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Effect of routinely assessing and addressing depression and diabetes distress on clinical outcomes among adults with type 2 diabetes: A systematic review

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Title: Effect of routinely assessing and addressing depression and diabetes distress on clinical outcomes among adults with type 2 diabetes: A systematic review

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Abstract

Objectives: This study examined the effect of using Patient-Reported Outcome Measures

(PROMs) routinely to assess and address depressive symptoms and diabetes distress among adults with type 2 diabetes.

Design: A systematic review of published peer-reviewed studies.

Data Sources: Medline, Embase, CINAHL Complete, PsycInfo, The Cochrane Library, and Cochrane Central Register of Controlled Trials were searched.

Eligibility criteria: Studies including adults with type 2 diabetes, published in English, from the inception of the databases to 3 August 2020 inclusive; and where the intervention included completion of a PROM of depressive symptoms and/or diabetes distress, with feedback of the responses to a healthcare professional.

Data extraction and synthesis: Using Covidence software, screening and risk of bias assessment were conducted by two reviewers independently with any disagreements resolved by a third reviewer.

Results: The search identified 3,581 citations, of which 147 full-text citations were assessed for eligibility, and eight studies met the inclusion criteria. Four studies involved assessment of depressive symptoms only, two studies assessed diabetes distress only, and two studies assessed both. All studies had an associated co-intervention. When depressive symptoms were assessed (n=6), a statistically significant between-group difference in depressive symptoms was observed in five studies; with a clinically significant (≥0.5%) between-group difference in HbA1c in one study. Diabetes distress was also assessed in this study. When diabetes distress was assessed (n=4), one study demonstrated statistically significant difference in depressive symptoms and diabetes distress; with a clinically significant between-group difference in HbA1c observed in two studies.

Conclusion: Studies are sparse in which PROMs are used to assess and address depressive symptoms or diabetes distress during routine clinical care of adults with type 2 diabetes. Further research is warranted to understand how to integrate PROMs into clinical care efficiently and determine appropriate interventions to manage identified problem areas.

PROSPERO registration number: CRD42020200246

Article Summary

Strengths and limitations of this study

- The review focuses on depressive symptoms and diabetes distress in people with type 2 diabetes, an important aspect of diabetes management.
- Systematic searching of five databases with independent review of abstracts and studies by two reviewers.
- Meta-analysis was not possible due to heterogeneity in method and frequency of PROM completion, communication of PROM responses to healthcare professionals, and differing associated co-interventions.

Keywords
Diabetes Mellitus, Type 2, Depression, Patient Reported Outcome Measures

Word Count: 3298

Introduction

Type 2 diabetes is a global health priority, with an estimated 463 million people with diabetes in 2017, set to rise to 700 million people in 2045.[1] Up to four in ten adults with type 2 diabetes experience emotional health problems, such as depression, anxiety, and diabetes distress.[2 3] While depression is a *general* negative affect; diabetes distress is the negative emotional or affective response specific to the day-to-day living with diabetes.[3-5] The relationship between diabetes distress and depressive symptoms is bi-directional: elevated diabetes distress is a predictor of future depression, and depression predicts future diabetes distress.[6 7] While early studies have linked depressive symptoms to sub-optimal glycaemia;[8] more recent research has demonstrated that diabetes distress affects glycaemia more than depressive symptoms.[5 9] Elevated depressive symptoms and diabetes distress are associated with reduced diabetes self-care and increased risk of diabetes-related complications, impaired quality of life, mortality, and an estimated 50% increase in healthcare costs.[6 10-15] Recent systematic reviews have focused on interventions for the management of diabetes distress; however, the first step is to identify people with depressive symptoms or diabetes distress requiring interventions in clinical practice.[16-18]

Guidelines have acknowledged the importance of assessing psychological well-being as part of diabetes care for over 25 years.[19] Given the growing evidence that diabetes-tailored psychological interventions reduce elevated distress and glycaemia, international diabetes guidelines have issued recommendations for routine assessment of depressive symptoms and diabetes distress.[16 20-25] Guidelines vary in terms of the specific patient-reported outcome measures (PROMs) recommended to assess depressive symptoms or diabetes distress. PROMs are standardised, validated questionnaires to assess latent constructs such as emotional well-being, treatment satisfaction, perceived health or functional status, or health-related quality of life.[26] Recent consensus from the International Consortium of Health Outcomes Measurement (ICHOM) recommends standardising the assessment of diabetes distress, depressive symptoms and general emotional well-being – with use of the Problem Areas In Diabetes (PAID) scale,

Patient Health Questionnaire – 9 (PHQ-9) and World Health Organisation – Five Well-Being Index (WHO-5), respectively – within clinical diabetes care. [27]

Despite these recommendations for using PROMs, 60% of healthcare professionals only discuss emotional issues if initiated by the person with diabetes.[28] Healthcare professionals need efficient systems to both assess and address depressive symptoms and diabetes distress as part of routine diabetes care.[3] For healthcare professionals to use PROMs, they need to understand the utility of PROMs in supporting people with type 2 diabetes clinically, not just for audit or research purposes,[29 30] and they need guidance in how to use and interpret PROM responses in clinical consultations.[31 32]

Thus, the aim of this systematic review is to examine the effect of using PROMs routinely to assess and address depressive symptoms and/or diabetes distress among adults with type 2 diabetes on: (1) glycaemia as measured by HbA1c; (2) self-reported depressive symptoms or diabetes distress; (3) self-reported general emotional well-being or health-related quality of life; (4) self-reported diabetes self-management; (5) referrals for psychiatric or psychological therapy; (6) self-reported quality of patient-professional communication; and (7) self-reported satisfaction with the consultation.

Methods

The protocol for this systematic review has been published,[33] and the methods are summarised below. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[34] This systematic review is registered on the International Prospective Register of Systematic Reviews (PROSPERO: CRD42020200246).

Eligibility criteria

Inclusion criteria: Studies were eligible if: the design was a randomised controlled trial (RCT), interrupted time-series study, (prospective or retrospective) cohort study, case-control study, or analytical cross-sectional study; participants were adults (18 years or older) with type 2 diabetes

from any country; interventions involved a) participants completing a PROM for depressive symptoms and/or diabetes distress *and* b) use of PROM responses by the healthcare professional in consultation with the person with type 2 diabetes.

Exclusion criteria: Studies were excluded if they involved: people under 18 years of age, type 1 diabetes or gestational diabetes; or the collection of PROM data but no use of the data in the clinical consultation.

Data sources and searches

A systematic search strategy was used to identify studies. The search was limited to papers published in English and before 3rd of August 2020. The search strategy was developed in consultation with a librarian from a biomedical library (complete search strategy: Supplementary Document 1). Databases searched included MEDLINE (Ovid), EMBASE (Ovid), CINAHL Complete (EBSCO), APA PsycInfo (Ovid), The Cochrane Library (Ovid), and Cochrane Central Register of Controlled Trials (Ovid).

Study selection and data extraction

Two reviewers (RM and a second member of the review team (JMN, BH, LC, DK or FCSH)) screened studies independently based on the inclusion criteria using Covidence software. Both reviewers screened the title and abstract of all eligible studies, followed by full-text screening of the shortlisted studies. Any disagreements about selection, assessment, and data extraction in the included studies were discussed between the two reviewers, and if required, a third reviewer was involved in the discussion. Reference lists were not checked for studies. Data extraction was undertaken by RM with 20% checked by LC. The extracted data were: study settings, participants, description of the interventions, comparators, study duration, length of follow-up, and outcome measures. The authors of the selected studies were contacted for additional data (when published details were insufficient), with one month allowed for response.

Quality assessment

Eligible studies were assessed for risk of bias by two reviewers (RM and a second member of the review team (JMN, BH or DK)) independently using the Cochrane Risk of Bias 2 tool.[35] Any disagreements were discussed between the two reviewers, and if required, a third reviewer was involved in the discussion.

Data synthesis

Due to heterogeneity regarding method and frequency of PROM completion, communication of PROM responses to healthcare professionals and differing associated co-interventions (actions based on PROM responses) it was not possible to conduct a meta-analysis. Therefore, the results are summarised narratively.

Patient and Public Involvement

Patients or public were not involved in the conduct of this systematic review.

Ethics approval

This is a systematic review, ethical approval was not required.

Results

The systematic search identified 3,581 citations, of which 147 full-text citations were assessed for eligibility, and eight studies met the inclusion criteria (Figure 1).

Insert Figure 1 here

Figure 1 PRISMA Flow Diagram[34]

Characteristics of included studies

The eight included studies were published between 2009 and 2019 (Table 1). The overall number of participants across all eight studies was N=2850, ranging from N=40 to N=1,306 per study. Five

of the eight studies were conducted in the USA,[36-40] with the remainder conducted in Australia,[41] Germany,[42] and Iceland.[43] Most study designs were RCTs (n=7), [36 37 39 40-43] one of which was a pilot study (n=1),[41] and one was an observational study (n=1).[38] Clinical settings varied across studies, including: general practice (n=3);[37 39 40] both primary care and hospital clinics (n=2); [36 38] specialist outpatient clinic (n=2);[41 43]and a specialist rehabilitation service (n=1).[42]

Insert Table 1 here

Table 1. Study characteristics

Author (year) Country	Clinical setting	Study design and n per arm	Intervention PROM	Method and frequency of PROM completion	Summary of actions based on PROM responses	Control arm
Cummings et al. (2019) [39] USA	Adults with symptoms of distress and/or depression attending general practice	12-month RCT: Intervention n=67/ usual care n=72	PHQ-9* DDS-17**	In-person completion with trained study team member twice, six months apart	Stratified treatment to 16 sessions of cognitive behavioural therapy or lifestyle coaching based on PROM responses	Educational materials and usual care with GP.
Dobler et al. (2018) [42] Germany	Adults attending specialist outpatient clinic, recruitment during inpatient rehabilitation stay	12-month RCT: Intervention n=98 / Control n=101	PAID**, WHO-5, PHQ-9*	Telephone completion with trained study team member, monthly	Behaviour motivation plan developed. Monthly follow-up telephone calls using PHQ-2 (with progression to PHQ9 if PHQ score ≥3) to identify and address emotional problems. Severity of symptoms guided counseling techniques, increase in call frequency, or referral	Written information on diet, physical activity by mail at 3 and 9 months.
Ell et al. (2011) [37] USA	Adults with PHQ9 response ≥10, attending primary care safety net clinics	24-month RCT: Intervention n=193/ Enhanced usual care n=194	PHQ-9*	Telephone completion with trained study team member once	Collaborative care model using structured stepped-care algorithm, with patient preferences for problem-solving therapy or anti-depressants guiding treatment	Standard care, depression educational pamphlets and social resource list. GPs informed of depression diagnosis.
Johnson et al. (2014) [40] USA	Adults with PHQ >10, attending	12-month RCT: Intervention n=95 / Active	PHQ-9*	Telephone completion with trained study	Case-managers delivered individualised care, in collaboration with psychiatrist and	GP notified by letter of elevated PHQ-9 responses.

