is stopped before - only for ITT set; CI: Confidence Interval; HbA_{1c}. N-(1-deoxy)-fructosyl-haemoglobin; PAID. problem areas in diabetes questionnaire; PHQ. patients health questionnaire. MCS. Mental component score

ESM Table 8. Exploratory endpoint variables and analyses [PP]

	Change from V1 to V2				Change from V1 to V3			
	IV	CO	Group difference		IV	CO	Group difference	
Measure	<i>n</i> * mean (SD) median (IQR)	<i>n</i> * mean (SD) median (IQR)	estimate [95% CI]	<i>p</i> - value	<i>n</i> * mean (SD) median (IQR)	<i>n</i> * mean (SD) median (IQR)	estimate (95% CI)	<i>p</i> - value
Responder proportion: proportion with HbA _{1c} in the target range (< 7 %) **	40 (34.5%)	28 (23.0%)	1.83 (0.92; 3.65)	0.0844	61 (55.5%)	36 (30.8%)	3.24 (1.66; 6.35)	0.000 7
Potential for remission: proportion with HbA _{1c} < 6.5 %**	15 (12.9%)	6 (4.9%)	2.87 (0.89; 9.23)	0.0766	31 (28.2%)	8 (6.8%)	6.52 (2.35; 18.11)	0.000 4
Absolute change in body weight (kg)	116 -1.72 (3.86) -1 (-3 - 1)	122 -1.08 (3.18) 0 (-2 - 0)	-0.63 (-1.53; 0.27)	0.1698	110 -4.07 (4.79) -4 (-7 - (-1))	116 -1.72 (3.85) -1 (-4 - 0)	-2.34 (-3.47; - 1.21)	<0.00 01
BMI (kg/m ²)	116 -0.57 (1.30) -0.39 (-0.99 - 0.19)	122 -0.38 (1.05) -0.02 (-0.71 - 0.07)	-0.19 (-0.49; 0.11)	0.2020	110 -1.34 (1.58) -1.23 (-2.30 - (- 0.24))	116 -0.59 (1.28) -0.37 (-1.35 - 0.03)	-0.75 (-1.12; - 0.37)	0.000 1
Absolute change in waist circumference (cm)	112 -2.86 (4.82) -3 (-6 - 0)	118 -2.88 (8.82) -2 (-3 - 0)	-0.08 (-1.92; 1.77)	0.9344	105 -4.21 (6.09) -3 (-8 - 0)	112 -3.21 (9.62) -2 (-5 - 1)	-0.81 (-2.89; 1.27)	0.445 0
Systolic blood pressure (mmHg)	90 -2.16 (14.87) -1 (-12 - 5)	92 0.7 (16.13) 3 (-9 - 10)	-3.16 (-7.52; 1.19)	0.1539	81 -4.17 (15.13) -4 (-15 - 4)	90 -1.28 (15.76) -2 (-10 - 10)	-2.07 (-6.51; 2.38)	0.360 2
Diastolic blood pressure (mmHg)	90 -0.09 (9.83)	92 1.10 (11.53)	-1.48 (-4.49; 1.53)	0.3330	81 -1.48 (9.32)	90 -1.77 (11.41)	-0.00 (-3.04; 3.03)	0.997 9

	0 (-5 - 5)	1 (-5 - 9)			-1 (-8 - 4)	0 (-7 - 5)		
Triglyceride (mg/dl)	25 -22.71 (122) -36 (-77 - 5)	22 -10.45 (103.48) -8 (-73 - 41)	-44.18 (-106.16; 17.80)	0.1588	23 -57.34 (112.74) -45 (-94 - 4)	17 -10.86 (95.58) -39 (-57 - 28)	-65.99 (- 159.75; 27.77)	0.161 9
HDL-Cholesterol (mg/dl)	24 0.67 (5.61) 1 (-2 - 4)	21 -0.33 (7.34) 1 (-6 - 3)	2.01 (-1.56; 5.58)	0.2639	18 3.95 (7.86) 5 (-1 - 7)	17 2.53 (8.23) 2 (-1 - 4)	1.88 (-2.75; 6.50)	0.420 1
LDL-Cholesterol (mg/dl)	32 -11.31 (38.63) -5 (-24 - 12)	24 -9.37 (34.01) -5 (-24 - 7)	2.79 (-13.42; 19.00)	0.7332	29 -1.98 (33.48) -4 (-11 - 20)	24 -5.64 (38.47) -6 (-22 - 18)	-2.95 (-19.68; 13.77)	0.726 2
Total Cholesterol (mg/dl)	30 -17.06 (40.13) -8 (-28 - 2)	22 -13.77 (40.63) -6 (-41 - 12)	-2.07 (-22.51; 18.38)	0.8407	21 -8.52 (53.36) -3 (-14 - 16)	18 -3.72 (55.66) -1 (-20 - 12)	-11.59 (- 38.52; 15.33)	0.393 8
eGFR (mL/min/1.73 m ²)	44 3.49 (7.43) 3 (0 - 10)	36 -1.04 (7.10) -1 (-6 - 2)	3.42 (0.29; 6.55)	0.0323	40 2.46 (7.88) 2 (-4 - 9)	39 -0.13 (14.21) 3 (-4 - 8)	3.15 (-1.52; 7.81)	0.184 6
SCORE2-Diabetes (% 10-year CVD risk)	6 -2.06 (1.54) -1.91 (-3.39 - (-0.92))	6 -0.3 (1.28) -0.27 (-0.64 - 0.17)	-1.62 (-3.24; 0.00)	0.0505	5 -3.16 (2.61) -1.75 (-4.68 - (-1.52))	4 -0.96 (1.33) -1.26 (-1.91 - (-0.02))	-3.87 (-6.76; -0.98)	0.012 1
Response rate: Relative change in body weight ≤ -5% **	16 (13.8%)	8 (6.6%)	2.24 (0.84; 5.97)	0.1050	43 (39.1%)	19 (16.4%)	3.46 (1.67; 7.17)	0.000 9
Physical component of quality of life (score)	107 1.20 (6.78)	119 -0.53 (7.91)	1.72 (-0.22; 3.65)	0.0815	101 1.89 (8.54)	111 1.61 (7.86)	0.20 (-1.98; 2.38)	0.857 8

