

Supplementary materials

Oral Health-Related Quality of Life in patients with type II Diabetes Mellitus: A Systematic Review and Meta-Analysis

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Search strategies

Table S1. PubMed search strategy.

#1	"oral health impact profile"[all]
#2	ohip[tw]
#3	"oral health"[all] AND "quality of life"[all]
#4	#1 OR #2 OR #3
#5	diabetes[all] OR diabetic[all] OR "diabetes mellitus"[mh]
#6	#4 AND #5

Table S2. Embase search strategy.

#1	'oral health impact profile' AND [embase]/lim
#2	'ohip' AND [embase]/lim
#3	'oral health' AND 'quality of life' AND [embase]/lim
#4	#1 OR #2 OR #3
#5	(diabetes OR diabetic OR 'diabetes mellitus'/de) AND [embase]/lim
#6	#4 AND #5

Table S3. CINAHL search strategy.

#1	"oral health impact profile"
#2	OHIP
#3	"oral health" AND "quality of life"
#4	(S1 OR S2 OR S3)
#5	diabetes OR diabetic OR "diabetes mellitus"
#6	S4 AND S5

Table S4. SCOPUS search strategy.

#1	TITLE-ABS-KEY ("oral health impact profile")
#2	TITLE-ABS-KEY (ohip)
#3	TITLE-ABS-KEY ("oral health" AND "quality of life")
#4	#1 OR #2 OR #3
#5	TITLE-ABS-KEY (diabetes OR diabetic OR "diabetes mellitus")
#6	#4 AND #5

Table S5. Selection criteria defined in a PECOS scheme.

PECOS	Inclusion criteria	Exclusion criteria
Population	The general population of adults (≥ 18 years old), not selected for any specific disease/condition (with the exception of type II diabetes mellitus) or comorbidity	- Children or adolescents - Patients selected according to the specific comorbidity (e.g. rheumatoid disease, malignancy, caries) or physiological condition (pregnant women, women in post-partum period) - Patients, which have dentures or be edentulous (these criteria should be clearly specified in the study; these criteria were not valid in calculation of mean OHIP-14 total score)
Exposure (group of exposed people)	Type II diabetes mellitus	- Type I diabetes mellitus - Unspecified diabetes or no results in type II diabetes mellitus subgroups
Comparator (control group of non-exposed people)	Patients without type II diabetes mellitus	Lack of non-diabetes group (this criterion was not valid in calculation of mean OHIP-14 total score)
Outcome	- Oral Health-Related Quality of Life (OHRQoL), as assessed by the Oral Health Impact Profile (OHIP-14), in both the diabetes group and the control group, or the difference between these groups - Severity of impacts: the mean OHIP-14 total score (the sum of ordinal responses) along with the standard deviation (SD) must be reported (or data that allows for its calculation must be available); studies were included if clearly stated that the OHIP-14 total score ranged from 0 to 56 points	- OHRQoL tool other than OHIP-14, including other OHIP versions (e.g. OHIP-5) and other questionnaires (e.g. GOHAI) - Adequate OHIP data not reported and cannot be calculated (e.g. publications reporting only median values, p values of between-group differences or regression analysis coefficients) - OHIP data reported without division into adequate diabetes and non-diabetic groups
Study design	Cohort, case-control, cross-sectional (comparison of DM2 vs. no-DM2) studies; in calculation of mean OHIP-14 total score also single-arm studies were included	- Non-primary research publication (review, comment, editorial, opinion) - Interventional study (in cases of interventional studies including non-diabetic cohort/arm, the inclusion of baseline OHIP-14 data, treated as cross-sectional or single-arm data [for diabetic patients], were considered) - Case series - Case report - Expert panel
Other	Studies published in English or Polish	Meeting abstracts and posters

Table S6. Detailed characteristics and main outcomes of the included studies.