Author (year) Country	Clinical setting	Study design and n per arm	Intervention PROM	Method and frequency of PROM completion	Summary of actions based on PROM responses	Control arm
	general practice	control n=62/ usual care n=71		team member at least monthly until PHQ-9 <10	endocrinologist, with treatment recommendations to GP based on a treatment algorithm and PROM responses	
Naik et al. (2019) [36] USA	Adults with T2D attending hospital and outpatient community Veterans Affairs clinics	12-month RCT: Intervention n=136 / Enhanced usual care (EUC) n=89	PHQ-9*	Telephone completion with trained study team member once 12 months	Nine telephone coaching sessions with trained study members using workbooks guiding the discussion and tracking progress to set and assess goals related to wellness, diet, exercise medication management.	Participants informed of PHQ-9 responses with educational materials.
Rees et al. (2017) [41] Australia	Adults with diabetes related retinopathy and moderate diabetes distress attending specialist outpatient clinic	6-month pilot RCT: Intervention n=21 / control n=19	DDS**	In-person completion with trained study member once	PROM responses guided eight 45–60-minute problem solving therapy sessions	Pamphlets on diabetes-specific topics
Sigurdardottir et al. (2009) [43] Iceland	Adults attending specialist outpatient clinic	6-month RCT: Intervention n=28 / Control n=25	PAID** DKT, DES, Summary of diabetes self-care measure	In-person completion at clinic with diabetes educator once	Diabetes educators delivered individual educational sessions based on empowerment theory. PROM responses identified barriers to goals with a weekly follow-up call for five weeks	Information booklet about T2D and attended usual diabetes clinics.
Wu et al. (2018) [38]	Adults attending	6-month observational:	PHQ-2, PHQ-9*	Initially completed via	PROM responses linked to clinical decision support that generated	Standard primary care. GPs offered optional training.

Author (year) Country	Clinical setting	Study design and n per arm	Intervention PROM	Method and frequency of PROM completion	Summary of actions based on PROM responses	Control arm
USA	primary care or hospital-based safety net clinics	Technology-facilitated care n=432/ supported care n=461/ usual care n=416		telephone with trained study member. Then monthly – quarterly completion via automated calls	action reminders for healthcare professionals depending on PROM responses	

*depression, **diabetes distress

DDS: Diabetes Distress Scale; DES: Diabetes Empowerment Scale; DKT: Diabetes Knowledge Test; GP: general practitioner; PAID: Problem Area In Diabetes scale, PHQ: Patient Health Questionnaire (2 items or 9 items), WHO-5: The World Health Organisation Five-item Well-Being Index

Risk of bias of included studies

Five of the eight studies were rated as having a low risk of bias (Table 2). [37 39-41 43] Methodological concerns were observed in three studies. [36 38 42] Dobber *et al.* reported outcomes for 98 of the 123 participants randomised to the intervention group and did not state how missing outcomes were dealt with; intention to treat was not reported.[42] Wu *et al.* assigned participants to intervention groups based on the clinic attended with non-random allocation.[38] Naik *et al.* reported 12-month outcome data for only 90 of the 136 intervention participants; intention to treat was not reported. [36] In most studies, due to the study design, participants and study team members could not be blinded to participants' group allocation. Two studies had small sample sizes.[41 43]

Insert Table 2 here

Table 2. Risk of bias assessment

Author (year)	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Cummings et al. (2019) [39]	Low	Low	Low	Low	Low	Low
Dobler et al. (2018) [42]	Low	Low	High	Low	Low	Some concerns
Ell et al. (2011) [37]	Low	High	Low	Low	Low	Low
Johnson et al. (2014) [40]	Some concerns	Low	Low	Low	Low	Low
Naik et al. (2019) [36]	Low	Low	Some concerns	Low	Low	Some concerns
Rees et al. (2017) [41]	Low	Low	Low	Low	Low	Low
Sigurdardottir et al. (2009) [43]	Low	Some concerns	Low	Low	Low	Low
Wu et al. (2018) [38]	Some concerns	Low	Some concerns	Some concerns	Low	Some concerns

Risk of bias as assessed using the Risk of Bias 2.[35]

Intervention

Interventions to assess depressive symptoms and/or diabetes distress

Four of the eight studies assessed depressive symptoms alone,[36-38 40] two assessed depressive symptoms and diabetes distress,[39 42] and two assessed diabetes distress alone.[41 43] All six studies assessing depressive symptoms used the Patient Health Questionnaire (PHQ).[36-40 42] One study used the PHQ-2 for brief screening with responses of more than three proceeding to the PHQ-9.[38] Diabetes distress was assessed in two studies using the Diabetes Distress Scale (DDS),[39 41] and in two studies using the Problem Areas In Diabetes (PAID) scale.[42 43]

PROMs were completed either in-person (n=4),[39-42] or via telephone (n=4).[36-38 43] In six studies, PROM responses were collected by study team members not involved in ongoing clinical care,[36 37 39-42] either via telephone,[36 37 40 42] or at the clinic with a study team member.[39 41] One study collected PROM responses using automated calls.[38] In one study, PROM completion was at the clinic with the diabetes educator.[43]

Feedback of PROM responses provided to treating healthcare professionals varied. Two studies trained case managers in making treatment recommendations to primary care health professionals based on case collaboration and treatment algorithms.[37 40] In studies where trained study members collected PROM responses, the mechanism by which PROM data was provided to the treating healthcare professionals was not reported.[41 42] In the Naik *et al.* study, the general practitioner received a secure message notifying the HbA1c results and PHQ-9 response.[36] Wu *et al.* used PHQ-9 responses to generate action reminders integrated with the disease management registry for healthcare professionals to review.[38]

Co-intervention associated with PROM responses

Each of the eight studies had a co-intervention associated with the PROM completion (see Table 1), which included telephone-assisted psychological therapy or coaching interventions,[36 39 41-43] or healthcare professional interventions of collaborative team care with case management and stepped care treatment algorithms.[37 40] Wu *et al.* linked PROM responses to a clinical decision

support tool that generated action reminders for healthcare professionals based on PROM responses within a disease management register.[38]

Insert Table 3 here

Table 3 Follow-up study outcomes between intervention and control groups

Author (year) Country	Intervention PROM	Length of follow up	HbA1c	Depressive symptoms	Diabetes distress	Other PROM outcomes	Self-management
Cummings et al. (2019) [39] USA	PHQ-9* DDS-17**	12 months	8.9% (2.1) vs 9% (2.2) p = 0.06	PHQ-9: 6.3 (5.9) vs. 7.9 (7) p = 0.01	DDS (RDD): 2.1 (1.2) vs 2.6 (1.3) p = 0.0001	Not assessed	SDSCA: 4.3 (1.4) vs. 3.98 (1.3) p = 0.03
Dobler et al. (2018) [42] Germany	PAID**, PHQ-9*	12 months	mean change -0.7% (1.4) vs. 0.1% (1.7) p = 0.006	PHQ-9: mean change -1.35 (4.3) vs. -0.23 (4.9) p = 0.057	PAID: mean change - 4.77 (14.4) vs. -1.4 (17) p = 0.069	WHO-5: 1.23 (5.7) vs. 0.1 (5.8) p = 0.044	Not assessed
Ell et al. (2011) [37] USA	PHQ-9*	24 months	9.1% (0.29) vs. 8.9% (0.29) p = 0.42	PHQ-9 (reported as >50% reduction): adjusted OR=1.87, 95%CI [1.05–3.32] p = 0.03	Not assessed	SF-12 mental: 44.76 (1.150) vs. 42.48 (1.17) p = 0.001	SDSCA: 3.6 (0.15) vs. 3.41 (0.2) p = 0.26
Johnson et al. (2014) [40] USA	PHQ-9*	12 months	mean change: -0.2% (1.3) vs. -0.2% (1.1) p = 0.47	PHQ-9: 7.1 (5.4) vs. 9.4 (5.9) p = <0.001	PAID-5: mean change -0.6 (0.8) vs. 0.2 (0.9) p = 0.03	EQ-5D: mean change 0.03 (0.1) vs. 0.04 (0.12) p =0.23	Not assessed
Naik et al. (2019) [36] USA	PHQ-9*	12 months	8.7% (1.6) vs 8.9% (2) p = 0.83	PHQ-9: 10.1 (6.9) vs 12.6 (6.5) p = 0.03	Not assessed	Not assessed	Not assessed
Rees et al. (2017) [41] Australia	DDS**	6 months	7.1% (1.1) vs. 8.4% (2.5) p =0.093	PHQ-9: 6.7 (5.9) vs. 9.9 (6.5) p = 0.144	DDS: 2.2 (1.1) vs. 2.5 (0.8) p = 0.427	Not assessed	SDSCA diet: 6.1 (1.1) vs. 5 (1.5) p = 0.026

Author (year) Country	Intervention PROM	Length of follow up	HbA1c	Depressive symptoms	Diabetes distress	Other PROM outcomes	Self-management
Sigurdardottir et al. (2009) [43] Iceland	PAID**	6 months	8.0% (1.16) vs. 7.8% (.081) p = 0.399	Not assessed	PAID: 19.1 (12.9) vs. 13.8 (12.6) p = 0.239	WBQ-12: 28.4 (6.1) vs. 27.4 (5.6) p = 0.544	SDSCA diet: 3.6 (0.4) vs. 3.4 (0.5) p = 0.122
Wu et al. (2018) [38] USA	PHQ-2, PHQ-9*	6 months	8.1% (0.16) vs. 8.0% (0.17) p = 0.57	PHQ-9: 5.16 (0.48) vs. 6.35 (0.49) p = 0.02	Not assessed	SF-12 mental: 49.87 (1.02) vs. 48.38 (1.04) p = 0.17 Satisfaction with diabetes care 4.20 (0.09) vs. 4.01 (0.09) p=0.05	SDSCA: 4.78 (0.12) vs. 4.66 (0.13) p = 0.38

Outcome data are always presented as intervention vs control. Note, Wu et al was an observational study involving three groups, with data related to intervention vs usual care represented here.