	1.31 (-3.22 - 5.22)	0.30 (-4.91 - 3.74)			1.11 (-3.22 - 6.63)	0.82 (-3.4 - 6.95)		
Response rate: Change in PCS $\geq$ 2 points **	49 (45.8%)	46 (38.7%)	1.79 (0.93; 3.43)	0.0804	42 (41.6%)	47 (42.3%)	1.17 (0.60; 2.28)	0.6483
Response rate: Change in MCS $\geq$ 2 points **	51 (47.7%)	49 (41.2%)	1.47 (0.78; 2.76)	0.2287	62 (61.4%)	47 (42.3%)	2.71 (1.40; 5.22)	0.0032
Response rate: Change in self-management (PAID) $\leq$ -10 points **	34 (32.4%)	24 (20.9%)	2.23 (1.07; 4.67)	0.0334	38 (38.0%)	31 (29.3%)	1.90 (0.92; 3.89)	0.0809
Response rate: Change in depressive symptoms (PHQ-9) $\leq$ -5 points **	10 (9.5%)	6 (5.2%)	2.65 (0.75; 9.36)	0.1294	15 (15.0%)	10 (9.4%)	2.27 (0.78; 6.60)	0.1311
PGIC (% of people indicating better) **	98 (83.8%)	104 (83.9%)	0.98 (0.52; 1.85)	0.9560	97 (82.9%)	105 (84.7%)	0.78 (0.41; 1.47)	0.4417
Diabetes medication discontinued (% incidence) **	13 (11.7%)	13 (11.0%)	0.78 (0.13; 4.89)	0.7920	12 (10.8%)	8 (6.8%)	3.71 (0.42; 32.61)	0.2360
Diabetes medication started (% incidence) **	20 (17.2%)	18 (14.5%)	1.23 (0.61; 2.49)	0.5591	21 (19.3%)	23 (19.7%)	0.97 (0.50; 1.89)	0.9303
Diabetes medication increased (% incidence) **	8 (7.2%)	7 (5.9%)	1.14 (0.13; 10.00)	0.9060	8 (7.2%)	7 (5.9%)	1.46 (0.17; 12.30)	0.7295
Diabetes medication reduced (% incidence) **	6 (5.4%)	7 (5.9%)	0.88 (0.08; 9.26)	0.9122	5 (4.5%)	4 (4.5%)	1.17 (0.06; 21.29)	0.9134

n*, number of non-missing values; **: OR with CI instead of parameter estimate; N-(1-deoxy)-fructosyl-hemoglobin; SF-36, short-form 36; PCS, physical component summary; MCS, mental component summary; PHQ-9, patient health questionnaire-9; PGIC, patients global impression of change; LDL-C, low-density lipoprotein-cholesterol; HDL-C, high-density lipoprotein-cholesterol; eGFR, estimated glomerular filtration rate; BMI, body-mass-index; Percentages for discontinued/increased/reduced diabetes medication refer to patients with diabetes medication at baseline and available data at V2 or V3; percentages for started medication refer to all patients with available data at V2 or V3.

