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Effect of routinely assessing and addressing depression and diabetes distress using patient-reported outcome measures in improving outcomes among adults with type 2 diabetes: a systematic review protocol

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ABSTRACT

Introduction Type 2 diabetes is a global health priority. People with diabetes are more likely to experience mental health problems relative to people without diabetes. Diabetes guidelines recommend assessment of depression and diabetes distress during diabetes care. This systematic review will examine the effect of routinely assessing and addressing depression and diabetes distress using patient-reported outcome measures in improving outcomes among adults with type 2 diabetes.

Methods and analysis MEDLINE, Embase, CINAHL Complete, PsycInfo, The Cochrane Library and Cochrane Central Register of Controlled Trials will be searched using a prespecified strategy using a prespecified Population, Intervention, Comparator, Outcomes, Setting and study design strategy. The date range of the search of all databases will be from inception to 3 August 2020. Randomised controlled trials, interrupted time-series studies, prospective and retrospective cohort studies, case–control studies and analytical cross-sectional studies published in peer-reviewed journals in the English language will be included. Two review authors will independently screen abstracts and full texts with disagreements resolved by a third reviewer, if required, using Covidence software. Two reviewers will undertake risk of bias assessment using checklists appropriate to study design. Data will be extracted using prespecified template. A narrative synthesis will be conducted, with a meta-analysis, if appropriate.

Ethics and dissemination Ethics approval is not required for this review of published studies. Presentation of results will follow the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidance. Findings will be disseminated via peer-reviewed publication and conference presentations.

PROSPERO registration number CRD42020200246.

Strengths and limitations of this study

► This systematic review will examine the effect of routinely assessing and addressing depression and diabetes distress in improving the outcomes of type 2 diabetes as part of routine care, which is recommended in clinical diabetes guidelines.

► Our review will assess the impact of patient-reported outcome use in type 2 diabetes on a range of clinical outcomes including glycaemia, depressive symptoms, diabetes distress, well-being and diabetes self-management.

► The literature is expected to be heterogeneous in terms of the patient-reported outcome measures used for depression and diabetes distress and may need to be reported as a narrative synthesis.

INTRODUCTION
Rationale

Type 2 diabetes (T2D) is a global health priority with an estimated 463 million people living with diabetes in 2017, set to rise to 700 million people in 2045.[1] T2D impacts not only on physical health but also on mental health. Up to 4 in 10 people with T2D experience problems related to mental health, such as depression, anxiety and diabetes distress.[2] Diabetes distress, the negative psychological reaction to the emotional burden of living with and managing diabetes, is experienced by up to 36% of people with T2D.[3 4] Depression and diabetes can coexist. Diabetes distress is not a diagnosable mental health issue but an emotional response related to the day-to-day living with diabetes.[5 6] Impaired mental health is associated with reduced self-management and increased risk of suboptimal glycaemia,

diabetes-related complications, impaired quality of life, mortality and an estimated 50% increase in healthcare costs.[7–13]

Diabetes guidelines have acknowledged the importance of psychological assessment as part of diabetes care for over 25 years.[14] The International Diabetes Federation recommends screening for depression with a validated tool in primary care diabetes clinics and referring those who screen positively to a mental healthcare professional with expertise in diabetes.[15] The American College for Endocrinology, The National Institute for Healthcare and Excellence in the UK, Royal Australian College of General Practitioners, American Diabetes Association and Diabetes Canada all have similar recommendations for routine psychological assessment as part of diabetes care.[15–20] Across these guidelines, there is considerable variation in terms of which patient-reported outcome measures (PROMs) are recommended. PROMs are standardised, validated questionnaires that are completed by patients to assess latent constructs such as emotional well-being, treatment satisfaction, perceived health or functional status or health-related quality of life.[21] Recent consensus from the International Consortium of Health Outcomes Measurement recommends annual psychological assessment as part of diabetes care using the Problem Areas in Diabetes scale (PAID), WHO-Five Well-Being Index (WHO-5) and Patient Health Questionnaire-9 (PHQ-9).[22]