Other PROM outcomes included general emotional well-being, mental health and health status, as well as satisfaction with diabetes care

DDS: Diabetes Distress Scale; 5-level EQ-5D: EuroQoL Five Dimensions; PAID: Problem Area in Diabetes scale, PHQ: Patient Health Questionnaire, RDD: Regimen-related Diabetes Distress (a subscale of the DDS); SDSCA: Summary of Diabetes Self-Care Activities, SF-12: 12-Item Short-Form Survey, WBQ: Well-being Questionnaire; WHO-5: The World Health Organisation Five-item Well-Being Index,

Outcomes

Reported outcomes across studies are detailed in Table 3. Referrals to psychology or psychiatry services were not reported. In three studies, in the control arm, healthcare professionals were informed of the elevated depressive symptoms.[36 37 40] In no study were healthcare professionals informed about elevated diabetes distress of participants in the control group.

All eight studies reported glycaemia, measured by HbA1c, as an outcome measure. Where PROM assessed depressive symptoms (n=6), a clinically significant between-group difference in HbA1c was observed only when diabetes distress was also assessed.[42] Where diabetes distress was assessed (n=4), a clinically significant between-group difference in HbA1c was observed in two studies.[41 42] Each of these studies had a co-intervention involving a series of psychological therapy sessions.[41 42] Studies using PROMs as part of stepped care algorithms with care coordination did not demonstrate a clinically or statistically significant glycaemic reduction.[37 40]

All but one study[43] examined the impact of PROMs use on depressive symptoms. Across all seven studies, depressive symptoms (measured with the PHQ-9) reduced in both arms. Where the intervention included assessment of depressive symptoms (n=6), statistically significant difference in depressive symptoms between groups was observed in five studies.[36-40] Where diabetes distress was assessed during the intervention (n=4)[39 41-43], three studies[39 41 42] reported depressive symptoms as an outcome measure, with a significant difference in depressive symptoms between groups observed in one study.[39] Five studies reported diabetes distress as an outcome measure.[39-43] Diabetes distress reduced in both the intervention and control arms across all five studies.[39-43] The difference between groups, favouring the intervention, was statistically significant in two studies. [39 40]

In the Cummings *et al.* study, when therapy was stratified based on elevated levels of depressive symptoms or diabetes distress, improved diabetes self-management was reported.[39] Similarly, in the Rees *et al.* study, when co-interventions focused on people with type 2 diabetes with elevated distress levels receiving individual psychological therapy, an improvement in diabetes

self-management was reported.[41] General emotional well-being, mental health and health status were reported using various measures, including the WHO-5, W-BQ, SF-12, and EQ-5D. No study reported patient-professional communication as an outcome. The Wu *et al.* study was the only one to assess satisfaction with diabetes care, and a statistically significant improvement in the intervention arm was observed.[38]

Discussion

Main findings

To our knowledge, this is the first systematic review to synthesise the evidence related to PROM use to assess and address depressive symptoms and/or diabetes distress in type 2 diabetes care, despite diabetes guidelines recommending this practice for the past 25 years. [20-25] The key finding is that very few studies have examined the use of PROMs to assess and address depressive symptoms and/or diabetes distress during routine type 2 diabetes care. When depressive symptoms were assessed (n=6), a statistically significant between-group difference in HbA1c was observed in one study.[42] Diabetes distress was also assessed in this study.[42] A statistically significant between-group difference in depressive symptoms was observed in five of six studies where depressive symptoms were assessed during the intervention.[36-40] Where diabetes distress was assessed, a clinically significant between-group difference in HbA1c was observed in two of four studies,[41 42] and a statistically significant difference in both depressive symptoms and diabetes distress was observed in one study.[39] Two studies targeting people with elevated diabetes distress or depressive symptoms demonstrated statistically and clinically significant reductions in glycaemia.[41 42] This review found little evidence of the best-associated co-intervention for people identified by PROMs with elevated depressive symptoms or diabetes distress despite guideline recommendations.[20-25]

Similar to this review's findings, a Cochrane review of PROM completion and feedback to healthcare professionals in the treatment of mental health conditions found insufficient evidence of impact on patient outcomes.[44] However, the interventions included in the Cochrane review were limited to PROM feedback to the healthcare professional, not linked to interventions.[44]

While healthcare professionals frequently treat co-existing depression and type 2 diabetes, emotional issues such as diabetes distress are discussed less frequently.[28] The most effective intervention to address PROM-identified elevated depressive symptoms or diabetes distress remains unclear. Details about how precisely PROMs were used by healthcare professionals in discussion with people with type 2 diabetes were lacking. Further exploration of how PROMs can be integrated into routine clinical practice with the escalation of care for people with elevated depressive symptoms or distress is needed. Considering the recent recommendations from ICHOM for PROM use during diabetes care,[27] healthcare professionals need guidance on the appropriate evidence-based intervention for elevated depressive symptoms or diabetes distress identified using a PROM in clinical practice.[29 30]

Studies demonstrating improved glycaemia had co-interventions of targeting people with elevated distress levels or depressive symptoms.[41 42] Dobber *et al.* increased frequency of follow-up counselling if elevated depressive symptoms were identified using the PHQ-9.[42] Sturt's systematic review regarding the effectiveness of interventions to reduce diabetes distress showed that interventions delivered by a general healthcare professional demonstrate an improvement in glycaemia and reduce diabetes distress.[17] However, participants included in Sturt's review had low levels of diabetes distress, and a further systematic review in 2018 identified that severe diabetes distress reduced with diabetes-specific psychological interventions.[16] Evidentially, targeted interventions are needed stratified on the basis of severity of distress.

Studies have reported that completing a measure of diabetes distress before a consultation can improve glycaemia and patient satisfaction among adults with type 1 and type 2 diabetes.[45] However, only Wu *et al.* explored changes in patient satisfaction with care – which is an important measure considering PROMs are reported as enablers of person-centred care.[46] No studies in our review explored the impact on patient-professional communication in the consultation, despite evidence suggesting PROM use in other clinical settings (oncology) improves communication, with PROMs initiating discussion of issues not otherwise addressed.[47]

Studies have also indicated that completion of a diabetes distress measure before a consultation, and discussion of those responses during the consultation, improves glycaemia and reduces diabetes distress among adults with type 1 and type 2 diabetes in specialist diabetes clinics. [7 45] Pouwer *et al.*'s study of people with type 1 and type 2 diabetes found monitoring of well-being, using the Well-being Questionnaire (W-BQ), during diabetes care resulted in improved mood. [48] While PROMs in these studies were embedded in routine care, they included people with type 1 and type 2 diabetes (without separate sub-group analyses) and were not conducted in general practice, where most type 2 diabetes care occurs.[49] In our review, PROMs were completed most frequently with a trained study team member, not by a healthcare professional involved in the person's clinical care.[36 37 39-42] While this may replicate the likely real-world administration of PROMs (e.g. by a receptionist, upon arrival at the clinic), it is suggested that screening for depressive symptoms is best performed as part of collaborative care by the treating doctor or diabetes educator.[50] In the future, it would be useful to explore models based on depressive symptoms or diabetes distress identified by the usual healthcare professional with stratification of actions based on responses.

Healthcare professionals need PROMs that provide responses that provoke action. However, the effective interventions in this study were resource-intensive, which will be difficult to replicate and sustain in routine clinical practice. Only one study used electronic prompts to healthcare professionals based on PHQ responses.[38] Several studies have highlighted that clinical systems for PROM response delivery to healthcare professionals need to fit with clinical workflow.[51-53] Even with the electronic delivery of PROM responses, the large volume of responses for healthcare professionals to review and the difficulty accessing PROM responses (due to storage on a dashboard separate from the electronic medical record) contribute to low use of PROMs in clinical settings.[52-54]

Strengths and limitations of the review

Key strengths of this review include adherence to the PRISMA guidelines,[34] a comprehensive search strategy of five electronic databases, and screening performed independently by two reviewers. The risk of bias was low in most studies, indicating outcomes of this review are based on high-quality studies. Depression and diabetes distress were assessed using well-validated measures, including PHQ, PAID, and the DDS. The focus on type 2 diabetes is also a strength, as people with type 2 diabetes receive their care mostly in primary care settings, and their needs and preferences are different from people with type 1 diabetes.[55 56]

The heterogeneity of included co-interventions, how PROMs were completed, and healthcare professionals received the PROM responses, limits the overall review, making comparisons between studies difficult. It was not possible to conduct a meta-analysis because of the wide range of interventions and co-interventions assessed. Two studies had a small sample size with limited statistical power.[41 43] Other limitations include the restriction of our search to published journal articles in the English language. All studies included were from high-income or upper-middle-income countries, with no studies from low-middle income countries identified. The inclusion criteria limited studies to populations with type 2 diabetes only, or where a sub-group analysis of participants with type 2 diabetes was included.