ESM Table 9. Exploratory analysis of CGM-related endpoints [ITT]

	Change from SP1 to SP2			
	Intervention group	Control group	Group difference	
Measure	<i>n</i> [*] mean (SD) median (IQR)	<i>n</i> [*] mean (SD) median (IQR)	estimate [95% CI]	<i>p</i> - value
TIR (70 - 180 mg/dl) (%)	116 -0.03 (0.19) -0.01 (-0.12 - 0.07)	115 -0.03 (0.19) -0.02 (-0.12 - 0.08)	0.01 (-0.04 ; 0.06)	0.6433
TITR (70 - 140 mg/dl) (%)	116 0 (0.22) 0.01 (-0.12 - 0.12)	115 -0.03 (0.18) -0.01 (-0.11 - 0.09)	0.05 (0.00 ; 0.10)	0.0516
TAR (> 180 mg/dl) (%)	116 0.03 (0.19) 0.01 (-0.07 - 0.12)	115 0.03 (0.19) 0.029 (-0.08 - 0.11)	-0.01 (-0.06 ; 0.04)	0.6786
TAR (> 250 mg/dl) (%)	116 0.01 (0.09) 0 (-0.01 - 0.02)	115 0.02 (0.11) 0 (-0.02 - 0.03)	-0.02 (-0.04 ; 0.01)	0.2152
TBR (54 - 69 mg/dl) (%)	116 0 (0.01) 0 (0 - 0)	115 0 (0) 0 (0 - 0)	0 (0 ; 0)	0.8210
TBR (< 54 mg/dl) (%)	116 0 (0) 0 (0 - 0)	115 0 (0) 0 (0 - 0)	0 (0 ; 0)	0.1710
AG (mg/dl)	116 1.90 (23.94) 0.32 (-12.71 - 15.38)	115 5.46 (26.03) 2.52 (-7.86 - 14.54)	-4.92 (-11.65 ; 1.81)	0.1508
GV SD (mg/dl)	116 -0.36 (7.97)	115 0.51 (10.80)	-2.26 (-4.76 ; 0.24)	0.0768

	-0.24 (-3.84 - 2.66)	-0.08 (-4.84 - 4.68)		
GV CV (%)	116 -0.01 (0.04) -0.01 (-0.02 - 0.02)	115 0 (0.05) -0.01 (-0.03 - 0.01)	-0.01 (-0.02 ; 0.00)	0.1974
MAGE (mg/dl)	115 -2.31 (20.15) -1.41 (-13.51 - 9.40)	115 0.17 (22.13) 0.59 (-11.74 - 10.93)	-5.78 (-11.16 ; -0.41)	0.0351
CONGA24 (mg/dl)	116 0.82 (9.54) 0.36 (-3.83 - 4.46)	115 0.26 (10.26) -0.31 (-6.90 - 5.08)	-0.79 (-3.33 ; 1.76)	0.5434

TIR. time in range; TITR. time in tight range; TAR. time above range; TBR. time below range; AG. average glucose concentration; GV. glucose variability; SD. standard deviation; CV. coefficient of variation; MAGE. mean amplitude of glycaemic excursions; CONGA24. continuous overall net glycaemic action 24-h; V. visit; GMI. glucose management indicator; IQR. interquartile range; SP1. first sensor phase; SP2. second sensor phase.

CGM-related endpoints are based on the primary linear mixed model for repeated measures.

ESM Table 10. Endpoint variables for exploratory CGM endpoints

endpoint	group	SP1	SP2
TIR 70-180 mg/dl (3.9-10.0 mmol/L)	IV	0.75 ± 0.22	0.72 ± 0.26
	CO	0.66 ± 0.22	0.64 ± 0.25
TBR <70 mg/dl (<3.9 mmol/L)	IV	0.00 ± 0.10	0.00 ± 0.00
	CO	0.00 ± 0.00	0.00 ± 0.00
TBR <54 mg/dl (<3.0 mmol/L)	IV	0.00 ± 0.00	0.00 ± 0.00
	CO	0.00 ± 0.00	0.00 ± 0.00
TAR >180 mg/dl (>10.0 mmol/L)	IV	0.25 ± 0.22	0.28 ± 0.26
	CO	0.34 ± 0.22	0.36 ± 0.25
TAR >250 mg/dl (>13.9 mmol/L)	IV	0.04 ± 0.10	0.05 ± 0.10
	CO	0.07 ± 0.11	0.09 ± 0.16
Coefficient of variation	IV	0.21 ± 0.04	0.20 ± 0.04
	CO	0.22 ± 0.05	0.22 ± 0.05
Coefficient of variation INTRA	IV	0.18 ± 0.03	0.18 ± 0.03
	CO	0.19 ± 0.04	0.19 ± 0.04
Coefficient of variation INTER	IV	0.09 ± 0.04	0.09 ± 0.04
	CO	0.10 ± 0.04	0.10 ± 0.06
SD of mean glucose	IV	33.44 ± 9.04	33.08 ± 9.48
	CO	37.74 ± 10.92	38.26 ± 13.20
Mean sensor glucose. mg/dl	IV	159.37 ± 28.40	161.27 ± 31.85
	CO	169.73 ± 28.84	175.19 ± 36.88
Mean sensor glucose. mmol/l	IV	8.85 ± 1.58	8.95 ± 1.77
	CO	9.42 ± 1.60	9.72 ± 2.05
TITR 70-140 mg/dl (3.9-7.8 mmol/l)	IV	0.38 ± 0.24	0.38 ± 0.27
	CO	0.30 ± 0.23	0.27 ± 0.22
Change in Glucose Management Indicator	IV	7.12 ± 0.68	7.17 ± 0.76
	CO	7.37 ± 0.69	7.50 ± 0.88
Extended hypoglycaemic event rate <70 mg/dl (<3.9 mmol/l). #1	IV	0.16 ± 0.98	0.05 ± 0.32
	CO	0.06 ± 0.27	0.07 ± 0.34
Extended hyperglycaemic event rate >250 mg/dl (>13.9 mmol/l). #2	IV	4.88 ± 6.33	5.24 ± 6.21
	CO	9.14 ± 13.47	8.55 ± 11.56
Proportion of participants with TIR 70-180 mg/dl (3.9-10.0 mmol/l) for >70% of each day	IV	0.23 ± 0.42	0.28 ± 0.45
	CO	0.13 ± 0.34	0.17 ± 0.37
Proportion of participants with TIR 70-180 mg/dl (3.9-10.0 mmol/l) with ≥5% points improvement from baseline	IV		0.24 ± 0.43
	CO		0.22 ± 0.41
Proportion of participants with TIR 70-180 mg/dl (3.9-10.0 mmol/l) with ≥10% points improvement from baseline	IV		0.11 ± 0.31
	CO		0.15 ± 0.36
	IV	0.88 ± 0.33	0.91 ± 0.28

