

Psychological interventions to improve self-management of type 1 and type 2 diabetes: a systematic review

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Scientific summary

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Background

For people with diabetes mellitus (hereafter referred to as diabetes) to achieve optimal glycaemic control and to avoid micro- and macrovascular disease, day-to-day self-management is essential. The nature of self-management varies from person to person: for someone with type 1 diabetes, it would involve managing multiple insulin injections or an insulin pump, together with frequent blood glucose testing, matching insulin to carbohydrate intake, exercise, and managing intercurrent illness, whereas for someone with type 2 diabetes, it may involve dietary management, exercise, taking medication to prevent or treat cardiovascular risk factors and taking medication or insulin to control their blood glucose levels. It is time-consuming; there are no days off and there are often no immediate rewards of doing it. Therefore, it is no surprise that more than one-third of people with type 2 diabetes and two-thirds of people with type 1 diabetes do not achieve target blood glucose levels.

Adequate training is essential for optimal diabetes self-management so people have the knowledge and skills to be effective at self-management, and the motivation to do it. Structured education programmes are widely available, if underutilised; potential benefits include improved diabetes outcomes, such as glycaemic control, psychological status, cardiovascular disease risk reduction and improved quality of life. However, motivation for diabetes self-management is also required and this can be affected by emotional issues, common with diabetes, such as depression, psychological distress and diabetes 'burn-out'.

Psychological interventions may help to improve motivation for self-management as they rely on the therapeutic alliance between the client and interventionist, usually involve talking or communicating, and may improve emotional and cognitive functioning. This research team previously conducted a systematic review and meta-analysis of psychological interventions for people with diabetes, up to 2003; overall, it was demonstrated that psychological interventions were effective in improving glycaemic control to clinically significant levels for adolescents/children with type 1 diabetes and adults with type 2 diabetes, but not adults with type 1 diabetes. However, since the last reviews were published, the types of psychological treatments tested have changed, as have standards in trial reporting and meta-analytic synthesis. In addition, it would also be important to determine whether or not psychological interventions represent value for money. The aim was to update the previous systematic review and meta-analyses to determine which psychological and psychotherapeutic interventions are most clinically effective and cost-effective in improving glycaemic control.

Objectives

The overall aim was to conduct a systematic review and meta-analysis of controlled trials of psychological treatments to:

1. assess the effectiveness of psychological interventions that aim to improve motivation for people with type 1 diabetes and people with type 2 diabetes so that they have improved (1) glycaemic control (2) diabetes self-management, (3) psychological distress and (4) health-related quality of life
2. examine the overall cost-effectiveness of psychological treatments in diabetes and to model the potential predicted savings in reducing the risk of diabetes complications long term
3. assess the effectiveness of different types or techniques of psychological treatments for (1) better self-management and (2) glycaemic control

4. examine whether or not psychological treatments are effective for populations who experience health inequalities, such as different ethnic groups, those with severe mental illness and those experiencing social deprivation
5. conduct subgroup analyses to identify the clinical characteristics of patients who have better or worse diabetes self-management or glycaemic control, for example by age, gender, complication status
6. describe the development of new psychological theories and techniques and any advancements in research methodologies, such as quality assurance of fidelity of intervention delivery or characteristics of control groups
7. identify gaps in the literature to make recommendations for primary research
8. summarise the data for translation into the NHS via Health Improvement Networks, Diabetes Strategic Networks, Diabetes UK and Clinical Commissioning Groups.

Methods

For children/adolescents and adults with type 1 diabetes and adults with type 2 diabetes, the main aim was to test the clinical effectiveness and cost-effectiveness of psychological interventions to improve glycaemic control by identifying randomised controlled trials and non-randomised controlled trials published since 2003.

For the randomised controlled trials, a systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and electronic databases were screened from 2003. The results of this screening were combined with a previous review (from inception of electronic databases to 2003) of the literature to determine cohort effects.

Two studies were undertaken to examine the cost-effectiveness of psychological interventions versus usual care: one for adults with type 1 diabetes and one for adults with type 2 diabetes.

For non-randomised controlled trials, a systematic review was conducted.

A public consultation with people with type 1 diabetes and type 2 diabetes was conducted in London and Sheffield, along with a presentation of preliminary results of the systematic review and meta-analysis.

Data sources

For randomised controlled trials, an all-language search was performed from February 2003 to July 2016 in the following databases: MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), The Cochrane Library, PsycINFO, EMBASE, Cochrane Controlled Trials Register, Web of Science, Dissertation Abstracts International and Clinicaltrials.gov. The abstracts of four diabetes conferences from 2012 to 2016 (Diabetes UK, American Diabetes Association, European Association for the Study of Diabetes and International Diabetes Federation) were also searched for reports of trials using psychological therapies.

The following electronic databases were searched for non-randomised controlled trials: EMBASE (2003 to January 2017), MEDLINE (2003 to January 2017) and PsycINFO (2003 to January 2017).

Study selection (inclusion criteria)

The following key search terms were used to search for randomised controlled trials in MEDLINE, and adapted for each database: 'psychological therapies' and 'mood disorders' and 'diabetes mellitus' and 'clinical trials'. An alternative strategy was used to identify non-randomised controlled trials.