Future directions

Considering the low number of eligible studies, further research is warranted to understand the most efficient co-interventions to associate with PROM responses and how to integrate PROMs to coordinate interventions in general practice where most type 2 diabetes care occurs. The interventions examined as part of this review required significant external staff involvement, while only one study used technology to assist with PROM collection and delivery to healthcare professionals. Future research could focus on similar interventions using technology for self-completing PROMs with actionable outcomes if elevated depressive symptoms or diabetes distress are identified. Further research is needed to explore if PROM assessment of depressive symptoms and diabetes distress in routine type 2 diabetes care impacts communication and patient satisfaction with care.

Conclusions

This systematic review summarized and critiqued studies using PROMs for assessing and addressing depressive symptoms and/or diabetes distress as part of clinical type 2 diabetes care. The findings showed few studies using PROMs, but most are effective in reducing depressive symptoms or diabetes distress, though co-interventions related to PROM use in type 2 diabetes care are heterogeneous. While guidelines recommend the routine assessment of depressive symptoms and diabetes distress using PROMs, a clear mechanism for implementing this in routine diabetes care or the most effective co-intervention is yet to be established.

PROSPERO registration number: CRD42020200246

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Competing Interests

The authors have no competing interests to declare.

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Author contributions

RM, JMN, BH, JE, JS, and CH conceived the study. RM, JMN, BH, DK, LC and FH performed the citation screening and risk of bias assessments. RM extracted the data with 20% also extracted

by LC. RM drafted the manuscript and revised it based on the feedback from co-authors. All authors approved the manuscript for submission.

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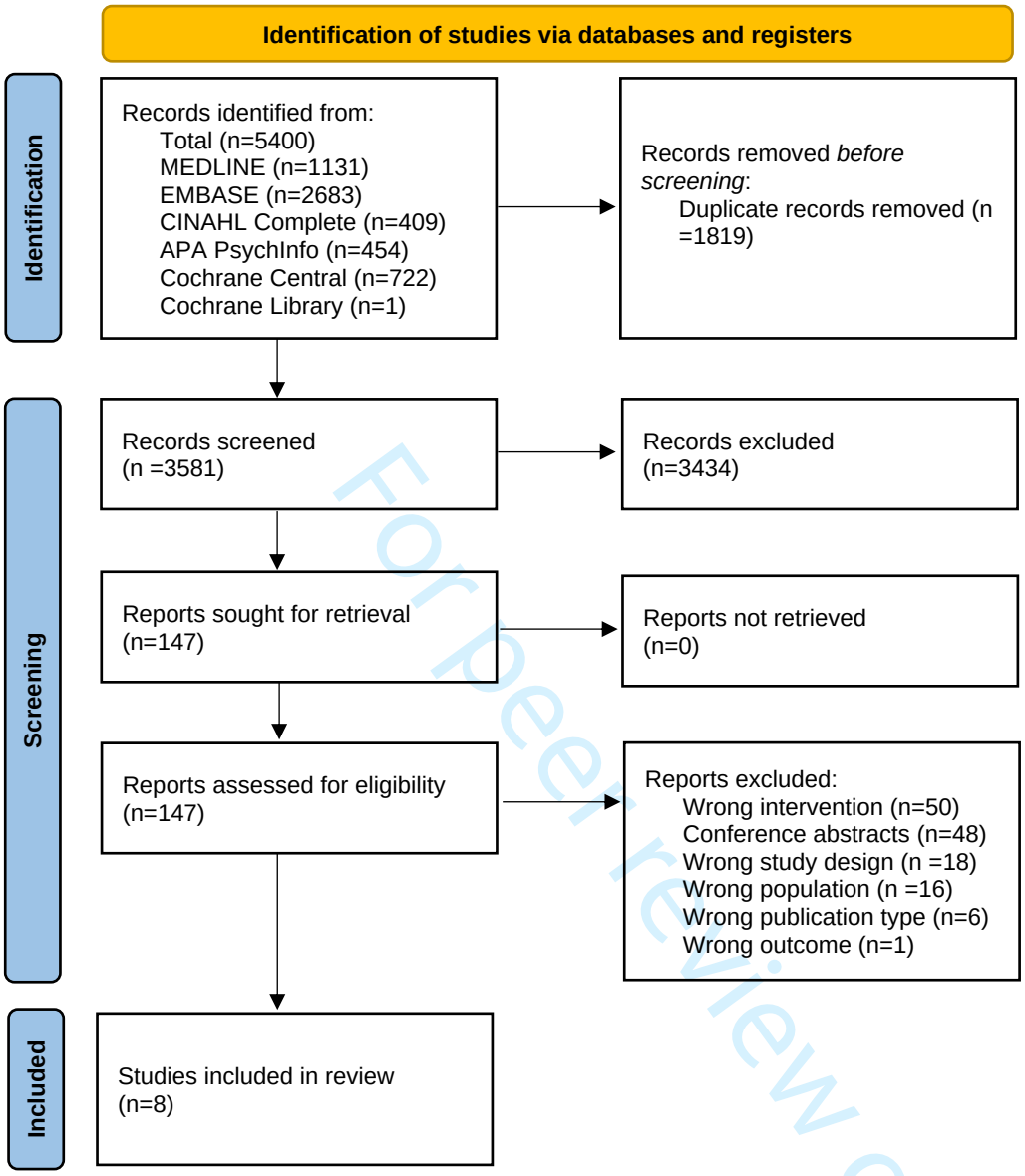

Supplementary Document 1.

Full Search Strategy – MEDLINE (OVID)

#	Searches
1.	PROMS
2.	PROs
3.	patient-reported outcome*
4.	patient outcome*
5.	(patient* adj1 (self-assess* or self-report* or self-monitor*))
6.	(assess adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*))
7.	(monitor* adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*))
8.	Problem Areas in Diabetes
9.	diabetes distress scale
10.	WHO-5
11.	K10
12.	PHQ
13.	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14.	Diabetes Mellitus, Type 2/ or Type 2 Diabetes.mp. or Type II Diabetes.mp. or T2DM.mp. or Diabetes Mellitus
15.	T2D
16.	NIDDM
17.	noninsulin dependent diabetes
18.	14 or 15 or 16 or 17
19.	wellbeing
20.	well-being
21.	psycholog*
22.	psychosocial*
23.	mental*
24.	anxiety
25.	depress*
26.	distress
27.	mood
28.	emotion

29.	19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30.	13 and 18 and 29
31.	limit 30 to (English language and humans)

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	5
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.	6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary Document 1
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.	6
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.	6
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.	6
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	6
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.	7
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.	N/A
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)).	N/A
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A
	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.	N/A
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
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.	8
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	10
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	17
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.	Table 3
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	?
	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.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Table 2
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	24
	23b	Discuss any limitations of the evidence included in the review.	26
	23c	Discuss any limitations of the review processes used.	26
	23d	Discuss implications of the results for practice, policy, and future research.	26
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.	27
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	5
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	27
Competing interests	26	Declare any competing interests of review authors.	27
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.	N/A

PRISMA 2020 Checklist

10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

BMJ Open

Effect of routinely assessing and addressing depression and diabetes distress on clinical outcomes among adults with type 2 diabetes: A systematic review

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Title: Effect of routinely assessing and addressing depression and diabetes distress on clinical outcomes among adults with type 2 diabetes: A systematic review

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Abstract

Objectives: This study examined the effect of using Patient-Reported Outcome Measures (PROMs) routinely to assess and address depressive symptoms and diabetes distress among adults with type 2 diabetes.

Design: A systematic review of published peer-reviewed studies.

Data Sources: Medline, Embase, CINAHL Complete, PsycInfo, The Cochrane Library, and Cochrane Central Register of Controlled Trials were searched.

Eligibility criteria: Studies including adults with type 2 diabetes, published in English, from the inception of the databases to 24 February 2022 inclusive; and where the intervention included completion of a PROM of depressive symptoms and/or diabetes distress, with feedback of the responses to a healthcare professional.

Data extraction and synthesis: Using Covidence software, screening and risk of bias assessment were conducted by two reviewers independently with any disagreements resolved by a third reviewer.

Results: The search identified 4,349 citations, of which 163 full-text citations were assessed for eligibility, and nine studies met the inclusion criteria. Five studies involved assessment of depressive symptoms only, two studies assessed diabetes distress only, and two studies assessed both. All studies had an associated co-intervention. When depressive symptoms were assessed (n=7), a statistically significant between-group difference in depressive symptoms was observed in five studies; with a clinically significant (≥0.5%) between-group difference in HbA1c in two studies. When diabetes distress was assessed (n=4), one study demonstrated statistically significant difference in depressive symptoms and diabetes distress; with a clinically significant between-group difference in HbA1c observed in two studies.

Conclusion: Studies are sparse in which PROMs are used to assess and address depressive symptoms or diabetes distress during routine clinical care of adults with type 2 diabetes. Further research is warranted to understand how to integrate PROMs into clinical care efficiently and determine appropriate interventions to manage identified problem areas.

PROSPERO registration number: CRD42020200246

Article Summary

Strengths and limitations of this study

- The review focuses on depressive symptoms and diabetes distress in people with type 2 diabetes, an important aspect of diabetes management.
- Systematic searching of six databases with independent review of abstracts and studies by two reviewers.
- Meta-analysis was not possible due to heterogeneity in method and frequency of PROM completion, communication of PROM responses to healthcare professionals, and differing associated co-interventions.