Proportion of participants with TBR <70 mg/dl (<3.9 mmol/l) for <4% of each day	CO	0.90 ± 0.30	0.90 ± 0.31
Proportion of participants with TBR <54 mg/dl (<3.0 mmol/l) for <1% of each day	IV	0.88 ± 0.33	0.89 ± 0.32
	CO	0.89 ± 0.32	0.90 ± 0.30
Proportion of participants with TAR >180 mg/dL (>10.0 mmol/L) for <25% of each day	IV	0.19 ± 0.39	0.26 ± 0.44
	CO	0.08 ± 0.27	0.13 ± 0.34
Proportion of participants with TAR <250 mg/dl (>13.9 mmol/l) for <5% of each day	IV	0.39 ± 0.49	0.42 ± 0.50
	CO	0.26 ± 0.44	0.29 ± 0.45
Proportion of participants with >10% points improvement in percentage of TIR 70-180 mg/dl (3.9-10.0 mmol/l) without an increase in TBR <54 mg/dl (<3.0 mmol/l) of >0.5%	IV		0.11 ± 0.31
	CO		0.15 ± 0.36
Proportion of participants with mean glucose <154 mg/dl (<8.6 mmol/l) and <1% TBR <54 mg/dl (<3.0 mmol/l)	IV	0.35 ± 0.48	0.37 ± 0.48
	CO	0.22 ± 0.41	0.20 ± 0.40
Proportion of participants with >70% TIR 70-180 mg/dl (3.9-10.0 mmol/l) and <4% TBR <70 mg/dl (<3.9 mmol/l)	IV	0.50 ± 0.50	0.46 ± 0.50
	CO	0.36 ± 0.48	0.34 ± 0.48
Proportion of participants with >70% TIR 70-180 mg/dl (3.9-10.0 mmol/l) and <1% TBR <54 mg/dl (<3.0 mmol/l)	IV	0.51 ± 0.50	0.46 ± 0.50
	CO	0.36 ± 0.48	0.34 ± 0.48

TIR. time in range; TITR. time in tight range; TAR. time above range; TBR. time below range; INTRA. intraindividual; INTER. Interindividual; SD. standard deviation. CGM values are reported on a proportional (0-1) scale without using a statistical model, SP1. first sensor phase; SP2. second sensor phase.

ESM Table 11. App usage endpoints assessed via glucura (intervention group if not noted otherwise) [ITT].

	Intervention Group	
	Mean (SD) Median (IQR)	<i>n</i>
Number of days active within the App between V1 and V2	50.51 (31.50)	151
	56 (17 - 82)	
Number of days active within the App between V2 and V3	41.65 (29.63)	127
	41 (13 - 71)	
Number of days since last activity within the App at V2	24.48 (32.55)	151
	2 (0 - 61)	
Number of days since last activity within the App at V3	30.15 (32.51)	127
	14 (0 - 66)	
1st usage W1	1 (0)	151
	1 (1 - 1)	
W2	0.95 (0.22)	151
	1 (1 - 1)	
W3	0.87 (0.33)	151
	1 (1 - 1)	
W4	0.75 (0.43)	151
	1 (1 - 1)	
W5	0.68 (0.47)	151
	1 (0 - 1)	
W6	0.64 (0.48)	151
	1 (0 - 1)	
W7	0.64 (0.48)	151
	1 (0 - 1)	
W8	0.62 (0.49)	151
	1 (0 - 1)	
W9	0.63 (0.48)	151
	1 (0 - 1)	
W10	0.59 (0.49)	151
	1 (0 - 1)	
W11	0.58 (0.49)	151
	1 (0 - 1)	
W12	0.58 (0.49)	151
	1 (0 - 1)	
W13	0.59 (0.49)	151
	1 (0 - 1)	

