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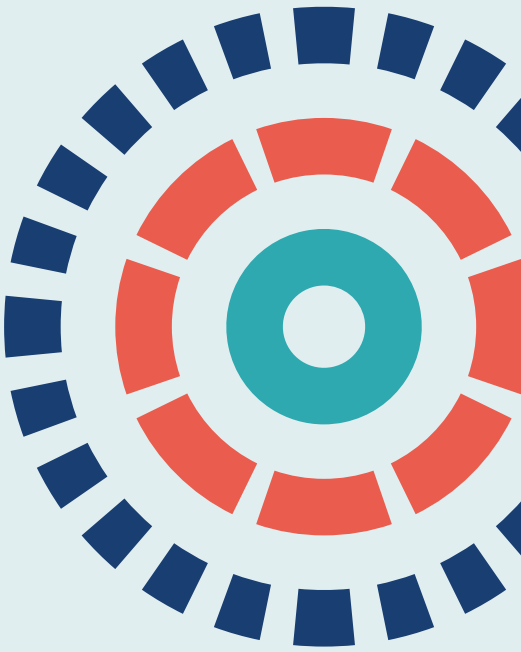

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This report

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Abstract

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

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Background: For people with diabetes mellitus to achieve optimal glycaemic control, motivation to perform self-management is important. The research team wanted to determine whether or not psychological interventions are clinically effective and cost-effective in increasing self-management and improving glycaemic control.

Objectives: The first objective was to determine the clinical effectiveness of psychological interventions for people with type 1 diabetes mellitus and people with type 2 diabetes mellitus so that they have improved (1) glycated haemoglobin levels, (2) diabetes self-management and (3) quality of life, and fewer depressive symptoms. The second objective was to determine the cost-effectiveness of psychological interventions.

Data sources: The following databases were accessed (searches took place between 2003 and 2016): MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library, PsycINFO, EMBASE, Cochrane Controlled Trials Register, Web of Science, and Dissertation Abstracts International. Diabetes conference abstracts, reference lists of included studies and Clinicaltrials.gov trial registry were also searched.

Review methods: Systematic review, aggregate meta-analysis, network meta-analysis, individual patient data meta-analysis and cost-effectiveness modelling were all used. Risk of bias of randomised and non-randomised controlled trials was assessed using the Cochrane Handbook (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).

Design: Systematic review, meta-analysis, cost-effectiveness analysis and patient and public consultation were all used.

Setting: Settings in primary or secondary care were included.

Participants: Adolescents and children with type 1 diabetes mellitus and adults with types 1 and 2 diabetes mellitus were included.

Interventions: The interventions used were psychological treatments, including and not restricted to cognitive–behavioural therapy, counselling, family therapy and psychotherapy.

Main outcome measures: Glycated haemoglobin levels, self-management behaviours, body mass index, blood pressure levels, depressive symptoms and quality of life were all used as outcome measures.

Results: A total of 96 studies were included in the systematic review (n = 18,659 participants). In random-effects meta-analysis, data on glycated haemoglobin levels were available for seven studies conducted in adults with type 1 diabetes mellitus (n = 851 participants) that demonstrated a pooled mean difference of –0.13 (95% confidence interval –0.33 to 0.07), a non-significant decrease in favour of psychological treatment; 18 studies conducted in adolescents/children with type 1 diabetes mellitus (n = 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 conducted in adults with type 2 diabetes mellitus (n = 12,009 participants) that demonstrated a pooled mean difference of –0.21 (95% confidence interval –0.31 to –0.10), equivalent to reduction in glycated haemoglobin levels of –0.33% or ≈3.5 mmol/mol. For type 2 diabetes mellitus, there was evidence that psychological interventions improved dietary behaviour and quality of life but not blood pressure, body mass index or depressive symptoms. The results of the network meta-analysis, which considers direct and indirect effects of multiple treatment comparisons, suggest that, for adults with type 1 diabetes mellitus (7 studies; 968 participants), attention control and cognitive–behavioural therapy are clinically effective and cognitive–behavioural therapy is cost-effective. For adults with type 2 diabetes mellitus (49 studies; 12,409 participants), cognitive–behavioural therapy and counselling are effective and cognitive–behavioural therapy is potentially cost-effective. The results of the individual patient data meta-analysis for adolescents/children with type 1 diabetes mellitus (9 studies; 1392 participants) suggest that there were main effects for age and diabetes duration. For adults with type 2 diabetes mellitus (19 studies; 3639 participants), baseline glycated haemoglobin levels moderated treatment outcome.