Keywords
Diabetes Mellitus, Type 2, Depression, Patient Reported Outcome Measures

Word Count: 3451

Introduction

Type 2 diabetes is a global health priority, with an estimated 463 million people with diabetes in 2017, set to rise to 700 million people in 2045.[1] Up to four in ten adults with type 2 diabetes experience emotional health problems, such as depression, anxiety, and diabetes distress.[2 3] While depression is a *general* negative affect; diabetes distress is the negative emotional or affective response specific to the day-to-day living with diabetes.[3-5] The relationship between diabetes distress and depressive symptoms is bi-directional: elevated diabetes distress is a predictor of future depression, and depression predicts future diabetes distress.[6 7] While early studies have linked depressive symptoms to sub-optimal glycaemia;[8] more recent research has demonstrated that diabetes distress affects glycaemia more than depressive symptoms.[5 9] Elevated depressive symptoms and diabetes distress are associated with reduced diabetes self-care and increased risk of diabetes-related complications, impaired quality of life, mortality, and an estimated 50% increase in healthcare costs.[6 10-15] Recent systematic reviews have focused on interventions for the management of diabetes distress; however, the first step is to identify people with depressive symptoms or diabetes distress requiring interventions in clinical practice.[16-18]

Guidelines have acknowledged the importance of assessing psychological well-being as part of diabetes care for over 25 years.[19] Given the growing evidence that diabetes-tailored psychological interventions reduce elevated distress and glycaemia, international diabetes guidelines have issued recommendations for routine assessment of depressive symptoms and diabetes distress.[16 20-25] Guidelines vary in terms of the specific patient-reported outcome measures (PROMs) recommended to assess depressive symptoms or diabetes distress. PROMs are standardised, validated questionnaires to assess latent constructs such as emotional well-being, treatment satisfaction, perceived health or functional status, or health-related quality of life.[26] Recent consensus from the International Consortium of Health Outcomes Measurement (ICHOM) recommends standardising the assessment of diabetes distress, depressive symptoms and general emotional well-being – with use of the Problem Areas In Diabetes (PAID) scale,

Patient Health Questionnaire – 9 (PHQ-9) and World Health Organisation – Five Well-Being Index (WHO-5), respectively – within clinical diabetes care. [27]

Despite these recommendations for using PROMs, 60% of healthcare professionals only discuss emotional issues if initiated by the person with diabetes.[28] Healthcare professionals need efficient systems to both assess and address depressive symptoms and diabetes distress as part of routine diabetes care.[3] For healthcare professionals to use PROMs, they need to understand the utility of PROMs in supporting people with type 2 diabetes clinically, not just for audit or research purposes,[29 30] and they need guidance in how to use and interpret PROM responses in clinical consultations.[31 32]

Thus, the aim of this systematic review is to examine the effect of using PROMs routinely to assess and address depressive symptoms and/or diabetes distress among adults with type 2 diabetes on: (1) glycaemia as measured by HbA1c; (2) self-reported depressive symptoms or diabetes distress; (3) self-reported general emotional well-being or health-related quality of life; (4) self-reported diabetes self-management; (5) referrals for psychiatric or psychological therapy; (6) self-reported quality of patient-professional communication; and (7) self-reported satisfaction with the consultation.

Methods

The protocol for this systematic review has been published,[33] and the methods are summarised below. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[34] This systematic review is registered on the International Prospective Register of Systematic Reviews (PROSPERO: CRD42020200246).

Eligibility criteria

Inclusion criteria: Studies were eligible if: the design was a randomised controlled trial (RCT), interrupted time-series study, (prospective or retrospective) cohort study, case-control study, or analytical cross-sectional study; participants were adults (18 years or older) with type 2 diabetes

from any country; interventions involved a) participants completing a PROM for depressive symptoms and/or diabetes distress *and* b) use of PROM responses by the healthcare professional in consultation with the person with type 2 diabetes.

Exclusion criteria: Studies were excluded if they involved: people under 18 years of age, type 1 diabetes or gestational diabetes; or the collection of PROM data but no use of the data in the clinical consultation.

Data sources and searches

A systematic search strategy was used to identify studies. The initial search was on 3 August 2020 and repeated on24 February 2022 using the same search terms (Supplementary File 1.) The search was limited to papers published in English and before 24 February 2022. The search strategy was developed in consultation with a librarian from a biomedical library (complete search strategy: Supplementary Document 1). Databases searched included MEDLINE (Ovid), EMBASE (Ovid), CINAHL Complete (EBSCO), APA PsycInfo (Ovid), The Cochrane Library (Ovid), and Cochrane Central Register of Controlled Trials (Ovid).

Study selection and data extraction

Following the initial search on 3rd August 2020, two reviewers (RM and a second member of the review team (JMN, BH, LC, DK or FCSH)) screened studies independently based on the inclusion criteria using Covidence software. Both reviewers screened the title and abstract of all eligible studies, followed by full-text screening of the shortlisted studies. Any disagreements about selection, assessment, and data extraction in the included studies were discussed between the two reviewers, and if required, a third reviewer was involved in the discussion. Following the updated search on 24th February 2022, RM screened additional identified title and abstract independently, with full-text screening of the shortlisted studies by RM. Reference lists were not checked for studies. Data extraction was undertaken by RM with 20% checked by LC or DK. The extracted data were: study settings, participants, description of the interventions, comparators, study duration, length of follow-up, and outcome measures. The authors of the selected studies

were contacted for additional data (when published details were insufficient), with one month allowed for response.

Quality assessment

Eligible studies were assessed for risk of bias by two reviewers (RM and a second member of the review team (JMN, BH or DK)) independently using the Cochrane Risk of Bias 2 tool or ROBINS-I.[35 36] Any disagreements were discussed between the two reviewers, and if required, a third reviewer was involved in the discussion.

Data synthesis

Due to heterogeneity regarding method and frequency of PROM completion, communication of PROM responses to healthcare professionals and differing associated co-interventions (actions based on PROM responses) it was not possible to conduct a meta-analysis. Therefore, the results are summarised narratively.

Patient and Public Involvement

Patients or public were not involved in the conduct of this systematic review.

Ethics approval

This is a systematic review, ethical approval was not required.

Results

The systematic search identified 4,512 citations, of which 163 full-text citations were assessed for eligibility, and nine studies met the inclusion criteria (Figure 1).

Insert Figure 1 here

Figure 1 PRISMA Flow Diagram[34]

Characteristics of included studies

The nine included studies were published between 2009 and 2020 (Table 1). The overall number of participants across all nine studies was N=3325, ranging from N=40 to N=1,306 per study. Six of the nine studies were conducted in the USA,[37-42] with the remainder conducted in Australia,[43] Germany,[44] and Iceland.[45] Most study designs were RCTs (n=6), [37 38 40 43-45] one of which was a pilot study (n=1).[43] The remaining three studies included case control study (n=2) [41 42] and an observational study (n=1).[39] Clinical settings varied across studies, including: general practice (n=4);[38 40 41 42] both primary care and hospital clinics (n=2); [37 39] specialist outpatient clinic (n=2);[43 45]and a specialist rehabilitation service (n=1).[44]

Insert Table 1 here

Table 1. Study characteristics

Author (year) Country	Clinical setting	Study design and n per arm	Intervention PROM	Method and frequency of PROM completion	Summary of actions based on PROM responses	Control arm
Cummings et al. (2019) [40] USA	Adults with symptoms of distress and/or depression attending general practice	12-month RCT: Intervention n=67/ usual care n=72	PHQ-9* DDS-17**	In-person completion with trained study team member twice, six months apart	Stratified treatment to 16 sessions of cognitive behavioural therapy or lifestyle coaching based on PROM responses	Educational materials and usual care with GP.
Dobler et al. (2018) [44] Germany	Adults attending specialist outpatient clinic, recruitment during inpatient rehabilitation stay	12-month RCT: Intervention n=98 / Control n=101	PAID**, WHO-5, PHQ-9*	Telephone completion with trained study team member, monthly	Behaviour motivation plan developed. Monthly follow-up telephone calls using PHQ-2 (with progression to PHQ9 if PHQ score ≥3) to identify and address emotional problems. Severity of symptoms guided counseling techniques, increase in call frequency, or referral	Written information on diet, physical activity by mail at 3 and 9 months.
Fortmann et al. (2020)[42] USA	Adults attending two primary care clinics	12-month case control study: Intervention n=236 / n=239	PHQ-2*, PHQ-9*	In-person completion with the registered nurse or certified diabetes educator, once	Positive screening on PROM resulted in referral to depression care manager with group-based cognitive behavioral therapy. Depression screening was part of a collaborative care model focused on cardiometabolic targets	Standard diabetes care without depression screening.
Ell et al. (2011) [38] USA	Adults with PHQ9 response ≥10,	24-month RCT: Intervention n=193/ Enhanced	PHQ-9*	Telephone completion with trained study	Collaborative care model using structured stepped-care algorithm, with patient preferences for	Standard care, depression educational pamphlets and social resource list. GPs informed of depression diagnosis.

Author (year) Country	Clinical setting	Study design and n per arm	Intervention PROM	Method and frequency of PROM completion	Summary of actions based on PROM responses	Control arm
	attending primary care safety net clinics	usual care n=194		team member once	problem-solving therapy or anti-depressants guiding treatment	
Johnson et al. (2014) [41] USA	Adults with PHQ >10, attending general practice	12-month case control: Intervention n=95 / Active control n=62/ usual care n=71	PHQ-9*	Telephone completion with trained study team member at least monthly until PHQ-9 <10	Case-managers delivered individualised care, in collaboration with psychiatrist and endocrinologist, with treatment recommendations to GP based on a treatment algorithm and PROM responses	GP notified by letter of elevated PHQ-9 responses.
Naik et al. (2019) [37] USA	Adults attending hospital and outpatient community Veterans Affairs clinics	12-month RCT: Intervention n=136 / Enhanced usual care (EUC) n=89	PHQ-9*	Telephone completion with trained study team member once	Nine telephone coaching sessions with trained study members using workbooks guiding the discussion and tracking progress to set and assess goals related to wellness, diet, exercise medication management.	Participants informed of PHQ-9 responses with educational materials.
Rees et al. (2017) [43] Australia	Adults with diabetes related retinopathy and moderate diabetes distress attending specialist outpatient clinic	6-month pilot RCT: Intervention n=21 / control n=19	DDS**	In-person completion with trained study member once	PROM responses guided eight 45–60-minute problem solving therapy sessions	Pamphlets on diabetes-specific topics
Sigurdardottir et al. (2009) [45]	Adults attending specialist	6-month RCT: Intervention	PAID** DKT, DES, Summary of	In-person completion at clinic with	Diabetes educators delivered individual educational sessions based on empowerment theory. PROM	Information booklet about T2D and attended usual diabetes clinics.