	Intervention Group	
	Mean (SD) Median (IQR)	<i>n</i>
2nd usage W1	1 (0)	127
	1 (1 - 1)	
W2	0.94 (0.23)	127
	1 (1 - 1)	
W3	0.83 (0.38)	127
	1 (1 - 1)	
W4	0.72 (0.45)	127
	1 (0 - 1)	
W5	0.65 (0.48)	127
	1 (0 - 1)	
W6	0.61 (0.49)	127
	1 (0 - 1)	
W7	0.61 (0.49)	127
	1 (0 - 1)	
W8	0.56 (0.50)	127
	1 (0 - 1)	
W9	0.56 (0.50)	127
	1 (0 - 1)	
W10	0.51 (0.50)	127
	1 (0 - 1)	
W11	0.52 (0.50)	127
	1 (0 - 1)	
W12	0.48 (0.50)	127
	0 (0 - 1)	
W13	0.41 (0.49)	127
	0 (0 - 1)	
Number of days with glucose-data available in the App (intervention group)	27.42 (24.92)	158
Number of days with glucose-data available (control group)	28.5 (18 - 30)	162
	28.0 (24.37)	
	29.0 (19.0 – 30.0)	

ESM Table 12. App usage endpoints assessed via glucura (intervention group only) [PP]

	Intervention Group	
	Mean (SD) Median (IQR)	<i>n</i>
Number of days active within the App between V1 and V2	55.71 (30.29)	116
	66.5 (23.5 – 83)	
Number of days active within the App between V2 and V3	41.96 (29.61)	112
	39 (13 - 72)	
Number of days since last activity within the App at V2	17.55 (28.85)	116
	1 (0 - 27)	
Number of days since last activity within the App at V3	29.08 (32.16)	112
	12 (0 - 62)	
1st usage week (W)1	1 (0)	116
	1 (1 - 1)	
W2	0.97 (0.18)	116
	1 (1 - 1)	
W3	0.91 (0.28)	116
	1 (1 - 1)	
W4	0.8 (0.40)	116
	1 (1 - 1)	
W5	0.75 (0.43)	116
	1 (0 - 1)	
W6	0.71 (0.46)	116
	1 (0 - 1)	
W7	0.73 (0.44)	116
	1 (0 - 1)	
W8	0.70 (0.46)	116
	1 (0 - 1)	
W9	0.73 (0.44)	116
	1 (0 - 1)	
W10	0.68 (0.47)	116
	1 (0 - 1)	
W11	0.67 (0.47)	116
	1 (0 - 1)	
W12	0.66 (0.47)	116
	1 (0 - 1)	
W13	0.69 (0.46)	116
	1 (0 - 1)	

	Intervention Group	
	Mean (SD) Median (IQR)	<i>n</i>
2nd usage W1	1 (0)	112
	1 (1 - 1)	
W2	0.95 (0.23)	112
	1 (1 - 1)	
W3	0.83 (0.38)	112
	1 (1 - 1)	
W4	0.73 (0.44)	112
	1 (0 - 1)	
W5	0.66 (0.48)	112
	1 (0 - 1)	
W6	0.62 (0.49)	112
	1 (0 - 1)	
W7	0.60 (0.49)	112
	1 (0 - 1)	
W8	0.57 (0.50)	112
	1 (0 - 1)	
W9	0.58 (0.50)	112
	1 (0 - 1)	
W10	0.53 (0.50)	112
	1 (0 - 1)	
W11	0.54 (0.50)	112
	1 (0 - 1)	
W12	0.49 (0.50)	112
	0 (0 - 1)	
W13	0.41 (0.49)	112
	0 (0 - 1)	
Number of days with glucose-data available in the App	33.3 (25.38)	117
	30 (23 - 34)	

ESM Table 13. Sensitivity analyses of the primary endpoint based on different methods to handle missing values as well as integrating the centre as a random effect