Limitations: Aggregate meta-analysis was limited to glycaemic control for type 1 diabetes mellitus. It was not possible to model cost-effectiveness for adolescents/children with type 1 diabetes mellitus and modelling for type 2 diabetes mellitus involved substantial uncertainty. The individual patient data meta-analysis included only 40–50% of studies.

Conclusions: This review suggests that psychological treatments offer minimal clinical benefit in improving glycated haemoglobin levels for adults with type 2 diabetes mellitus. However, there was no evidence of benefit compared with control interventions in improving glycated haemoglobin levels for people with type 1 diabetes mellitus.

Future work: Future work should consider the competency of the interventionists delivering a therapy and psychological approaches that are matched to a person and their life course.

Study registration: This study is registered as PROSPERO CRD42016033619.

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List of abbreviations

ADaPT	A Diabetes and Psychological Therapies study
BFST-D	Behavioral Family Systems Therapy for Diabetes
BGAT	blood glucose awareness training
BMI	body mass index
CBT	cognitive–behavioural therapy
CEAC	cost-effectiveness acceptability curve
CES-D	Center for Epidemiologic Studies Depression Scale
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CONSORT	Consolidated Standards of Reporting Trials
CVD	cardiovascular disease
DAFNE	Dose Adjustment For Normal Eating
DBP	diastolic blood pressure
DESMOND	Diabetes Education and Self Management for Ongoing and Newly Diagnosed
DKA	diabetic ketoacidosis
DUA	data use agreement
EVPI	expected value of perfect information
EVPPI	expected value of perfect parameter information
FP	female participant
FV	fitted value
GBP	Great British pounds
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HbA_{1c}	glycated haemoglobin
HCHS	Hospital and Community Health Service
HTA	health technology assessment
ICC	intracluster correlation coefficient
ICER	incremental cost-effectiveness ratio
ID	identification
IDF	International Diabetes Federation
IPD	individual patient data
KCL	King's College London
LADDER	Lay ADvice for Diabetes and Endocrine Research
MI	motivational interviewing
MP	male participant
NICE	National Institute for Health and Care Excellence
NMA	network meta-analysis
nRCT	non-randomised controlled trials
PHQ-9	Patient Health Questionnaire-9 items
PPI	patient and public involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSA	probabilistic sensitivity analysis
PSB	payer strategy-specific burden
PSS	Personal Social Services
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
REPOSE	Relative Effectiveness of Pumps over Structured Education
RoB	risk of bias

SAVI	Sheffield Accelerated Value of Information
SBP	systolic blood pressure
SD	standard deviation
SDSCA	Summary of Diabetes Self-Care Activities Measure
SMD	standardised mean difference
SPHR	School for Public Health Research
SUCRA	surface under the cumulative ranking
T1DM	type 1 diabetes mellitus
T2DM	type 2 diabetes mellitus
TAU	treatment as usual
UKPDS	UK Prospective Diabetes Study
WHO	World Health Organization

Plain English summary

Living with diabetes mellitus (hereafter referred to as diabetes) involves taking on new roles and responsibilities and is key to success in achieving the best diabetes control. There are education programmes that help people with diabetes to access the information and skills needed but managing diabetes is hard and must be done 24/7, causing people to lose motivation. There are many emotional reasons for this. This research team aimed to discover if talking therapies that are designed to help people challenge their negative thoughts and feelings and be more motivated and confident could help improve their self-management and blood glucose levels. The team also wanted to find out if talking therapies could be good value for money and people with diabetes were asked for their views on the research. To conduct the research, electronic databases were searched for studies that have used talking therapies to support diabetes management.