Study (country)	Design, sampling	Study population	OHRQoL assessment	Diabetic group	Non-diabetes group	Main reported outcomes of OHIP-14 assessment in diabetic/control groups:
Nayak 2017 (India) [1]	Case-control; sampling method not described	Source population: were recruited from the monthly diabetic outpatient clinic of a private hospital, and type II diabetic patients who were visiting the outpatient department of the dental college during the study period (October 2013–March 2014). <u>Inclusion criteria:</u> - NR <u>Exclusion criteria:</u> - NR	OHIP-14 <u>administration:</u> personal interview about any of the difficulties in the previous 12 months	No definition of type II diabetes mellitus was provided. N = 138	Subjects who reported during the same period without diabetes and with similar age group. N = 128	1) Statistically significant difference was found when overall total OHIP score was compared among control and test groups: 25.82 (SD: 14.48) vs 30.64 (SD: 14.93), respectively, $p = 0.008$. 2) Out of seven domains OHIP-14, six showed statistically significant difference, to the detriment of diabetic patients: physical pain (1.75 [SD: 1.18] vs 2.12 [SD: 1.18], $p = 0.013$), psychological discomfort (1.82 [SD: 1.10] vs 2.19 [SD: 1.15], $p = 0.008$), physical disability (1.88 [SD: 1.07] vs 2.27 [SD: 1.10], $p = 0.005$), psychological disability (1.88 [SD: 1.12] vs 2.22 [SD: 1.11], $p = 0.0135$), social handicap (1.89 [SD: 1.16] vs 2.25 [SD: 1.13], $p = 0.012$) and handicap (1.86 [SD: 1.16] vs 2.21 [SD: 1.12], $p = 0.0115$). No significant differences were noted in functional limitation domain (1.82 [SD: 1.16] vs 2.06 [SD: 1.13], $p = 0.08$). 3) Out of 14 questions, OHIP-4 ($p = 0.02$), OHIP-6 ($p = 0.03$), OHIP-8 ($p = 0.02$), OHIP-13 ($p = 0.006$), and OHIP-14 ($p = 0.006$) were statistically significant, to the detriment of diabetic patients.

Study (country)	Design, sampling	Study population	OHRQoL assessment	Diabetic group	Non-diabetes group	Main reported outcomes of OHIP-14 assessment in diabetic/control groups:
<i>Khalifa 2020</i> (The United Arab Emirates) [2]	Case-control, matched controls (age), sampling method not described	<u>Source population:</u> adults with T2DM were selected from a list of patients attending the clinics at the University Dental Hospital Sharjah and University Hospital Sharjah. <u>Inclusion criteria:</u> • diagnosis of T2DM was based on subjects' existing medical records • at least 10 natural teeth • no known major medical complications such as coronary heart disease • no antibiotic use during the last 3 months • no steroidal or nonsteroidal anti-inflammatory medication use during the last 3 weeks • no treatment with immunosuppressive chemotherapy • no professional periodontal treatment received during the last 6 months <u>Exclusion criteria:</u> • NR	<u>OHIP-14 administration:</u> self-administered	Diagnosis of T2DM was based on subjects' existing medical records. N = 88	Age-, marital status-, and level of education-matched non-diabetic individuals, registered at the same hospitals. To confirm that participants in the control group were not diabetic, fasting blood glucose levels were checked and those with values above 110 mg/dl were excluded. N = 88	1) No significant differences ($p = 0.37$) were found between diabetic patients and the control group in the assessment of the mean OHIP-14 total score (13.7 [SD: 9.7] vs 12.4 [SD: 9.5], respectively), as well as its particular domains: functional limitation (1.5 [SD: 1.4] vs 1.2 [SD: 1.6], $p = 0.2$), physical pain (2.5 [SD: 2.1] vs 2.4 [SD: 2.0], $p = 0.6$), psychological discomfort (2.2 [SD: 1.9] vs 2.0 [SD: 1.9], $p = 0.72$), physical disability (2.7 [SD: 1.8] vs 2.6 [SD: 1.9], $p = 0.6$), psychological disability (1.9 [SD: 1.7] vs 1.7 [SD: 1.7], $p = 0.38$), social handicap (1.5 [SD: 1.6] vs 1.2 [SD: 1.4], $p = 0.17$) and handicap (1.3 [SD: 1.6] vs 1.4 [SD: 1.5], $p = 0.63$). 2) Among diabetic patients, CAL was significantly ($p < 0.05$) associated with the social disability ($B = 0.98$ [95% CI: 0.11; 1.88]) and handicap ($B = 1.2$ [95% CI: 0.36; 2.01]) domains ($p < 0.05$).