Author (year) Country	Clinical setting	Study design and n per arm	Intervention PROM	Method and frequency of PROM completion	Summary of actions based on PROM responses	Control arm
Iceland	outpatient clinic	n=28 / Control n=25	diabetes self-care measure	diabetes educator once	responses identified barriers to goals with a weekly follow-up call for five weeks	
Wu et al. (2018) [39] USA	Adults attending primary care or hospital-based safety net clinics	6-month observational: Technology-facilitated care n=432/ supported care n=461/ usual care n=416	PHQ-2, PHQ-9*	Initially completed via telephone with trained study member. Then monthly – quarterly completion via automated calls	PROM responses linked to clinical decision support that generated action reminders for healthcare professionals depending on PROM responses	Standard primary care. GPs offered optional training.

*depression, **diabetes distress

DDS: Diabetes Distress Scale; DES: Diabetes Empowerment Scale; DKT: Diabetes Knowledge Test; GP: general practitioner; PAID: Problem Area In Diabetes scale, PHQ: Patient Health Questionnaire (2 items or 9 items), WHO-5: The World Health Organisation Five-item Well-Being Index

Risk of bias of included studies

Four of the nine studies were rated as having a low risk of bias (Supplementary File 2). [38 40 41 43 45] Three studies were non-randomised studies of interventions, and at moderate risk of bias due to risk of baseline confounding. [39 41 42] Methodological concerns were observed in three studies. [37 39 44] Dobber *et al.* reported outcomes for 98 of the 123 participants randomised to the intervention group and did not state how missing outcomes were dealt with; intention to treat was not reported.[44] Naik *et al.* reported 12-month outcome data for only 90 of the 136 intervention participants; intention to treat was not reported. [37] In most studies, due to the study design, participants and clinical study team members delivering the intervention could not be blinded to participants' group allocation. Two studies were pilot studies with small sample sizes.[43 45] Despite being a pilot study, the Rees *et al.* had sufficient power to detect differences in glycaemia , but lower power for depressive symptoms or diabetes distress. [43] Sigurdardottir *et al.* did not include power calculations. [45]

Intervention

Interventions to assess depressive symptoms and/or diabetes distress

Five of the nine studies assessed depressive symptoms alone,[37-39 41 42] two assessed depressive symptoms and diabetes distress,[40 44] and two assessed diabetes distress alone.[43 45] All seven studies assessing depressive symptoms used the Patient Health Questionnaire (PHQ).[37-42 44] One study used the PHQ-2 for brief screening with responses of more than three proceeding to the PHQ-9.[39] Diabetes distress was assessed in two studies using the Diabetes Distress Scale (DDS),[40 43] and in two studies using the Problem Areas In Diabetes (PAID) scale.[44 45]

PROMs were completed either in-person (n=5),[40-44] or via telephone (n=4).[37-39 45] In six studies, PROM responses were collected by study team members not involved in ongoing clinical care,[37 38 40 41 43 44] either via telephone,[37 38 41 44] or at the clinic with a study team member.[40 43] One study collected PROM responses using automated calls.[39] In two study, PROM completion was at the clinic with the diabetes educator.[42 45]

Feedback of PROM responses provided to treating healthcare professionals varied. Three studies trained case managers in making treatment recommendations to primary care health professionals based on case collaboration and treatment algorithms.[38 41 42] In studies where trained study members collected PROM responses, the mechanism by which PROM data was provided to the treating healthcare professionals was not reported.[43 44] In the Naik *et al.* study, the general practitioner received a secure message notifying the HbA1c results and PHQ-9 response.[37] Wu *et al.* used PHQ-9 responses to generate action reminders integrated with the disease management registry for healthcare professionals to review.[39]

Co-intervention associated with PROM responses

Each of the nine studies had a co-intervention associated with the PROM completion (see Table 1), which included telephone-assisted psychological therapy or coaching interventions,[37 40 43-45] or healthcare professional interventions of collaborative team care with case management and stepped care treatment algorithms.[38 41 42] Wu *et al.* linked PROM responses to a clinical decision

support tool that generated action reminders for healthcare professionals based on PROM responses within a disease management register.[39]

Insert Table 2 here

Table 2 Follow-up study outcomes between intervention and control groups

Author (year) Country	Intervention PROM	Length of follow up	HbA1c	Depressive symptoms	Diabetes distress	Other PROM outcomes	Self-management
Cummings et al. (2019) [40] USA	PHQ-9* DDS-17**	12 months	8.9% (2.1) vs 9% (2.2) p = 0.06	PHQ-9: 6.3 (5.9) vs. 7.9 (7) p = 0.01	DDS (RDD): 2.1 (1.2) vs 2.6 (1.3) p = 0.0001	Not assessed	SDSCA: 4.3 (1.4) vs. 3.98 (1.3) p = 0.03
Dobler et al. (2018) [44] Germany	PAID**, PHQ-9*	12 months	mean change -0.7% (1.4) vs. 0.1% (1.7) p = 0.006	PHQ-9: mean change -1.35 (4.3) vs. -0.23 (4.9) p = 0.057	PAID: mean change - 4.77 (14.4) vs. -1.4 (17) p = 0.069	WHO-5: 1.23 (5.7) vs. 0.1 (5.8) p = 0.044	Not assessed
Ell et al. (2011) [38] USA	PHQ-9*	24 months	9.1% (0.29) vs. 8.9% (0.29) p = 0.42	PHQ-9 (reported as >50% reduction): adjusted OR=1.87, 95%CI [1.05–3.32] p = 0.03	Not assessed	SF-12 mental: 44.76 (1.150) vs. 42.48 (1.17) p = 0.001	SDSCA: 3.6 (0.15) vs. 3.41 (0.2) p = 0.26
Fortmann et al. (2020)[42] USA	PHQ-2, PHQ-9*	12 months	mean change: -0.5% vs. 0.0% p = 0.011	Only assessed in intervention arm	Only assessed in intervention arm	Not assessed	Only assessed in intervention arm
Johnson et al. (2014) [41] USA	PHQ-9*	12 months	mean change: -0.2% (1.3) vs. -0.2% (1.1) p = 0.47	PHQ-9: 7.1 (5.4) vs. 9.4 (5.9) p = <0.001	PAID-5: mean change -0.6 (0.8) vs. 0.2 (0.9) p = 0.03	EQ-5D: mean change 0.03 (0.1) vs. 0.04 (0.12) p =0.23	Not assessed
Naik et al. (2019) [37] USA	PHQ-9*	12 months	8.7% (1.6) vs 8.9% (2) p = 0.83	PHQ-9: 10.1 (6.9) vs 12.6 (6.5) p = 0.03	Not assessed	Not assessed	Not assessed

Author (year) Country	Intervention PROM	Length of follow up	HbA1c	Depressive symptoms	Diabetes distress	Other PROM outcomes	Self-management
Rees et al. (2017) [43] Australia	DDS**	6 months	7.1% (1.1) vs. 8.4% (2.5) p =0.093	PHQ-9: 6.7 (5.9) vs. 9.9 (6.5) p = 0.144	DDS: 2.2 (1.1) vs. 2.5 (0.8) p = 0.427	Not assessed	SDSCA diet: 6.1 (1.1) vs. 5 (1.5) p = 0.026
Sigurdardottir et al. (2009) [45] Iceland	PAID**	6 months	8.0% (1.16) vs. 7.8% (.081) p = 0.399	Not assessed	PAID: 19.1 (12.9) vs. 13.8 (12.6) p = 0.239	WBQ-12: 28.4 (6.1) vs. 27.4 (5.6) p = 0.544	SDSCA diet: 3.6 (0.4) vs. 3.4 (0.5) p = 0.122
Wu et al. (2018) [39] USA	PHQ-2, PHQ-9*	6 months	8.1% (0.16) vs. 8.0% (0.17) p = 0.57	PHQ-9: 5.16 (0.48) vs. 6.35 (0.49) p = 0.02	Not assessed	SF-12 mental: 49.87 (1.02) vs. 48.38 (1.04) p = 0.17 Satisfaction with diabetes care 4.20 (0.09) vs. 4.01 (0.09) p=0.05	SDSCA: 4.78 (0.12) vs. 4.66 (0.13) p = 0.38

Outcome data are always presented as intervention vs control. Note, Johnson et al. was a case control study involving three groups, with data related to intervention and active control represented here. Wu et al. was an observational study involving three groups, with data related to intervention vs usual care represented here.

Other PROM outcomes included general emotional well-being, mental health and health status, as well as satisfaction with diabetes care

DDS: Diabetes Distress Scale; 5-level EQ-5D: EuroQoL Five Dimensions; PAID: Problem Area in Diabetes scale, PHQ: Patient Health Questionnaire, RDD: Regimen-related Diabetes Distress (a subscale of the DDS); SDSCA: Summary of Diabetes Self-Care Activities, SF-12: 12-Item Short-Form Survey, WBQ: Well-being Questionnaire; WHO-5: The World Health Organisation Five-item Well-Being Index,

Outcomes

Reported outcomes across studies are detailed in Table2. Referrals to psychology or psychiatry services were not reported. In three studies, in the control arm, healthcare professionals were informed of the elevated depressive symptoms.[37 38 41] In no study were healthcare professionals informed about elevated diabetes distress of participants in the control group.