It was found that:

- For adults with type 2 diabetes, talking therapies improved diabetes control by only a small amount, although such therapies could represent value for money. People with type 2 diabetes who had talking therapy reported improved diet and quality of life. For adults with type 1 diabetes, some types of talking therapies could improve diabetes control, although this result was uncertain. Talking therapies were not effective for children or adolescents in improving diabetes control but there was not enough data to see if the therapies improved general health and well-being.
- When the results were presented to people with diabetes, they still wanted access to these treatments, even though results of this research did not suggest, overall, that talking therapies help improve diabetes control.
- Now that this research is complete, it is suggested that future studies look at whether or not more sessions of talking therapies should be delivered over a longer time period and whether or not the therapies should match the needs of the person with diabetes more closely.

Scientific summary

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, whose 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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Chapter 1 Background

Diabetes mellitus (hereafter referred to as diabetes) is a common chronic, non-communicable disease, affecting an estimated 415 million people globally.[1] Of these, 90% have type 2 diabetes mellitus (T2DM),[2] and the remainder have type 1 diabetes mellitus (T1DM).[3] T1DM and T2DM differ in their aetiology and pathophysiology but both exhibit altered glucose metabolism, specifically hyperglycaemia, that can lead to microvascular complications. The difference in aetiology is significant because T1DM generally results in complete dependence on exogenous insulin injection, as there is complete destruction of beta cells owing to an autoimmune response, and this has implications for self-management and psychological adaptation. What causes T1DM is not known although there is a genetic predisposition and a complex interaction with environmental factors. It typically develops in younger people, usually before 40 years of age, and 1 in 300 children are affected by the age of 18 years in the USA.[4] T2DM is associated with insulin resistance and a more gradual destruction of pancreatic beta cells that may or may not lead to complete insulin insufficiency. Obesity, ethnicity, old age and inactivity are associated with the onset of T2DM and hypercholesterolaemia and hypertension often pre date diagnosis; therefore, T2DM is also considered a cardiovascular disease. Self-management for T2DM often involves treatment for weight loss, and management of blood pressure and lipids is essential.[5,6] However, self-management of blood glucose control to re-establish normoglycaemia, without significant hypoglycaemia (caused by over-treatment, change in activity levels or intake of carbohydrates) is important for both T1DM and T2DM,[7,8] although the targets set are typically higher for T2DM because there is some evidence for an increased risk of cardiovascular events and mortality in elderly people and those with comorbidity who experience hypoglycaemia.[9,10] Diabetes is costly to health services: in the UK it uses ≈10% of the annual NHS budget.[11] Most of the cost relates to treatment and management of complications that are often preventable.

Self-management and structured education

Self-management of diabetes, for people with a relatively new onset of T2DM, involves behaviour change in terms of diet and exercise and attending diabetes appointments and eye screening. It is recommended that someone with T2DM taking oral antidiabetic medication should spend 2 hours per day managing their diabetes, for example taking tablets and organising tablets for the day or week; problem-solving regarding blood glucose levels, snacks or medicine; shopping and reading labels on food products; exercise; attending support groups or finding out information that can aid self-management; and scheduling appointments.[12] However, for people with T1DM who are dependent on exogenous insulin injection and for people with T2DM that has progressed, self-management becomes more time-consuming and may involve activities specified for T2DM and additional tasks, such as taking tablets, monitoring food and carbohydrate consumption, testing blood glucose levels and acting on the results, managing exercise, sickness, travel and administering insulin or another injectable therapy. People with T1DM have the additional pressures of managing multiple daily injections or an insulin pump.