Study (country)	Design, sampling	Study population	OHRQoL assessment	Diabetic group	Non-diabetes group	Main reported outcomes of OHIP-14 assessment in diabetic/control groups:
<i>Chen 2023</i> (control group before therapy; China) [3]	Single-arm study (originally RCT trial); sampling method not described	<u>Source population:</u> patients with T2DM and CP admitted to the Department of Stomatology in Hainan Medical College Second Affiliated Hospital, China. <u>Inclusion criteria:</u> • met the diagnostic criteria for T2DM • disease course of more than 1 year • met the diagnostic criteria for CP • had 15 or more teeth • obtained informed consent <u>Exclusion criteria:</u> • concurrent cardiovascular disease • history of antibiotic or nonsteroidal anti-inflammatory drug treatment within the previous six months • history of periodontal treatment within the previous six months • smoking history	<u>OHIP-14 administration:</u> unclear	No definition of type II diabetes mellitus was provided. N = 45	NA	1) Mean (SD) OHIP-14 total score before treatment: 14.82 (1.71)
<i>Kakoei 2016</i> (Iran) [4]	Single-arm study (cross-sectional study); sampling method not described	<u>Source population:</u> patients with diabetes, consecutively selected from those referring to public hospitals in Kerman, Iran. <u>Inclusion criteria:</u> • diabetes • 17-75 years of age <u>Exclusion criteria:</u>	<u>OHIP-14 administration:</u> self-administered	The diagnostic criteria in diabetic group were as follows: hemoglobin A1c of 6.5% or higher; fasting plasma glucose (FPG) of 126 mg/dl or	NA	1) Mean (SD) OHIP-14 total score before treatment: 3.63 (6.50) 2) No significant relationships were observed between the mean scores of OHRQoL and gender, education, affliction with candidiasis (yes: 6.01 [SD: 3.25] vs. no: 7.23 [SD: 6.01], $p = 0.350$), and history of frequent abscess (yes: 6.42

Study (country)	Design, sampling	Study population	OHRQoL assessment	Diabetic group	Non-diabetes group	Main reported outcomes of OHIP-14 assessment in diabetic/control groups:
		- patients taking any medications with oral manifestations - smokers - patients with mental problems		higher in two occasions or 2-hour FPG of 200 mg/dl or higher in two occasions; patients with classic symptoms and signs of hyperglycemia, hyperglycemia crises and a random plasma glucose level of 200 mg/dl or higher. In addition, the subjects reported minimum use of medications to control other systemic conditions and did not use any medications with oral manifestations. N = 121		[SD: 3.51] vs. no: 7.40 [SD: 4.57], $p = 0.780$); there was a weak, but significant relationship between the score of OHRQoL and blood glucose level and age ($p = 0.002$ and $p = 0.016$, respectively) – with an increase in age and blood glucose level the score of OHRQoL increased, indicating a decrease in OHRQoL; the mean score of OHRQoL had significant relationships with xerostomia (yes: 7.75 [SD: 5.22] vs. no: 3.25 [SD: 1.45], $p = 0.005$), tongue blade sign (yes: 7.92 [SD: 5.32] vs. no: 4.29 [SD: 2.03], $p = 0.031$), and burning sensation in the oral cavity (yes: 6.50 [SD: 3.10] vs. no: 6.16 [SD: 6.02], $p = 0.003$)

Study (country)	Design, sampling	Study population	OHRQoL assessment	Diabetic group	Non-diabetes group	Main reported outcomes of OHIP-14 assessment in diabetic/control groups:
Mohsin 2017 (Pakistan) [5]	Single-arm study (cross-sectional study); sampling method not described	<u>Source population:</u> patients attending diabetic clinic at Baqai Institute of Diabetology and Endocrinology. <u>Inclusion criteria:</u> - type II diabetes - aged ≥ 30 years <u>Exclusion criteria:</u> - patients with type 1 and gestational diabetes	<u>OHIP-14 administration:</u> self-administered	No definition of type II diabetes mellitus was provided. N = 101	NA	1) Mean (SD) OHIP-14 total score: 5.67 (5.71) 2) Mean (SD) score of OHIP-14 particular domains: functional limitation (1.31 [SD: 1.17]), physical pain (1.12 [SD: 1.24]), psychological discomfort (1.13 [SD: 1.44]), physical disability (0.45 [SD: 0.93]), psychological disability (0.49 [SD: 0.93]), social handicap (0.712 [SD: 1.03]) and handicap (0.42 [SD: 0.82]) 3) The mean score of OHIP of females was higher than males in terms of total score ($p = 0.012$), functional limitations domain ($p = 0.012$) and physical pain domain ($p = 0.019$) and these differences were statistics significant; no correlation was found between glycemic control (HbA1c, $p = 0.995$) or other biochemical parameters and OHIP-14 total score