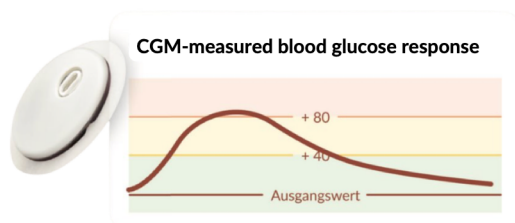
	Baseline (V1)		Follow-up (V3)		Change from V1 to V3			
	IV	CO	IV	CO	IV	CO	Group difference	
Measure	<i>n</i> [*] mean (SD) median (IQR)	<i>n</i> [*] mean (SD) median (IQR)	<i>n</i> [*] mean (SD) median (IQR)	<i>n</i> [*] mean (SD) median (IQR)	<i>n</i> [*] mean (SD) median (IQR)	<i>n</i> ^{**} mean (SD) median (IQR)	estimate (95% CI)	<i>p</i> -value
Jump-to-Reference method	158 7.77 (0.74) 7.5 (7.2 – 8.2)	162 7.85 (0.84) 7.6 (7.2 – 8.1)	158 7.10 (0.03) mean (SD) of means 0.95 (0.03) mean (SD) of SDs	162 7.53 (0.03) mean (SD) of means 0.97 (0.02) mean (SD) of SDs	158 -0.67 (0.03) mean (SD) of means 0.94 (0.03) mean (SD) of SDs	162 -0.32 (0.03) mean (SD) of means 0.91 (0.02) mean (SD) of SDs	-0.35 (-0.57; -0.13)	0.0015
Baseline observation carried forward method (BOCF)	158 7.77 (0.74) 7.5 (7.2 – 8.2)	162 7.85 (0.84) 7.6 (7.2 – 8.1)	158 7.14 (0.92) 7.0 (6.5 – 7.5)	162 7.60 (0.97) 7.4 (6.9 – 8.1)	158 -0.63 (0.87) -0.6 (-1.2 – 0.0)	162 -0.25 (0.84) -0.2 (-0.6 - 0.1)	-0.38 (-0.57; -0.20)	0.0001
Complete case	158 7.77 (0.74) 7.5 (7.2 – 8.2)	162 7.85 (0.84) 7.6 (7.2 – 8.1)	126 6.96 (0.89) 6.9 (6.4 - 7.3)	137 7.50 (0.97) 7.4 (6.9 - 8.0)	126 -0.80 (0.91) -0.8 (-1.4 - (-0.3))	137 -0.30 (0.91) -0.3 (-0.7 - 0.2)	-0.50 (-0.72; -0.28)	<0.0001

Centre as a random effect	158	162	126	137	126	137	-0.47	<0.0001
	7.77 (0.74)	7.85 (0.84)	6.96 (0.89)	7.50 (0.97)	-0.80 (0.91)	-0.30 (0.91)	(-0.68; -0.25)	
	7.5 (7.2 – 8.2)	7.6 (7.2 – 8.1)	6.9 (6.4 - 7.3)	(7.4 (6.9 - 8.0)	-0.8 (-1.4 - (-0.3))	-0.3 (-0.7 - 0.2)		

Supplementary Figures

ESM Figure 1. Screenshots of the glucura digital therapeutic app interface

supplement: insights of the DTx glucura



A CGM is worn for 14 days. Based on the individual glucose data collected during this sensor phase, AI is then used to predict blood glucose responses to tracked meals.



AI-powered prediction of blood glucose response to the tracked meal

Photo-based meal tracking

- 1 take a picture
- 2 AI detects ingredients and portion sizes
- 3 save entry to food-diary
- 4 track blood glucose response