Diabetes self-management programmes for T1DM and T2DM aim to equip people with the knowledge and skills they need to be confident in self-managing their diabetes, and there is evidence that these are effective in terms of improved patient outcomes, including glycated haemoglobin (HbA_{1c}) levels; cardiovascular risk factors; quality of life (QoL); and measures of psychological health. However, these improvements do not necessarily remain at long-term follow-up, although improvements in QoL, how people think and feel about diabetes (illness cognitions) and satisfaction with treatment do.[13,14] Despite national roll-out in the UK, attendance rates are low, those most in need do not attend[15–19] and attendance per se does not guarantee effective diabetes self-management.

The importance of motivation

When we talk about diabetes self-management, we are referring to health-related behaviour that we know can improve an individual's health; therefore, for many people, this can involve making changes to what they are already doing. Knowledge, skills and confidence to manage diabetes are important but so is motivation to put it into practice. Although the definition of motivation as intrinsic or extrinsic in relation to diabetes self-management is up for debate,[20] people with diabetes may or may not find performing the behaviours personally rewarding. Others have considered motivation to be the likelihood or probability that someone will make behavioural change.[21] There are a number of health psychology models that have been proposed to explain behaviour that have motivation at their core, such as the Health Belief Model,[22] which considers 'likelihood of taking action'; the theory of reasoned action[23] and the theory of planned behaviour,[24] in which motivation either influences 'behavioural intention' or is similar in concept to 'perceived behavioural control'; and Protection Motivation Theory,[25,26] which was originally based on how fear can motivate behaviour and coping appraisal, and now considers the efficacy of the behavioural response and an individual's perception that they can perform the behaviour, known as 'self-efficacy'.

Motivation to perform effective self-management tasks for people with diabetes might be low as the barriers to doing it are great. We know that < 30% of people with T1DM achieve national targets[27] and 30% of people with T2DM in primary care do not achieve target HbA_{1c} levels.[15,28] Diabetes self-management is complex and is not restricted to one target behaviour, such as smoking cessation. Furthermore, as there are no 'days off', diabetes self-management is a 24/7 activity and the 'rewards' of good glycaemic control or lowering of cardiovascular risk may not be immediate. Motivation to manage diabetes may be affected by previous attempts and occasions in which things do not go according to plan. For example, when people who are insulin treated are aiming for target blood glucose and HbA_{1c} levels, they may find that increasing insulin may put them at risk of hypoglycaemia; this may then dissuade them from future attempts to achieve tight blood glucose control.

Psychological barriers are common and may also interfere with motivation for diabetes self-management. For example, people who are depressed may find that they have little motivation to perform self-management tasks such as testing their blood glucose levels, or eating healthy food; they may also rate their QoL as poor.[29,30] Other psychological barriers may include anxiety disorders,[31] abnormal eating behaviours,[32] fear of hypoglycaemia,[33] fear of complications,[34] fear of self-testing or self-injecting,[35] psychological insulin resistance,[36] diabetes burn-out[37,38] and diabetes-specific distress.[38,39] Therefore, psychological interventions that aim to improve motivation and/or reduce psychological barriers to diabetes self-management may improve glycaemic control and QoL, and are considered an important adjunct to support people with diabetes self-management.

Psychological interventions

Psychological interventions differ from educational interventions that aim to improve self-management by increasing diabetes knowledge. Psychological interventions rely on the therapeutic alliance, usually talking or communicating, between a patient and the interventionist to not only improve motivation for self-management, but also promote change in emotional and cognitive functioning.[40,41] Although there is still a lack of any consensus definition of psychological interventions that can be applied to increase motivation for diabetes self-management, they can be categorised by their theoretical framework.[42–44] These include psychoanalytical/psychodynamic therapies, often intensive and longer treatments, which explore internal conflicts perhaps arising from early life experiences that affect personality development and interpersonal functioning;[45,46] cognitive–behavioural therapy (CBT) and it's variations and techniques, which is a brief therapy that targets the current cognitions and emotions associated with behaviours, such as diabetes self-care, and is widely used to treat depression and a broad range of mental health disorders with an underlying assumption that these disorders will remit;[47] and counselling or person-centred therapy,[48] which can be focused, for example motivational interviewing (MI): a very brief therapy