Study (country)	Design, sampling	Study population	OHRQoL assessment	Diabetic group	Non-diabetes group	Main reported outcomes of OHIP-14 assessment in diabetic/control groups:
Tabesh 2023 (Iran) [6]	Single-arm study (cross-sectional study); sampling method not described	<u>Source population:</u> type II diabetic patients referred to the Department of Oral Medicine at the School of Dentistry of Isfahan University of Medical Sciences, Iran. <u>Inclusion criteria:</u> - confirmed diagnosis of type II DM - literacy sufficient to fill out the questionnaires <u>Exclusion criteria:</u> - presence of any systemic diseases affecting the salivary glands, such as Sjögren's syndrome, alcoholism, a corticosteroid or hormone therapy - history of head and neck radiotherapy/chemotherapy	<u>OHIP-14 administration:</u> self-administered	No definition of type II diabetes mellitus was provided. N = 200	NA	- Mean (SD) OHIP-14 total score: 13.76 (8.41) - Mean (SD) score of OHIP-14 particular domains: functional limitation (2.15 [SD: 1.59]), physical pain (2.46 [SD: 1.89]), psychological discomfort (2.35 [SD: 1.84]), physical disability (1.91 [SD: 1.60]), psychological disability (1.83 [SD: 1.68]), social handicap (1.39 [SD: 1.51]) and handicap (1.65 [SD: 1.55]) - As the XI score increased, the total OHIP14 score also increased, which translates into worse OHRQoL ($p < 0.001$; $r = 0.444$ – significant impact was also observed for all domain of the OHIP-14 questionnaire); significant relationships were observed between the mean scores of OHRQoL and age ($p < 0.001$; $r = 0.254$), fasting blood glucose ($p = 0.040$; $r = 0.146$), HbA1c ($p = 0.030$; $r = 0.198$), disease duration ($p < 0.001$; $r = 0.421$) and denture wearing ($p < 0.001$); there is no significant association in the case of gender ($p = 0.815$)
Verhulst 2019 (The Netherlands) [7]	Single-arm study (cross-sectional study – part of a cluster-randomized controlled trial);	<u>Source population:</u> patients with T2DM that attended the primary care system in Amsterdam (aiming at a total of 24 offices). <u>Inclusion criteria:</u>	<u>OHIP-14 administration:</u> self-administered	No definition of type II diabetes mellitus was provided. N = 764	NA	- Mean (SD) OHIP-14 total score: 2.5 (5.2) - Mean (SD) score of OHIP-14 particular domains: functional limitation (0.3 [SD: 0.8]), physical pain (0.8 [SD: 1.4]), psychological discomfort (0.5

Study (country)	Design, sampling	Study population	OHRQoL assessment	Diabetic group	Non-diabetes group	Main reported outcomes of OHIP-14 assessment in diabetic/control groups:
	sampling method not described	• ≥18 years • diagnosed with T2DM • follows the standardized primary care protocol, including an annual examination • understands spoken and written Dutch <u>Exclusion criteria:</u> • NR				[SD: 1.2), physical disability (0.30 [SD: 0.90]), psychological disability (0.3 [SD: 0.9]), social handicap (0.2 [SD: 0.7]) and handicap (0.2 [SD: 0.7]) 3) Mean (SD) OHIP-14 total score in particular subgroups: pain in mouth (yes: 5.1 [SD: 7.4] vs no: 2.0 [SD: 4.6], $p < 0.001$), xerostomia (yes: 3.0 [SD: 5.7] vs no: 2.2 [SD: 4.9], $p < 0.05$), bad breath (yes: 3.5 [SD: 6.1] vs no: 2.2 [SD: 4.9], $p < 0.01$), periodontitis (yes: 2.6 [SD: 4.7] vs no: 0.8 [SD: 3.4], $p < 0.001$) and edentulous (yes: 3.6 [SD: 7.0] vs no: 2.3 [SD: 4.8], $p < 0.05$)

Abbreviations: NA – not applicable; NR – not reported.