Despite these long-standing recommendations for PROM use as a component of the assessment of depression and diabetes distress as part of diabetes care and the known consequences of impaired mental health, less than one-third of people with diabetes recall healthcare professionals asking about anxiety or depression symptoms.[23] While use of PROMs enables people with diabetes to self-reflect on their condition with increased patient concerns being discussed with healthcare professionals,[24] healthcare professionals report low rates of training in care for people with mental health issues related to diabetes, with two-thirds identifying the need for training in managing the psychological aspects of diabetes care.[25] Barriers to the assessment of diabetes distress reported by healthcare professionals include lack of confidence when addressing mental health as part of diabetes care.[26] Recent systematic reviews have focused on the role and benefits of interventions for the management of diabetes distress; however, the first step in delivering psychological care is to identify those who require such interventions.[27–29] With the rising prevalence of T2D worldwide, the majority of whom are managed in general practice, and specialist psychological support with expertise in diabetes care being scarce, there is an urgent need to ensure integrated mental health assessment to enable holistic diabetes care.[16] We need to develop an efficient system to assess for diabetes distress as part of routine diabetes care provided in general practice.[6]

The current study

For PROMs to be successfully implemented into routine diabetes care amidst increasing pressures on clinical time (particularly in primary care), clinicians need to understand the utility of the tools to support the patient and improve clinical outcomes, not just for audit or research purposes.[30 31] To engage healthcare professionals in the use of PROMs for the assessment of depression and diabetes distress, we must understand the impact that performing these assessments in routine diabetes care has on clinical, process of care and patient-reported outcomes. Impact may be mediated by the method of completion (eg, online or paper-based assessment), the type of healthcare professional and their setting (eg, primary vs specialist care). The resulting insights will provide a foundation for further translation of the guidelines recommending mental health assessment as part of routine diabetes care.

Objectives

This review will examine the effect of routinely assessing and addressing depression and diabetes distress on clinical and patient-reported outcomes among adults with T2D.

METHODS AND ANALYSIS

This protocol was prepared using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines.[32]

Patient and public involvement

This protocol was discussed with members of our consumer advisory group. The aims, methods and type of healthcare professionals who received the feedback of the PROM were discussed. The consumer advisory group agreed with the aims and methods of the review. Several members indicated the importance of including studies involving any healthcare professional, not just doctors and nurses, in the review.

Eligibility criteria
Study characteristics

Randomised controlled trials, interrupted time-series studies, prospective and retrospective cohort studies, case–control studies and analytical cross-sectional studies published in the English language will be included. Qualitative studies, case studies, animal studies and conference abstracts will be excluded.

Population

Our target study population is adults (18 years of age or older) with T2D from any country. Studies including children and adolescents (under 18 years of age), people without T2D (eg, type 1 diabetes or gestational diabetes) will be excluded.

Intervention

The intervention includes both of the following:

1. Completion of PROMs by an adult with T2D, including self-completed or interviewer-administered measures of:
   – Depressive symptoms, for example, PHQ[33]; the Beck Depression Inventory[33] or Centre of Epidemiological Studies-Depression.[34]
   – Diabetes distress, for example, Problem Areas in Diabetes[35] or Diabetes Distress Scale (DDS).[36] The PROMs to be included will be broadened based on the PROMs measuring depressive symptoms or diabetes distress identified during the search.
2. Feeding of PROM responses back to and/or use of PROM responses by the treating healthcare professional in consultation with the person with T2D.

The PROMs to be included will be broadened based on the PROMs measuring depressive symptoms or diabetes distress identified during the search.

Outcomes

Our primary outcome of interest is glycaemia as measured by glycated haemoglobin (HbA1c).