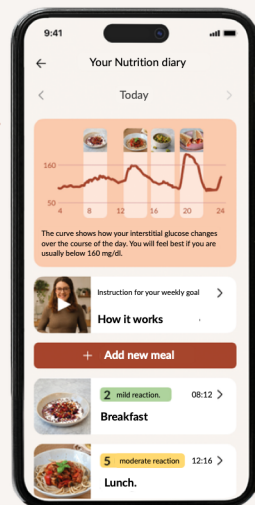
Tagliatelle
420 kcal - 140 g

Parmesan cheese
129 kcal - 30 g

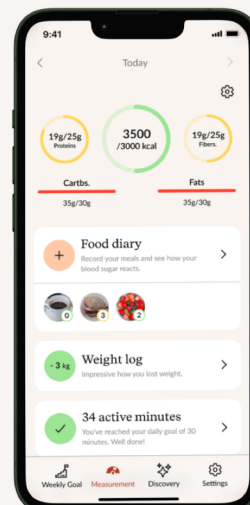
Rocket
7 kcal - 20 g

Cherry tomatoes
18 kcal - 60 g

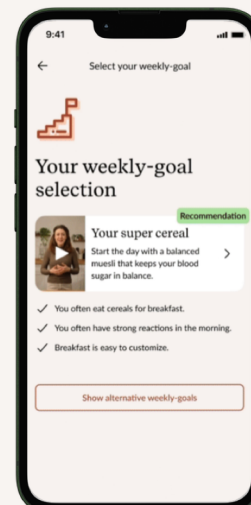
food diary & glucose response



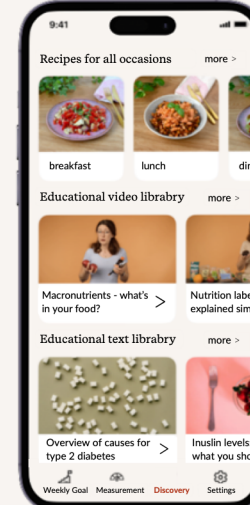
nutrition and physical activity data



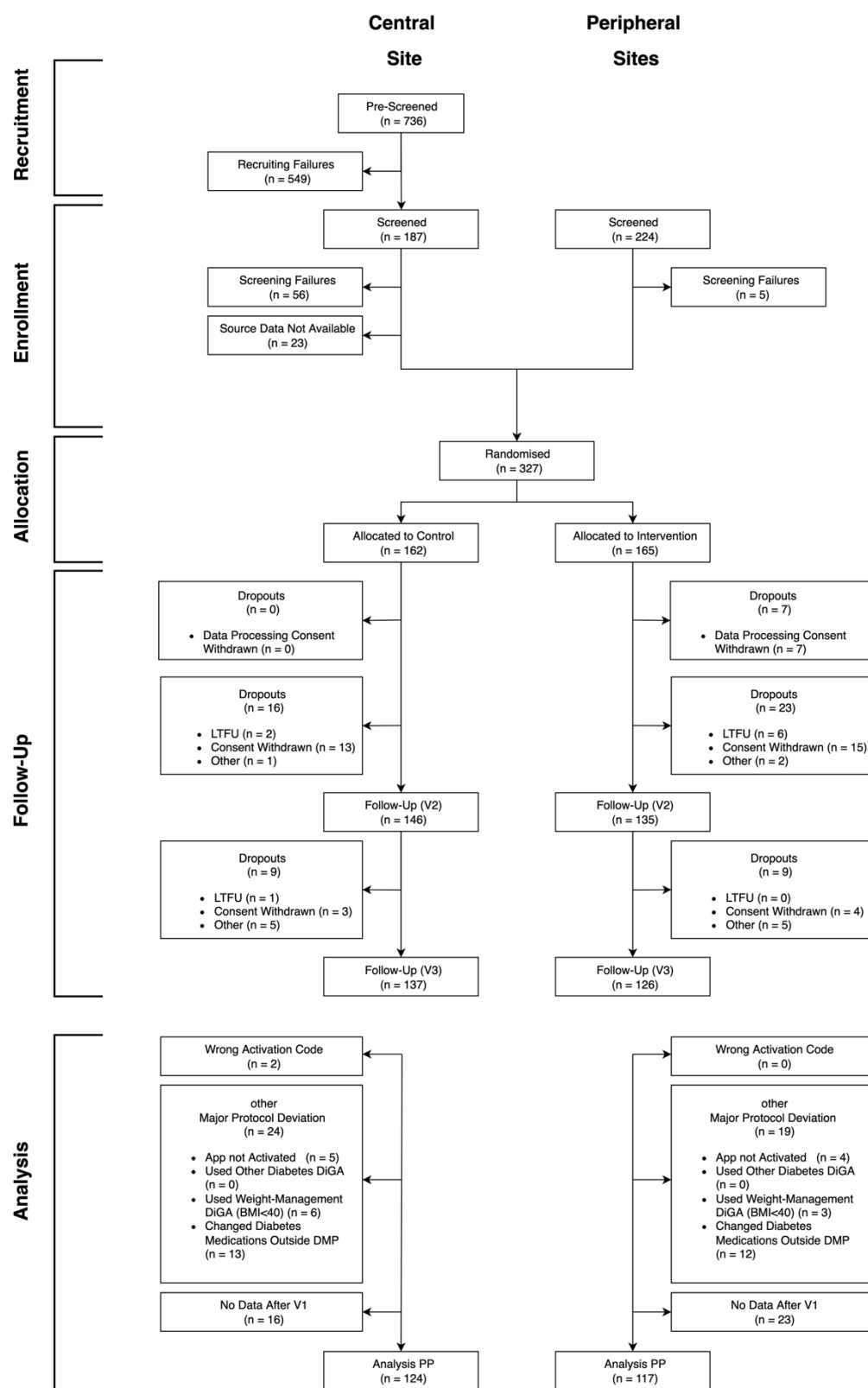
individual weekly goals



recipes & knowledge/education



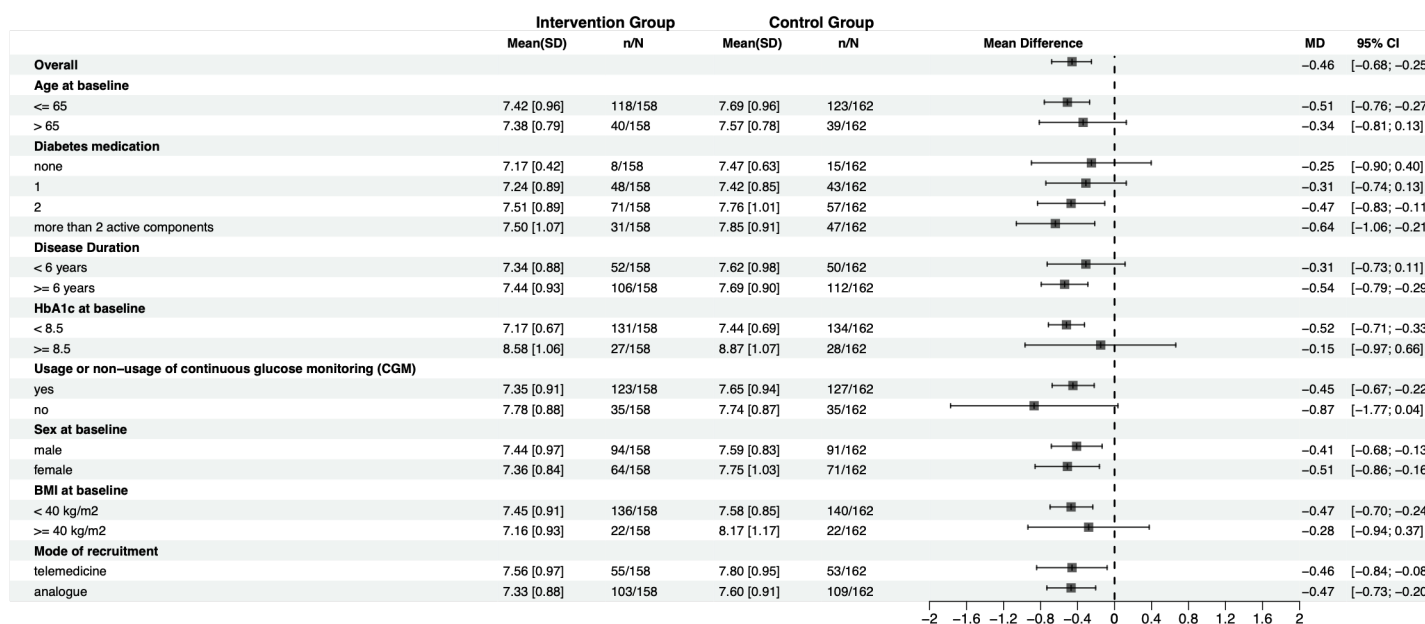
ESM Figure 2. Study flow



7 individuals allocated to the intervention group withdrew data processing consent after randomisation and required complete data deletion.

Per pre-specified definition criteria, the ITT cohort comprised 320 participants. Individuals could present with more than 1 protocol deviation. LTFU. Lost to follow-up.

ESM Figure 3. Forest plot of pre-specified subgroup analyses for the primary endpoint (change in HbA_{1c} from baseline to 6 months, ITT population)



Subgroup analysis of the efficacy of glucura® as compared to the control regarding the change of HbA_{1c}

*based on subpopulation: BMI = 40 kg/m²; HbA_{1c}, N-(1-deoxy)-fructosyl-hemoglobin; BMI, body-mass-index; CGM, continuous glucose monitor; usage of CGM, using continuous glucose monitoring during the sensor phases; SD, standard deviation; MD, mean difference; CI, confidence interval

List of participating investigators

Central study centre:

Institute for Diabetes Technology. Research and Development Company mbH at the University of Ulm.
Dr. Guido Freckmann.

Peripheral study centres:

1. Diabetes Centre Ludwigsburg. Ludwigsburg. Dr. Jörg Gloyer