Table S7. Quality of the included studies, based on the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies developed by NHLBI [8].

Criteria (exposure: diabetes; outcome: OHRQoL measured with OHIP-14)	<i>Nayak 2017</i>	<i>Khalifa 2020</i>	<i>Chen 2023</i>	<i>Kakoei 2016</i>	<i>Mohsin 2017</i>	<i>Tabesh 2023</i>	<i>Verhulst 2019</i>
1. Was the research question or objective in this paper clearly stated?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the study population clearly specified and defined?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Was the participation rate of eligible persons at least 50%?	CD	CD	CD	CD	CD	CD	CD
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5. Was a sample size justification, power description, or variance and effect estimates provided?	No	Yes	No	No	No	No	No
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	CD	CD	CD	CD	CD	CD	CD
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	CD	CD	CD	CD	CD	CD	CD
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10. Was the exposure(s) assessed more than once over time?	NA	NA	NA	NA	NA	NA	NA
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
12. Were the outcome assessors blinded to the exposure status of participants?	CD	Yes	CD	CD	CD	CD	CD
13. Was loss to follow-up after baseline 20% or less?	NA	NA	NA	NA	NA	NA	NA
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	No	Yes	Yes	Yes	Yes	Yes	Yes
QUALITY RATING	Fair	Fair	Fair	Fair	Fair	Fair	Fair

Abbreviations: CD – cannot determine; NA – not applicable; NR – not reported.

Table S8. Results of the univariate and bivariate meta-regression analyses for the mean difference in total OHIP score, fixed model.

Analysis	Parameter	Nb of studies	Point estimate (β coefficient)	Standard error	Z-value	p-value (2-sided)	95% confidence interval
Univariate: age	Intercept	6	20.651	22.1422	0.933	0.351	-22.747; 60.049
	Mean age [years]		-0.240	0.3830	-0.627	0.531	-0.991; 0.511
Univariate: proportion of males	Intercept	5	11.381	11.2069	1.016	0.310	-10.584; 33.347
	Proportion of males [%]		-0.132	0.2640	-0.501	0.616	-0.650; 0.385
Bivariate: age, proportion of males	Intercept	5	13.898	23.6392	0.588	0.557	-32.434; 60.230
	Mean age [years]		-0.098	0.3843	-0.256	0.798	-0.852; 0.655
	Proportion of males [%]		-0.068	0.5610	-0.121	0.904	-1.167; 1.032

Table S9. PRISMA 2020 checklist [9, 10].

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title, keywords
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction, paragraphs 1–4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction, paragraph 5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Methods: Search strategy, Data analysis and Supplementary materials
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Methods: Search strategy
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary materials: tables S1–S4
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Methods: Data analysis, paragraph 1
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Methods: Data analysis, paragraph 2
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Methods: Search strategy Data analysis (paragraph 3) and Supplementary materials (Table S5)
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding	Methods: Data

Section and Topic	Item #	Checklist item	Location where item is reported
		sources). Describe any assumptions made about any missing or unclear information.	analysis, paragraph 2
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Methods: Data analysis (paragraph 4) and Supplementary materials (Table S7)
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Data analysis, paragraph 5
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Data analysis, paragraph 2, 5, 6
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Data analysis, paragraph 5, 6
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Data analysis, paragraph 6
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Data analysis, paragraph 5, 6
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Data analysis, paragraph 5, 6
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Data analysis (subgroup analyses, meta-regression)
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Data analysis, paragraph 2
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Data analysis, paragraph 4 (GRADE assessment)
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Results of systematic review, Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Not applicable

Section and Topic	Item #	Checklist item	Location where item is reported
Study characteristics	17	Cite each included study and present its characteristics.	Results, characteristics of included studies, Table 1, Table 2 and Table S6
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Results, reliability of included studies (NHLBI assessment) and Table S7
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Results and Figure 2, Figure 3 and Figure 4 and Table S8, Figure S1, Figure S2
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Not applicable
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Results and Figure 2, Figure 3 and Figure 4
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Results (comparison of T2DM vs healthy individuals, variability among studies, sensitivity analysis and correlation of baseline characteristics with OHRQoL) and Figure 2, Figure 3 and Figure 4
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Results, sensitivity analysis
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Not applicable
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Results, reliability of included studies (GRADE assessment)

Section and Topic	Item #	Checklist item	Location where item is reported
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion, paragraphs 1-6
	23b	Discuss any limitations of the evidence included in the review.	Discussion, paragraphs 7
	23c	Discuss any limitations of the review processes used.	Discussion, paragraph 7
	23d	Discuss implications of the results for practice, policy, and future research.	Conclusions
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Not registered
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Internal protocol, available upon request from the authors
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Not applicable
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Funding statement
Competing interests	26	Declare any competing interests of review authors.	Conflict of interest statement
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Available upon request from the authors

Table S10. GRADE assessment [11].