Secondary outcomes of interest include:

1. Reported depressive symptoms and diabetes distress responses at follow-up.
2. Reported psychological well-being or health-related quality of life at follow-up, for example, the WHO-5, EQ-5D[37] or SF-36.[38]
3. Reported diabetes self-management at follow-up, for example, change in diabetes self-management as measured by the Summary of Diabetes Self-Care Activities.[39]
4. Number of referrals for psychiatric or psychological assessment or therapy.
5. Reported patient and doctor communication.
6. Reported satisfaction with consultation.

Information sources

The following databases will be searched: MEDLINE (Ovid), Embase (Ovid), CINAHL Complete (EBSCO), APA PsycInfo (Ovid), The Cochrane Library (Ovid) and Cochrane Central Register of Controlled Trials (Ovid). The search strategy will be specific to MEDLINE (Ovid) but adapted for other databases using the appropriate controlled vocabulary prior to conducting the searches. There will be no restriction on publication date.

Reference lists and correspondence

We will screen reference lists (of included trial reports and systematic reviews) to identify additional studies and will contact experts in the field for information on unpublished studies, or to request additional trial data. As the terminology of 'patient-reported outcome measures' and 'PROMs' has been adopted relatively recently in the literature, we will also search specifically for common validated measures of depressive symptoms or diabetes distress.

Table 1 Abbreviated search strategy

Type 2 diabetes	PROMs	Mental health
Diabetes Mellitus, Type 2/	Patient Reported Outcome/	depress*
Type 2 Diabetes	Patient-reported outcome*	distress*
Type II Diabetes	PROM	emotion*
T2DM	PRO	psycholog*
Diabetes Mellitus	K10	psychosocial
NIDDM	PHQ	wellbeing
	PAID	well-being
	DDS	"well being"
		mental

*truncation operator.
DDS, Diabetes Distress Scale; NIDDM, non-insulin-dependent diabetes mellitus; PAID, Problem Areas in Diabetes; PHQ, Patient Health Questionnaire; PROM, patient-reported outcome measure; T2DM, type 2 diabetes mellitus.

Search strategy

The abbreviated search strategy is listed in table 1. The initial searches will be conducted with MEDLINE, and adjustments will be made before the final search of all databases. The full MEDLINE search is in online supplemental file 1. The date range of the search of all databases will be from inception to 3 August 2020. The initial search strategy was conducted on 3 August 2020.

Data management

Search results will be imported to EndNote (V.X9.3.3, Clarivate Analytics) for removal of duplicates. Unique records will be imported to Covidence for the selection and screening process.[40]

Selection process

All abstracts will be screened by two reviewers independently against the predefined eligibility criteria outlined. Any inter-reviewer disagreements will be discussed and resolved, where necessary, with a third reviewer. Full-text screening of all positively screened abstracts will be conducted by two reviewers independently, with disagreements resolved using the same procedure. Reasons for exclusion of full texts will be recorded using Covidence.

Data extraction process

Data will be extracted from all included studies and recorded in a data extraction form following a prespecified Participants, Intervention, Comparator, Outcomes framework (see online supplemental file 2). The data extraction form will be refined and adjusted if necessary.

Data to be extracted
Participants

N, age (years), gender, socioeconomic status, education level, diabetes duration (years), HbA1c, insulin treatment (Y/N), comorbidities (number and type), known

mental health diagnosis, prior referral to psychologist or psychiatrist, baseline PROM scores (including depression and diabetes distress), severe diabetes distress (eg, PAID >40, DDS >18), ratings of doctor–patient communication (if available).

Intervention

Specific instrument/PROM used, frequency of completion, method of completion, location of completion, feedback of PROM responses to healthcare professional, type of healthcare professional receiving PROM responses, method of feedback, training on interpretation of PROM responses, associated action given to the healthcare professional based on the outcomes, feedback on the PROM responses to the person with diabetes, associated action PROM responses for the person with diabetes, other co-interventions, for example, additional training in motivational interviewing/guidance handbooks/extra psychological support for people with diabetes.

Comparator

Details of treatment provided to the comparison group.

Outcome

Primary and secondary outcomes specified and collected, and time points reported.