All nine studies reported glycaemia, measured by HbA1c, as an outcome measure. Where PROM assessed depressive symptoms (n=7), a clinically significant between-group difference in HbA1c was observed in two studies.[42 44] Where diabetes distress was assessed (n=4), a clinically significant between-group difference in HbA1c was observed in two studies.[43 44] Each of these studies had a co-intervention involving a series of psychological therapy sessions.[43 44] Only one of three studies using PROMs as part of stepped care algorithms with care coordination demonstrated a statistically significant glycaemic reduction. [42]

All but two studies examined the impact of PROMs use on depressive symptoms. [42 45] Across all seven studies, depressive symptoms (measured with the PHQ-9) reduced in both arms. Where the intervention included assessment of depressive symptoms (n=7), statistically significant difference in depressive symptoms between groups was observed in five studies.[37-41] Where diabetes distress was assessed during the intervention (n=4)[40 43-45], three studies[40 43 44] reported depressive symptoms as an outcome measure, with a significant difference in depressive symptoms between groups observed in one study.[40] Five studies reported diabetes distress as an outcome measure.[40 41 43-45] Diabetes distress reduced in both the intervention and control arms across all five studies.[40 41 43-45] The difference between groups, favouring the intervention, was statistically significant in two studies. [40 41]

In the Cummings *et al.* study, when therapy was stratified based on elevated levels of depressive symptoms or diabetes distress, improved diabetes self-management was reported.[40] Similarly, in the Rees *et al.* study, when co-interventions focused on people with type 2 diabetes with elevated distress levels receiving individual psychological therapy, an improvement in diabetes

self-management was reported.[43] General emotional well-being, mental health and health status were reported using various measures, including the WHO-5, W-BQ, SF-12, and EQ-5D. No study reported patient-professional communication as an outcome. The Wu *et al.* study was the only one to assess satisfaction with diabetes care, and a statistically significant improvement in the intervention arm was observed.[39]

Discussion

Main findings

To our knowledge, this is the first systematic review to synthesise the evidence related to PROM use to assess and address depressive symptoms and/or diabetes distress in type 2 diabetes care, despite diabetes guidelines recommending this practice for the past 25 years. [20-25] The key finding is that very few studies have examined the use of PROMs to assess and address depressive symptoms and/or diabetes distress during routine type 2 diabetes care. When depressive symptoms were assessed (n=7), a statistically significant between-group difference in HbA1c was observed in two studies.[42 44] A statistically significant between-group difference in depressive symptoms was observed in five of six studies where depressive symptoms were assessed during the intervention.[37-41] Where diabetes distress was assessed, a clinically significant between-group difference in HbA1c was observed in two of four studies,[43 44] and a statistically significant difference in both depressive symptoms and diabetes distress was observed in one study.[40] Two studies targeting people with elevated diabetes distress or depressive symptoms demonstrated statistically and clinically significant reductions in glycaemia.[43 44] This review found little evidence of the best-associated co-intervention for people identified by PROMs with elevated depressive symptoms or diabetes distress despite guideline recommendations.[20-25]

Similar to this review's findings, a Cochrane review of PROM completion and feedback to healthcare professionals in the treatment of mental health conditions found insufficient evidence of impact on patient outcomes.[46] However, the interventions included in the Cochrane review were limited to PROM feedback to the healthcare professional, not linked to interventions.[46] While healthcare professionals frequently treat co-existing depression and type 2 diabetes,

emotional issues such as diabetes distress are discussed less frequently.[28] While over 238 unique PROMs for people with type 2 diabetes have been identified ,the most effective intervention to implement and then address PROM-identified elevated depressive symptoms or diabetes distress remains unclear.[47] Details about how precisely PROMs were used by healthcare professionals in discussion with people with type 2 diabetes were lacking. Further exploration of how PROMs can be integrated into routine clinical practice with the escalation of care for people with elevated depressive symptoms or distress is needed. Considering the recent recommendations from ICHOM for PROM use during diabetes care,[27] healthcare professionals need guidance on the appropriate evidence-based intervention for elevated depressive symptoms or diabetes distress identified using a PROM in clinical practice.[29 30]

Studies demonstrating improved glycaemia had co-interventions of targeting people with elevated distress levels or depressive symptoms.[43 44] Dobber *et al.* increased frequency of follow-up counselling if elevated depressive symptoms were identified using the PHQ-9.[44] Sturt's systematic review regarding the effectiveness of interventions to reduce diabetes distress showed that interventions delivered by a general healthcare professional demonstrate an improvement in glycaemia and reduce diabetes distress.[17] However, participants included in Sturt's review had low levels of diabetes distress, and a further systematic review in 2018 identified that severe diabetes distress reduced with diabetes-specific psychological interventions.[16] Evidentially, targeted interventions are needed stratified on the basis of severity of distress.

Studies have reported that completing a measure of diabetes distress before a consultation can improve glycaemia and patient satisfaction among adults with type 1 and type 2 diabetes.[48] However, only Wu *et al.* explored changes in patient satisfaction with care – which is an important measure considering PROMs are reported as enablers of person-centred care.[49] No studies in our review explored the impact on patient-professional communication in the consultation, despite evidence suggesting PROM use in other clinical settings (oncology) improves communication, with PROMs initiating discussion of issues not otherwise addressed.[50]

Studies have also indicated that completion of a diabetes distress measure before a consultation, and discussion of those responses during the consultation, improves glycaemia and reduces diabetes distress among adults with type 1 and type 2 diabetes in specialist diabetes clinics. [7 48] Pouwer *et al.*'s study of people with type 1 and type 2 diabetes found monitoring of well-being, using the Well-being Questionnaire (W-BQ), during diabetes care resulted in improved mood. [51] While PROMs in these studies were embedded in routine care, they included people with type 1 and type 2 diabetes (without separate sub-group analyses) and were not conducted in general practice, where most type 2 diabetes care occurs.[52] In our review, PROMs were completed most frequently with a trained study team member, not by a healthcare professional involved in the person's clinical care.[37 38 40 41 43 44] While this may replicate the likely real-world administration of PROMs (e.g. by a receptionist, upon arrival at the clinic), it is suggested that screening for depressive symptoms is best performed as part of collaborative care by the treating doctor or diabetes educator.[53] In the future, it would be useful to explore models based on depressive symptoms or diabetes distress identified by the usual healthcare professional with stratification of actions based on responses.

Healthcare professionals need PROMs that provide responses that provoke action. However, the effective interventions in this study were resource-intensive, which will be difficult to replicate and sustain in routine clinical practice. Only one study used electronic prompts to healthcare professionals based on PHQ responses.[39] Several studies have highlighted that clinical systems for PROM response delivery to healthcare professionals need to fit with clinical workflow.[54-56] Even with the electronic delivery of PROM responses, the large volume of responses for healthcare professionals to review and the difficulty accessing PROM responses (due to storage on a dashboard separate from the electronic medical record) contribute to low use of PROMs in clinical settings.[55-57]

Strengths and limitations of the review

Key strengths of this review include adherence to the PRISMA guidelines,[34] a comprehensive search strategy of six electronic databases, and screening performed independently by two reviewers. The risk of bias was low in most studies, indicating outcomes of this review are based on high-quality studies. Depression and diabetes distress were assessed using well-validated measures, including PHQ, PAID, and the DDS. The focus on type 2 diabetes is also a strength, as people with type 2 diabetes receive their care mostly in primary care settings, and their needs and preferences are different from people with type 1 diabetes.[58 59]

The heterogeneity of included co-interventions, how PROMs were completed, and healthcare professionals received the PROM responses, limits the overall review, making comparisons between studies difficult. It was not possible to conduct a meta-analysis because of the wide range of interventions and co-interventions assessed. Two studies had a small sample size with limited statistical power.[43 45] Other limitations include the restriction of our search to published journal articles in the English language. This may explain why all studies included were from high-income or upper-middle-income countries, with no studies from low-middle income countries identified. The inclusion criteria limited studies to populations with type 2 diabetes only, or where a sub-group analysis of participants with type 2 diabetes was included.

Future directions

Considering the low number of eligible studies, further research is warranted to understand the most efficient co-interventions to associate with PROM responses and how to integrate PROMs to coordinate interventions in general practice where most type 2 diabetes care occurs. The interventions examined as part of this review required significant external staff involvement, while only one study used technology to assist with PROM collection and delivery to healthcare professionals. Future research could focus on similar interventions using technology for self-completing PROMs with actionable outcomes if elevated depressive symptoms or diabetes distress are identified. Further research is needed to explore if PROM assessment of depressive symptoms and diabetes distress in routine type 2 diabetes care impacts communication and patient satisfaction with care.

Conclusions

This systematic review summarized and critiqued studies using PROMs for assessing and addressing depressive symptoms and/or diabetes distress as part of clinical type 2 diabetes care. The findings showed few studies using PROMs, but most are effective in reducing depressive symptoms or diabetes distress, though co-interventions related to PROM use in type 2 diabetes care are heterogeneous. While guidelines recommend the routine assessment of depressive symptoms and diabetes distress using PROMs, a clear mechanism for implementing this in routine diabetes care or the most effective co-intervention is yet to be established.

PROSPERO registration number: CRD42020200246

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Competing Interests

The authors have no competing interests to declare.

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Author contributions

RM, JMN, BH, JE, JS, and CH conceived the study. RM, JMN, BH, DK, LC and FH performed the citation screening and risk of bias assessments. RM extracted the data with 20% also extracted

by LC. RM drafted the manuscript and revised it based on the feedback from co-authors. All authors approved the manuscript for submission.

Data availability statement

Data are available upon reasonable request to the corresponding author.