(usually four sessions) developed to strengthen motivation for behaviour change, particularly health-related behaviours.[49–51] Other psychotherapies[52] include interpersonal therapy,[53] family or systemic therapies[54] and variations such as narrative and art therapy.[52,55,56]

How psychological interventions in diabetes have evolved

We previously conducted a systematic review and meta-analysis of psychological interventions for people with diabetes up to 2003. In that meta-analysis, for adults with T1DM (11 studies), there was no statistically significant improvement in glycaemic control for adults who received a psychological intervention compared with those in a control group,[57] but in children and adolescents (10 studies) there was a small clinically significant improvement: a reduction in HbA_{1c} levels equivalent to 6 mmol/mol. An improvement of ≈4 mmol/mol is considered effective at lowering the risk of microvascular complications.[58] For T2DM (12 studies), glycaemic control was also significantly improved for adults who received a psychological intervention (e.g. counselling, CBT, psychodynamic therapy) compared with the control group, equivalent to a reduction in HbA_{1c} levels of 8 mmol/mol.[40]

Since the last review, the types of psychological interventions studied have changed. In the 1980s, stress management and relaxation training interventions were popular, whereas since the late 1990s onwards there has been an explosion of CBT and counselling techniques, and variations of MI interventions have become the norm in clinical practice. Research and treatment for specific clinical groups have grown; therefore, there have been systematic reviews with a specific clinical problem or subgroups of the diabetes population, such as CBT for adults with depression and diabetes,[59,60] people with eating disorders in T1DM,[61] the effectiveness of MI for people with T2DM[62] and family interventions for children and adolescents with T1DM.[63,64] In T1DM, a growth in psychological research for adults with hypoglycaemia unawareness has resulted in clinical trials, currently under way in the UK, the USA and Europe.[65,66]

Another major change relates to the improved reporting of clinical trials and the introduction of Consolidated Standards of Reporting Trials (CONSORT) in 2001.[67] Similarly, there have been changes in treatment comparison groups: fewer studies have used treatment as usual (TAU) and more have used an attention control group, such as diabetes education or a different psychological intervention. Not offering treatment for adolescents/children with diabetes could be considered unethical.

Therefore, limitations of the studies described in our early reviews include the poor methodological quality of many of the included studies; insufficient studies to compare the relative effectiveness of specific categories of psychological intervention, such as CBT versus counselling or MI; whether or not choice of control groups had an impact on the overall findings; specialism of the therapist; and which clinical subgroups benefit the most.

Recent systematic reviews and meta-analyses have focused on some of these elements. However, none to date have considered the cost-effectiveness of psychological interventions or the relative effectiveness of psychological interventions and attention controls, nor have they employed newer methods of synthesis such as network and individual patient data (IPD) meta-analysis.

Current review

The aim of the current review was to update the systematic reviews of psychological interventions conducted in 2003, using the same protocol, to assess whether or not the effectiveness of such interventions in improving the primary outcome (i.e. glycaemic control for people with T1DM and T2DM) has changed. In addition, we wanted to evaluate whether or not psychological interventions could be considered cost-effective based on the primary outcome. We also wanted to detect whether or not these treatments could improve emotional health, such as depressive symptoms and QoL, and diabetes self-management behaviours; therefore, these

were included as secondary outcomes. We employed three methods of meta-analysis: (1) aggregate (same as the 2003 review); (2) IPD, which allows the use of individual patient characteristics when data are available; and (3) network meta-analysis (NMA) to perform indirect comparisons and simultaneous analysis of clinical trials involving different treatments or control groups. IPD meta-analysis and NMA were not performed for secondary outcomes. Finally, this review also reports on the cost-effectiveness of psychological interventions in diabetes.