Titles and abstracts of studies, identified by electronic searches, were independently inspected by two researchers. Abstracts were selected if they described a controlled trial of a psychological or behavioural intervention for people with type 1 diabetes or type 2 diabetes. If there was ambiguity in the description of the study or intervention, then the study was included in the second stage. The second stage of study

selection involved eligibility assessment of full-text papers by the same two researchers; differences over inclusion of studies at this stage of study selection were resolved by consensus and discussion with a third researcher.

Problems were encountered in relying on identifying psychological treatments using titles and abstracts only, as some studies do not explicitly describe the psychological treatment in the abstract. Therefore, previously rejected abstracts were screened a second time to reduce the risk of excluding potentially eligible papers.

Participants

Participants included adolescents and children with type 1 diabetes aged 5–17 years, adults with type 1 diabetes and adults with type 2 diabetes.

Interventions

Studies of psychological interventions were identified using the following criteria and were included if they met all of the following criteria: (1) they relied on communication, using the therapeutic alliance between the patient and therapist; (2) the intervention was facilitated by psychologists, psychotherapists and therapists in training, or facilitated by persons trained in a psychological method/supervised by a clinical psychologist or therapist; (3) the intervention was based on a psychological model; and (4) the intervention aimed to improve outcome changes in emotional, cognitive or behavioural functioning, including diabetes self-management.

Control groups included usual care (generally usual diabetes care), waiting list control, attention control, diabetes education or a less intensive psychological intervention.

Outcomes

The primary outcome was a change in glycaemic control glycated haemoglobin levels, measured as a percentage or in mmol/mol, between baseline and 1-year follow-up.

Secondary outcomes of interest were changes in (1) self-management activities, (2) psychological functioning, (3) clinical outcomes, (4) economic outcomes using unit costs or (5) adverse effects. For studies to be eligible, they had to include the primary outcome with or without secondary outcomes.

Data extraction

Data were extracted on publication characteristics; participant baseline characteristics, such as type of diabetes, age, gender, ethnicity, clinical subgroup, socioeconomic setting, duration of diabetes, complication status, receipt of structured education and occupation; intervention characteristics, such as type of therapy, number of sessions attended, duration of therapy sessions and overall duration of therapy, psychological theoretical framework used, use of manual, specialty of therapist, training of therapist, fidelity assessment of therapist, description of techniques used, format of delivery, mode of delivery, and use of booster or maintenance sessions; control characteristics; and outcome characteristics.

Data synthesis

A systematic review, an aggregate meta-analysis, a network meta-analysis, an individual patient data meta-analysis and cost-effectiveness modelling were all conducted.

Study level

Narrative synthesis was used to describe individual studies in terms of setting, participants, psychological intervention, type of comparator and primary and secondary outcomes.

Meta-analyses

An aggregate meta-analysis was conducted to determine the mean difference between baseline and follow-up (closest to 12 months) scores between the psychological intervention and control groups, standardised by calculating Cohen's *d*, for each of the included studies.

For the main outcome, glycated haemoglobin levels, we conducted a network meta-analysis to allow for simultaneous analysis of multiple treatments and incorporate direct and indirect treatment comparisons and evidence. Cost-effectiveness modelling for the outcome of glycated haemoglobin levels was conducted using network meta-analysis data.

For studies included in the aggregate meta-analysis, study teams were contacted for individual patient data and a one-stage meta-analysis was conducted to explore predictors and moderators of response for glycated haemoglobin levels.

Quality assessment

The quality of randomised controlled trials was assessed using Cochrane Handbook Tool for Risk of Bias (Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, *et al.* The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;**343**:d5928).

Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used to determine the quality of the evidence of the outcomes under investigation and the subsequent translational strength of recommendations for clinical practice.

The quality of non-randomised controlled trials was assessed using the Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) created by the Cochrane Methods Bias group and Cochrane Non-Randomized Studies for Interventions Methods Group.

Results

Systematic review and meta-analyses of randomised controlled trials of psychological treatments in diabetes

A total of 96 randomised controlled trials (18,659 participants) were included in the systematic review. In random-effects meta-analysis, data on glycated haemoglobin levels were available for seven studies conducted in adults with type 1 diabetes (851 participants) that demonstrated a pooled mean difference of -0.13 (95% confidence interval CI -0.33 to 0.07), a non-statistically significant decrease in favour of psychological treatment compared with control; 18 studies conducted in adolescents/children with type 1 diabetes (2583 participants) that demonstrated a pooled mean difference of 0.00 (95% confidence interval -0.18 to 0.18), indicating no change; and 49 studies in adults with type 2 diabetes (12,009 participants) that demonstrated a statistically significant pooled mean difference of -0.21 (95% confidence interval -0.31 to -0.10), equivalent to a reduction in glycated haemoglobin levels of -0.33% or ≈ 3.5 mmol/mol for psychological treatment compared with control interventions. A reduction of ≈ 4 mmol/mol is considered clinically important as it reduces the incidence of microvascular disease. For type 2 diabetes, there was evidence of psychological interventions improving dietary behaviour and quality of life compared with control interventions, but not blood pressure, body mass index or depressive symptoms. It was not possible to conduct meta-analyses for secondary outcomes in studies of people with type 1 diabetes.