2. Medicum Rosenheim MVZ GmbH. Rosenheim. Dr. med. Monika Pihusch
3. Diabetes Centre Hamburg West (dzhw). Hamburg. Prof. Jens Aberle. MD
4. Center for Diabetology Bergedorf. Hamburg. Dr. med. Olaf Backhus
5. Diabetes Practice Bad Mergentheim. Bad Mergentheim. Dr. Simon Vidal
6. Centre for Digital Diabetology Hamburg/Diabetes Centre Hamburg City. Hamburg. Dr. Jens Kröger
7. Specialist Practice for Diabetes and Nutritional Medicine. Münster. Dr. med. Winfried Keuthage
8. Endocrinology Centre Ulm. Ulm. Prof. Dr. med. Werner Kern
9. Joint Practice Dr. Täschner/Dr. Bonigut. Leipzig. Dr. Heidrun Täschner
10. Trojniak - Hennig Diabetes Practice. Großröhrsdorf. Dr. Joanna Trojniak-Hennig
11. Diabetes Practice Groth. Rellingen. Hauke Groth
12. Diabetes Centre Neustadt. Neustadt. Dr. Olaf Ney
13. Joint practice at Dreilingsberg. Travemünde. Jörg Sandmann. MD
14. Karlsburg Clinic – Clinic for Diabetes and Metabolic Diseases. Karlsburg. PD Dr. med. Dr. rer. nat. Petra Augstein
15. University of Bayreuth - BaySpo - Bayreuth Centre for Sports Science. Bayreuth. Prof. Othmar Moser
16. Diabetes Specialist Practice Dr. med. Beate Lukas. Halle (Saale). Dr. med. Beate Lukas
17. Diabetes Specialist Practice Dr. med. Astrid Schmidt-Reinwald. Trier. Dr. med. Astrid Schmidt-Reinwald
18. MVZ Asbach-Bäumenheim. Asbach-Bäumenheim. Peter Sagemüller
19. Study Group Dres. Koenemann/Steinmann. Bünde. Dr. Kai Koenemann
20. Family doctor diabetes practice Melle. Melle. Dr. Simone Rudolf

21. Mesut Durmaz Practice. Hof. Mesut Durmaz
22. Langer Practice. Berlin. Melanie Langer
23. MVZ Mayen. Mayen. Dr. Bernhard Landers