Study design and setting

Study design, total duration of study, number of study centres and location, study setting, participants' recruitment, protocol adherence, study drop-out rate.

Outcomes and prioritisation

If sufficient studies are identified, a meta-analysis will be conducted using RevMan.[41] For our primary outcome, glycaemia, we will divide studies into groups based on the reporting of HbA1c as a continuous variable or a categorical variable. We will calculate risk ratios with 95% CIs for dichotomous data.

For continuous outcomes, such as depressive symptoms or diabetes distress, well-being or self-management mean differences (MDs) with 95% CIs will be used. When studies use different scales or measurements for the same underlying construct, we will use the standardised MD and the associated 95% CI. For categorical (binary) outcomes, such as referrals for psychological therapy, we will use logistic regression to calculate ORs and the associated 95% CIs.

Dealing with missing data

We will contact authors to confirm study characteristics and obtain missing data where possible (for example, when a study has both participants with type 1 diabetes and T2D). We will allow for a maximum of 1 month and three emails for responses. We will document all correspondence and report responses in the final review.

Risk of bias in individual studies

Two reviewers will independently assess the risk of bias in each of the included studies using the risk of bias for randomised trials and Risk Of Bias In Non-randomised Studies-Interventions for non-randomised studies of interventions, as recommended by the Cochrane Handbook.[42–44] Any inter-reviewer disagreements about risk of bias will be discussed and resolved with a third reviewer.

Data synthesis

A meta-analysis will be conducted if appropriate using RevMan, that, is if the interventions, participants, study design, outcomes and number of identified papers are sufficiently homogeneous. Between study statistical heterogeneity will be assessed using the I^2 statistic. If sufficient studies, a funnel plot will be created to assess publication bias. If a meta-analysis is not possible, the outcomes will be discussed in a narrative synthesis.

A narrative synthesis and summary of findings will describe the findings from each included study. We will present the following details: the number and characteristics of participants in each study, study setting and design, PROM used, risk of bias of the study, findings for effects on participant outcomes including PROM responses, HbA1c, and on the clinical and process of care outcomes.

Confidence in the cumulative evidence

As recommended by the Cochrane Handbook, we will use the Grading of Recommendations, Assessment, Development and Evaluation criteria to grade the quality and strength of evidence.[45]

ETHICS AND DISSEMINATION

Ethics was not required for this study as it does not involve the collection of individual patient data. We will disseminate results via peer-reviewed publication, conference presentations and local networks via newsletters and social media. This systematic review is part of the lead author's (RM) PhD.

DISCUSSION

This systematic review will synthesise the evidence related to the impact of assessing depression and diabetes distress using PROMs on glycaemia, the well-being of people with diabetes and processes of care. People with diabetes are more likely to experience mental health issues; to address this we must understand the most effective ways of assessing depression and diabetes distress in diabetes care.[2] Our review will make an important contribution to the development of an intervention to allow for assessment of depression and diabetes distress in general practice. Given the majority of people with diabetes attend their general practitioner as part of routine care, we suspect this is the

appropriate context for these assessments to occur.[46] As impaired mental health is associated with increased risk of suboptimal glycaemia and self-management strategies, general practice is well positioned to provide holistic care related to both mental health and diabetes self-management.[7–9]

Key strengths of this systematic review will be the adherence to the PRISMA guidelines and an experienced team of reviewers with all screening and data extraction checked independently by two reviewers. A limitation of this review is that there are a wide variety of PROMs used for the assessment of depression and diabetes distress in T2D care and we expect a heterogeneous group of articles, which may result in a meta-analysis potentially not being performed. The restriction of studies to those written in English may also be a limitation.

This review will highlight key areas and most effective ways of conducting assessment of depressive symptoms and diabetes distress in clinical care. Future directions include using the results from this systematic review to guide the development of an intervention to allow for the translation of international guidance for assessment of depressive symptoms and diabetes distress routinely during diabetes care.