Subgroup analyses were conducted to compare type of therapy and interventionist. The results demonstrated that, for adults and adolescents/children with type 1 diabetes, there was no statistically significant difference in clinical effectiveness for type of intervention (adult: cognitive-behavioural therapy vs. counselling; adolescent/child: counselling vs. family therapy) or interventionist (psychology professional vs. diabetes specialist), although study heterogeneity was high for counselling interventions and those delivered by diabetes specialists to adolescents/children. For adults with type 2 diabetes, the results of

subgroup analyses determined no statistically significant differences between cognitive-behavioural therapy and counselling studies, as both were clinically effective, although study heterogeneity was high for counselling. Nor were there statistically significant differences between interventionist, as both psychology professionals and diabetes specialists were effective in delivering psychological treatments, but study heterogeneity was high for diabetes specialists.

The results of the network meta-analysis for type 1 diabetes adults (seven studies; 908 participants) suggest that attention control and cognitive-behavioural therapy are clinically effective and cognitive-behavioural therapy is cost-effective in improving glycaemic control. For adults with type 2 diabetes (50 studies; 12,409 participants), the results suggested that cognitive-behavioural therapy and counselling are clinically effective and that cognitive-behavioural therapy is potentially the most cost-effective intervention.

The results of the individual patient data meta-analysis for adolescents/children with type 1 diabetes (9 studies; 1392 participants) suggest main effects for age and duration of diabetes; therefore, participants who were younger at baseline and those with longer duration of diabetes at baseline improved their glycated haemoglobin levels the most, independent of treatment arm. For type 2 diabetes (19 studies; 3639 participants), baseline glycated haemoglobin levels moderated the treatment outcome, with higher baseline values associated with greater improvement in glycated haemoglobin levels. Individual patient data were limited to 40–50% of included studies.

Systematic review of non-randomised controlled trials of psychological treatments in diabetes

Fourteen studies (1791 participants) met the inclusion criteria and were included in the systematic review; these comprised six studies conducted in adults with type 1 diabetes ($n = 416$), seven studies conducted in adults with type 2 diabetes ($n = 1317$) and one study with a mixed type 1 diabetes and type 2 diabetes population ($n = 58$). Only one of the five adult type 1 diabetes studies demonstrated a statistically significant difference between intervention and control, with a greater reduction in glycated haemoglobin level in the intervention group. For other outcomes, there were statistically significant between-group differences in positive coping for stress management in favour of the psychological intervention group compared with the control (usual care) group for one study.

For type 2 diabetes, two out of the six studies demonstrated a statistically significant difference between the psychological intervention and control groups, with greater improvement in glycated haemoglobin levels in the intervention group.

For secondary outcomes, three studies reported statistically significant between-group differences in favour of the psychological intervention group compared with the control group for self-reported readiness to change, self-efficacy, self-care, depression, anxiety and stress.

Public consultation

When the preliminary findings of the evidence synthesis were presented to people with diabetes, one of the main themes generated from the focus groups was the lack of available psychological support and treatment; this was something that they felt would benefit them.

Conclusions

Implications for health care

This review does not support the use of psychological treatments compared with control interventions to improve diabetes self-management and glycaemic control for people with type 1 diabetes. For adults with type 2 diabetes, there is weak evidence of borderline clinical significance, and psychological treatments are potentially cost-effective, although there is much uncertainty in the cost-effectiveness models. There has been a non-statistically significant reduction in the magnitude of the effect, since the previous review.

Psychological interventions included in this review were typically cognitive–behavioural therapy or counselling interventions and may not be sufficiently intensive to improve glycaemic control. Although reporting of studies has improved, there are questions to be asked in terms of whether or not the interventionists delivering the psychological treatments were competent to do so. Other issues include the lack of description in the psychological ingredients reported in the abstracts of papers. Finally, there is also the question of whether or not short-term interventions are appropriate for people with diabetes, as this a lifelong condition.

Recommendations for research

Based on the findings of this evidence synthesis and gaps in the literature, the following research questions or priorities are recommended:

- Promote the use of consolidated outcome sets in trials of psychological interventions to ensure that treatment efficacy is not limited to glycaemic control, particularly for studies involving people with type 1 diabetes.
- Encourage researchers to be more explicit in their description of psychological techniques/interventions in titles and abstracts to enable future reviewers to identify studies.
- Determine long-term cost-effectiveness of psychological interventions.
- Develop different models of psychological care depending on what stage a person is at in their life journey with diabetes.
- Determine whether or not psychological interventions are effective at improving motivation for diabetes self-management when interventionists are competent to deliver the intervention.
- Develop a multifactorial intervention involving psychology and education to address psychological distress, such as depressive symptoms, and diabetes self-management.

Study registration

This study is registered as PROSPERO CRD42016033619.

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This report

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