Chapter 2 Research question

The overall aim was to summarise evidence from randomised controlled trials (RCTs) and conduct a systematic review, meta-analysis and cost-effectiveness analysis of controlled trials of psychological interventions, specifically to:

- assess the effectiveness of psychological interventions that aim to improve motivation for patients with T1DM and T2DM so that they have (1) improved glycaemic control, (2) improved diabetes self-management, (3) reduced psychological distress and (4) improved health-related quality of life
- examine the overall cost-effectiveness analysis of psychological interventions in diabetes and to model the potential predicted savings in reducing the risk of diabetes complications long term
- compare the clinical effectiveness of different types or techniques of psychological interventions for improved glycaemic control and better self-management
- examine whether or not psychological interventions are effective in addressing populations who experience health inequalities, such as different ethnic groups, those with severe mental illness and those experiencing social deprivation
- 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
- describe the development of new psychological theories and techniques, and of any advancements in research methodologies, such as quality assurance of fidelity of intervention delivery or characteristics of control groups
- identify gaps in the literature to make recommendations for primary research
- summarise the data for translation to the NHS via Health Improvement Networks, Diabetes Strategic Networks, Diabetes UK and Clinical Commissioning Groups.

Chapter 3 Review methods

Protocol and registration

This systematic review and meta-analysis is registered with PROSPERO (registration number CRD42016033619). The study protocol is available on the project web page: www.journalslibrary.nihr.ac.uk/programmes/hta/1421310#/ (accessed 14 May 2019).

The methods are reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and relevant extensions.[68] We matched the methods reported here, when possible, for the systematic reviews conducted from the inception of the electronic databases to 2003 by Ismail *et al.*[40] and Winkley *et al.*[57] This enabled us to pool data from the current review with an older cohort of studies. Intervention methodologies and psychological technologies have improved, and this method avoids contaminating the modern review with methodological biases and limitations of under-reporting in older studies. We include a list of the additions to the original review, as well as changes between the current protocol and review in *Appendix 1*.

Part A: systematic review, randomised controlled trial meta-analysis, network meta-analysis and individual patient data meta-analysis methods

Eligibility criteria

Types of studies

Published and unpublished RCTs of interventions to improve self-management were included in the systematic review; non-randomised controlled trials (nRCTs) were included in a separate review (see *Part B: non-randomised controlled trial systematic review methods* and *Chapter 7*). Pre-and-post observational and *n*-of-1 studies were excluded as there is no control group. If there were multiple publications of the same study, the publication that reported the outcome of interest at the relevant time period was included, and in some cases data were extracted from other publications, such as long-term follow-ups or study protocols, for more detailed information regarding the intervention under investigation. There was no restriction on language or the publication status of included studies. Non-English-language study reports were screened and data extracted by a native speaker.

Types of participants

Participants of all ages diagnosed with T1DM or T2DM were included as the population under investigation. People with T1DM and T2DM were considered separately as they are distinct clinical groups. T1DM was stratified by age, adults (≥ 18 years) and adolescents/children (< 18 years). Participants with other medical conditions were excluded, unless the separate analysis for people with diabetes was available or could be provided. People with prediabetes, impaired glucose tolerance or gestational diabetes were excluded as, again, these are distinct and separate clinical groups. If studies included participants with T1DM and T2DM, authors were contacted for the data and separate analysis. If authors did not respond or were unable to provide a separate analysis per diabetes type, studies were included in the systematic review but not the meta-analysis.

Types of intervention (health technologies)

Interventions were described as psychological and were included if they met all of the following criteria:

- They relied on communication, using the therapeutic alliance between a patient and therapist.
- 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.

- The intervention was based on a psychological model.
- The intervention aimed to improve outcome changes in emotional, cognitive or behavioural functioning, including diabetes self-management.