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Supplementary Document

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)

Supplementary Document

Data extraction Form

Reviewer Name	
Date extraction performed	
Study Name	
First Author	
Year	

Study Characteristics

	Response	Notes
Setting		
Country		
Study design		
Period of study		
Number of study centres		
Aims and objectives		

Population

POPULATION	Response	Notes
Total number of participants		
Total number of participants with T2D		
Recruitment methods		
Sampling method		
Inclusion criteria		
Exclusion criteria		

COMPARATOR	Response	Notes
Was there a comparator group	Yes/ No	
Total number of participants with T2D		

Baseline characteristics

	Intervention	Comparator/Control
Age, mean (SD)		
Male sex, N (%)		
Ethnicity, N (%)		
Socioeconomic status		
Diabetes duration, mean (SD)		
HbA1c, mean (SD)		

Supplemental material

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Insulin treatment N(%)		
Known mental health diagnosis N(%)		
Prior referral to psychologist or psychiatrist N(%)		
Baseline depression or diabetes distress score		Note scale used for measurement
High diabetes distress (PAID >40 DDS >18), N (%)		Note scale used for measurement
Rating of doctor-patient communication		

Intervention

	Response	Notes
PROM used to assess depression or diabetes distress		
Frequency of completion (eg monthly, 6 monthly, annual)		
Method of Completion (eg paper based or online)		
Location of completion (eg at home/in clinic waiting room/with healthcare professional/specify professional type		
Feedback of PROM response to healthcare professional (how eg paper based/electronic database/patient brought in the results)		
Type of healthcare professional (eg nurse, doctor, specialist)		
Training on interpretation of PROM response (if yes what eg duration or training, method eg individual group session, handbook)		
Was there an associated action given to the healthcare professional based on the response (if yes how and what were the recommended actions))		
Did the person with diabetes receive feedback on the PROM response? If yes how eg paper based or online		

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Did the person with diabetes receive an associated action PROM response?		
Other co-interventions eg additional training in motivational interviewing/guidance handbooks/extra psychological support for people with diabetes		

Comparator/Control

Comparator (details of treatment as usual)		

Outcomes

1. Glycaemia

	Response	Notes
Measure of glycemia as an outcome	Yes No	
Length of follow up		
What was glycemic outcome treated as	☐Continuous outcome ☐Categorical outcome ☐Both	

Reviewer uses 1 of the columns below depending on whether glycaemic outcome is measured as continuous or categorical

Intervention	Continuous: Mean (SD)	p-value	Categorical: OR (95% CI)	p-value

Control	Continuous: Mean (SD)	p-value	Categorical: OR (95% CI)	p-value

2. Depression or diabetes distress score

	Response	Notes
Measure of depression or diabetes distress score as an outcome	Yes No	
Measure used		
Length of follow up		

Intervention	Continuous: Mean (SD)	p-value	Note
Control	Continuous: Mean (SD)	p-value	

3. Well-being score

	Response	Notes
Well-being score as an outcome	Yes No	
Measure used		
Length of follow up		

Intervention	Continuous: Mean (SD)	p-value	Note
Control	Continuous: Mean (SD)	p-value	

4. Self-management

	Response	Notes
Measure of self-management as an outcome	Yes No	
Measure used		
Length of follow up		

Intervention	Continuous: Mean (SD)	p-value	Note
Control	Continuous: Mean (SD)	p-value	

5. Referral for psychology or psychiatry therapy

	Response	Notes

Referral for psychology therapy as an outcome	Yes No	
Length of follow up		

Intervention	Binary: N(%) referred psychology or psychiatry	Note
Control		

6. Doctor patient communication

	Response	Notes
Doctor patient communication as an outcome	Yes No	
Measure used		
Length of follow up		

Intervention	Continuous: Mean (SD)	p-value	Note
Control	Continuous: Mean (SD)	p-value	

7. Satisfaction with consultation

	Response	Notes
Satisfaction with consultation as an outcome	Yes No	
Measure used		
Length of follow up		

Intervention	Continuous: Mean (SD)	p-value	Note
Control	Continuous: Mean (SD)	p-value	