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other ⁶	T2DM	healthy	Relative (95% CI)	Absolute (95% CI)		
OHIP-14 total												
2	Non-RCT ¹	Serious ²	Not serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 2.68 (0.47; 4.89)	-	⊕⊕ LOW	CRITICAL
Functional limitations												
2	Non-RCT ¹	Serious ²	Not serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 0.26 (0.02; 0.49)	-	⊕⊕ LOW	IMPORTANT
Physical Pain												
2	Non-RCT ¹	Serious ²	Not serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 0.32 (0.06; 0.58)	-	⊕⊕ LOW	IMPORTANT
Psychological Discomfort												
2	Non-RCT ¹	Serious ²	Not serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 0.34 (0.09; 0.58)	-	⊕⊕ LOW	IMPORTANT
Physical Disability												
2	Non-RCT ¹	Serious ²	Not serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 0.34 (0.10; 0.57)	-	⊕⊕ LOW	IMPORTANT
Psychological Disability												

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other ⁶	T2DM	healthy	Relative (95% CI)	Absolute (95% CI)		
2	Non-RCT ¹	Serious ²	Not serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 0.31 (0.07; 0.55)	-	⊕⊕ LOW	IMPORTANT
Social Disability												
2	Non-RCT ¹	Serious ²	Not serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 0.34 (0.11; 0.58)	-	⊕⊕ LOW	IMPORTANT
Handicap												
2	Non-RCT ¹	Serious ²	Serious ³	Not serious ⁴	Not serious ⁵	None	226	216	WMD = 0.17 (-0.27; 0.60)	-	⊕ VERY LOW	IMPORTANT

1 only non-RCT studies, whose quality was assessed as "fair" according to the NHLBI scale, were included in the meta-analysis.

2 no blinding was used in the included studies.

3 the proportion of the variability in effect estimates that is due to true heterogeneity rather than chance is not important in most conducted meta-analyses ($p \geq 0.1$ in Cochran's Q test and the meta-analysis was conducted via fixed effects model; the exception being the analysis of the handicap domain of the OHIP-14 scale (the meta-analysis was conducted via random effects model, $p = 0.0963$ in Cochran's Q test).

4 the included studies meet the adopted PECOS criteria.

5 no significant deficiencies were found to be reported.

6 e.g. imprecise estimate of effect size or too few data, strong or very strong association between intervention and endpoint, high probability of publication bias, dose-dependence of the effect, unadjusted confounding factors that would likely reduce the observed effect.

Figure S1. Prediction line determined by meta-regression analysis for mean age as an independent variable.