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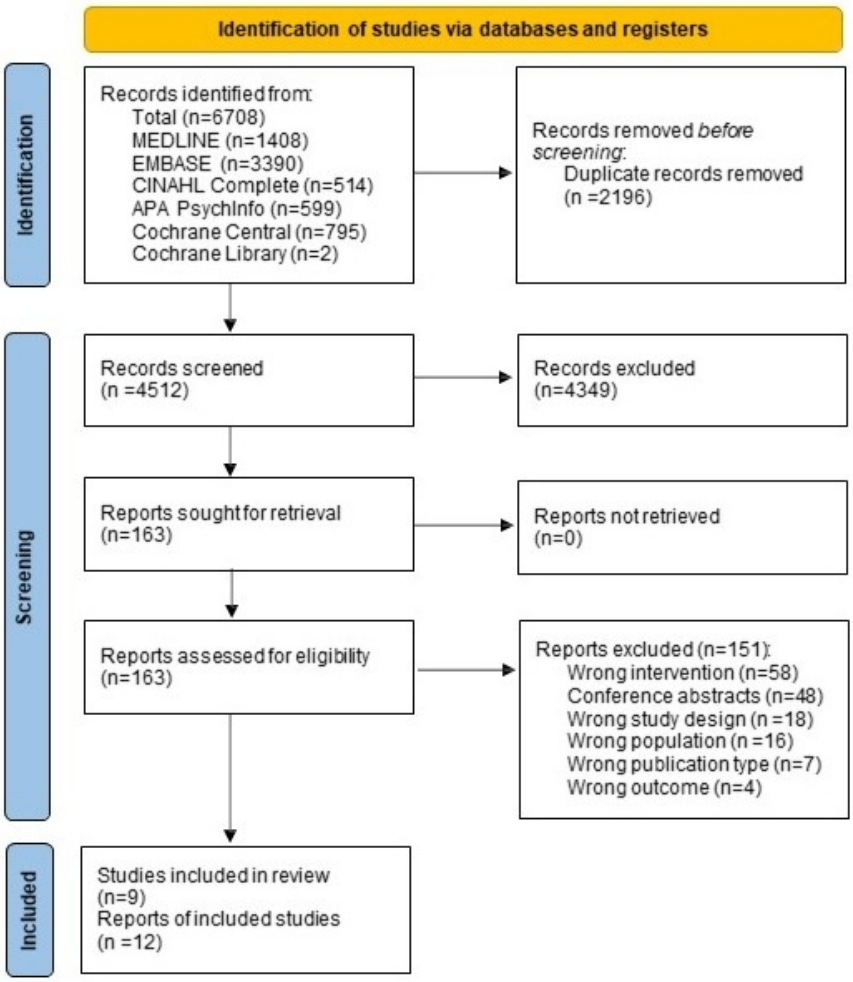

Figure 1. PRISMA Flow diagram

159x164mm (96 x 96 DPI)

Supplementary File 1

Full Search Strategy – Ovid MEDLINE

1.	PROMS.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2.	PROs.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3.	patient-reported outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4.	patient outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6.	Diabetes Mellitus, Type 2/ or Type 2 Diabetes.mp. or Type II Diabetes.mp. or T2DM.mp. or Diabetes Mellitus.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7.	(assess adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
8.	(monitor* adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
9.	Problem Areas in Diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
10.	diabetes distress scale.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
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12.	K10.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
13.	PHQ.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
14.	patient reported outcome.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
15.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
16.	1 or 2 or 3 or 4 or 5 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17.	T2D.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
18.	NIDDM.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

19.	noninsulin dependent diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
20.	6 or 17 or 18 or 19
21.	wellbeing.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
22.	well-being.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
23.	psycholog*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
24.	psychosocial*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
25.	mental*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
26.	anxiety.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
27.	depress*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
28.	distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
29.	mood.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
30.	emotion.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
31.	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32.	16 and 20 and 31
33.	limit 32 to (english language and humans)

Search Strategy – Embase

1.	exp non insulin dependent diabetes mellitus/
2.	exp diabetes mellitus/
3.	Type II Diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4.	T2DM.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5.	T2D.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6.	NIDDM.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7.	1 or 2 or 3 or 4 or 5 or 6
8.	exp patient-reported outcome/
9.	PROMS.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
10.	PROs.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11.	patient-reported outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
12.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
13.	(assess adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
14.	(monitor* adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
15.	Problem Areas in Diabetes.mp.
16.	diabetes distress scale.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
17.	WHO-5.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
18.	K10.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
19.	PHQ.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
20.	exp wellbeing/
21.	exp psychological wellbeing assessment/
22.	well-being.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
23.	psycholog*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

24.	psychosocial*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
25.	mental*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
26.	exp mental health/
27.	exp anxiety/
28.	depression/
29.	distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
30.	exp mood/
31.	exp emotion/
32.	20 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
33.	8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 21
34.	7 and 32 and 33
35.	limit 34 to (human and english language)

Search Strategy – APA PsycArticles

1.	PROMS.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2.	PROs.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3.	patient-reported outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4.	patient outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6.	Diabetes Mellitus, Type 2/ or Type 2 Diabetes.mp. or Type II Diabetes.mp. or T2DM.mp. or Diabetes Mellitus.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7.	(assess adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
8.	(monitor* adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
9.	Problem Areas in Diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
10.	diabetes distress scale.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11.	WHO-5.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
12.	K10.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
13.	PHQ.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
14.	patient reported outcome.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
15.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
16.	1 or 2 or 3 or 4 or 5 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17.	T2D.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
18.	NIDDM.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
19.	noninsulin dependent diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
20.	6 or 17 or 18 or 19

21.	wellbeing.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
22.	well-being.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
23.	psycholog*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
24.	psychosocial*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
25.	mental*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
26.	anxiety.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
27.	depress*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
28.	distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
29.	mood.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
30.	emotion.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
31.	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32.	16 and 20 and 31
33.	limit 32 to (english and human)

Search Strategy – Cochrane Central Register of Controlled Trials

1.	PROMS.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2.	PROs.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3.	patient-reported outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4.	patient outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6.	Diabetes Mellitus, Type 2/ or Type 2 Diabetes.mp. or Type II Diabetes.mp. or T2DM.mp. or Diabetes Mellitus.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7.	(assess adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
8.	(monitor* adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
9.	Problem Areas in Diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
10.	diabetes distress scale.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11.	WHO-5.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
12.	K10.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
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16.	1 or 2 or 3 or 4 or 5 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17.	T2D.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
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19.	noninsulin dependent diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
20.	6 or 17 or 18 or 19

21.	wellbeing.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
22.	well-being.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
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24.	psychosocial*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
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26.	anxiety.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
27.	depress*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
28.	distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
29.	mood.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
30.	emotion.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
31.	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32.	16 and 20 and 31
33.	limit 32 to english language

Search Strategy – Cochrane Database of Systematic Reviews

1.	PROMS.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2.	PROs.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3.	patient-reported outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4.	patient outcome*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6.	Diabetes Mellitus, Type 2/ or Type 2 Diabetes.mp. or Type II Diabetes.mp. or T2DM.mp. or Diabetes Mellitus.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7.	(assess adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
8.	(monitor* adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
9.	Problem Areas in Diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
10.	diabetes distress scale.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11.	WHO-5.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
12.	K10.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
13.	PHQ.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
14.	patient reported outcome.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
15.	(patient* adj1 (self-assess* or self-report* or self-monitor*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
16.	1 or 2 or 3 or 4 or 5 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17.	T2D.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
18.	NIDDM.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
19.	noninsulin dependent diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
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21.	wellbeing.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
22.	well-being.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
23.	psycholog*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
24.	psychosocial*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
25.	mental*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
26.	anxiety.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
27.	depress*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
28.	distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
29.	mood.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
30.	emotion.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
31.	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32.	16 and 20 and 31

Search Strategy – CINAHL Complete

S3	((wellbeing or well-being or well being) OR psychological OR distress OR psychosocial OR anxiety OR depression OR (mood or emotions or feelings)) AND (S1 AND S2)
S2	diabetes mellitus OR diabetes type 2 OR diabetes mellitus type 2 OR Type II Diabetes OR type 2 diabetes OR type 2 diabetes mellitus OR t2dm OR t2d OR niddm OR non-insulin dependent diabetes OR non insulin dependent diabetes mellitus
S1	(proms or patient-reported outcome measures) OR PROs OR ((patient* adj1 (self-assess* or self-report* or self-monitor*))) OR ((assess adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*))) OR ((monitor* adj4 (distress* or emotion* or psycholog* or psychosocial or wellbeing or well-being or depress* or mental*))) OR Problem Areas in Diabetes OR diabetes distress scale OR WHO-5 OR K10 OR PHQ OR patient reported outcome

Supplementary File 2. Risk of bias assessment

Table 1. Risk of bias as assessed using the Risk of Bias 2.[35]

Author (year)	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Cummings et al. (2019) [40]	Low	Low	Low	Low	Low	Low
Dobler et al. (2018) [44]	Low	Low	High	Low	Low	Some concerns
Ell et al. (2011) [38]	Low	High	Low	Low	Low	Low
Naik et al. (2019) [37]	Low	Low	Some concerns	Low	Low	Some concerns
Rees et al. (2017) [43]	Low	Low	Low	Low	Low	Low
Sigurdardottir et al. (2009) [45]	Low	Some concerns	Low	Low	Low	Low

Table 2. Risk of bias as assessed using the Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) assessment tool. [36]

Author (year)	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall Bias
Johnson et al. (2014) [41]	Moderate	Low	Low	Low	Moderate	Low	Low	Moderate
Fortmann et al. (2020) [42]	Moderate	Low	Low	Low	Low	Low	Low	Moderate
Wu et al. (2018) [39]	Moderate	Low	Low	Low	Moderate	Moderate	Low	Moderate

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	5
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.	6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary Document 1
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.	6
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.	6
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.	6
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	6
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.	7
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.	N/A
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)).	N/A
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A
	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.	N/A
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
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.	8
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	10
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	17
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.	Table 3
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	?
	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.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Table 2
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	24
	23b	Discuss any limitations of the evidence included in the review.	26
	23c	Discuss any limitations of the review processes used.	26
	23d	Discuss implications of the results for practice, policy, and future research.	26
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.	27
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	5
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	27
Competing interests	26	Declare any competing interests of review authors.	27
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.	N/A

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10.1136/bmj.n71

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