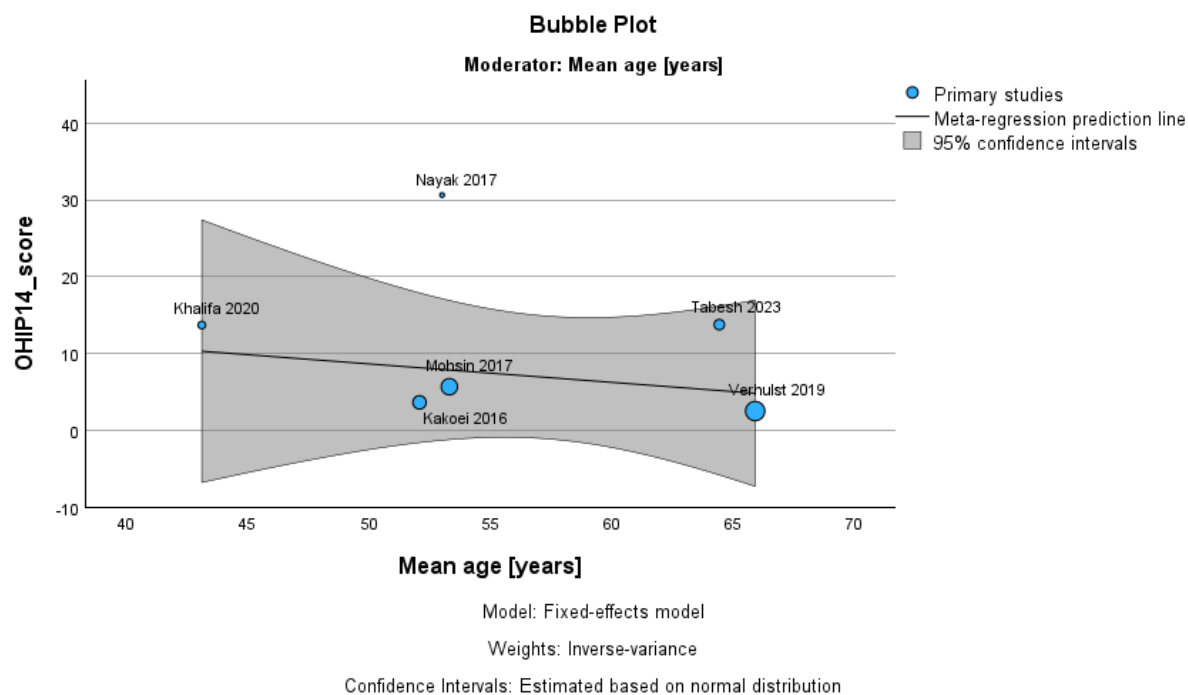
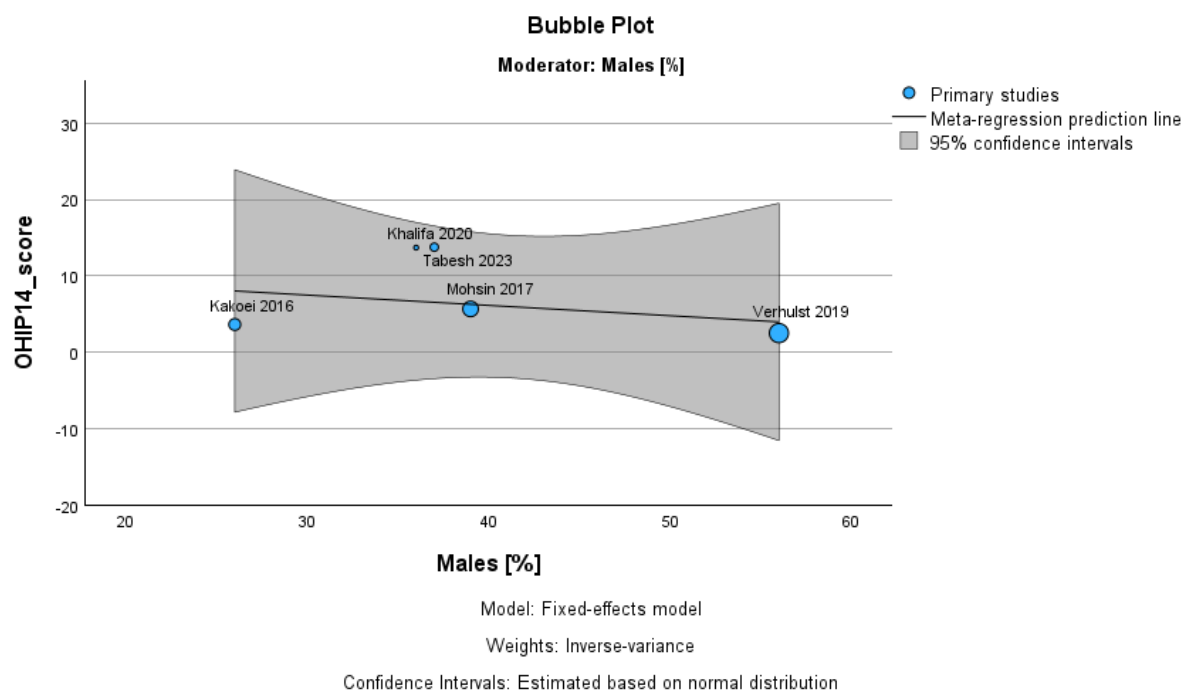


Figure S2. Prediction line determined by meta-regression analysis for proportion of males



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