If these criteria were unclear and the intervention could not be clearly described as psychological, then authors were contacted for more information. The psychological interventions were classified into the following categories: psychoanalytical/psychodynamic (including some that used elements of psychotherapy, such as in collaborative care treatments), CBT; counselling (including MI); family therapy; and creative therapy (including music, narrative, art therapy and psychodrama). Studies that used self-help (unless guided by a therapist) were excluded, as were those for which there was no information on dose delivered.

Control groups included usual care (generally usual diabetes care), waiting list control, attention control, diabetes education or a less intensive psychological intervention (i.e. fewer sessions/frequency/duration; delivered by interventionists with less/no psychological training).

Types of outcome measures

The primary outcome of interest was change in glycaemic control, such as HbA_{1c}, which refers to average plasma glucose concentration over the previous 8–12 weeks. HbA_{1c} is measured using percentage or mmol/mol, between baseline and 1-year follow-up. The secondary outcomes of interest were (1) changes in self-management activities [e.g. self-monitoring blood glucose, self-examination, diet, physical activity, oral antidiabetes medication adherence, uptake of insulin therapy, increased clinic attendance], (2) change in psychological functioning (e.g. depressive symptoms, diabetes distress, anxiety, QoL), (3) clinical outcomes [body mass index (BMI)], blood pressure], (4) economic outcomes using unit costs and (5) adverse effects [e.g. incidents of severe hypoglycaemia, diabetic ketoacidosis (DKA), diabetes complications]. For studies to be eligible, they had to have included the primary outcome with or without secondary outcomes. Secondary outcomes were used for meta-analysis when five or more studies provided data for that outcome.

Identification of studies

Information sources

The following electronic databases were searched from January 2003 to July 2016: MEDLINE (Ovid); Cumulative Index to Nursing and Allied Health Literature (CINAHL), The Cochrane Library, PsycINFO, EMBASE (Ovid), Cochrane Controlled Trials Register and Web of Science. When protocols or conference abstracts were identified through database searching, authors were contacted if full-text articles could not be found. If authors did not respond or were unable to provide a full text, the studies were excluded.

In addition, national and international diabetes conference abstracts were searched from 2012 to July 2016 for reports of any trials using psychological therapies. These included Diabetes UK, the American Diabetes Association, the European Association for the Study of Diabetes and the International Diabetes Federation (IDF). The reference lists of included studies and reviews were searched for additional studies. The US government clinical trials registry [https://clinicaltrials.gov (accessed 1 July 2016)] was searched for potential relevant studies that were 'active, not recruiting' with an estimated completion of 2016. Authors were contacted for full-text papers, if such papers were available.

Search

The following key search terms were used for MEDLINE and adapted for each database: 'psychological therapies' and 'mood disorders' and 'diabetes mellitus' and 'clinical trials' (see *Appendix 2*). The Scottish Intercollegiate Guidelines Network filter for RCTs was used for 'clinical trials' in MEDLINE, EMBASE and CINAHL, and adapted for others.

Study selection

Titles and abstracts of studies, identified by electronic searches, were inspected independently by two researchers (RU and KW). In the first stage, abstracts were selected if they described a controlled trial of a

psychological or behavioural intervention for people with T1DM or T2DM. If there was ambiguity in the description of the study or intervention, then the study was included into the second stage. The second stage of study selection involved eligibility assessment of full-text papers by the same two researchers. The inter-reliability for study selection was (Cohen's kappa = 0.945) conducted on this second stage process. Any differences over inclusion of studies at this stage of study selection were resolved by consensus and discussion with a third researcher (KI).

We encountered problems relying on identifying psychological interventions using titles and abstracts only, as some studies do not explicitly describe the psychological intervention in the abstract. Therefore, we rescreened previously rejected abstracts for a second time to reduce the risk of excluding potentially eligible papers.

Data collection process

Data extraction forms were developed in line with the protocol and piloted on five studies from the scoping searches by two independent researchers (RU and KW) (see *Appendix 3*). If there was more than one psychological intervention group (e.g. a three- or four-arm controlled trial), all arms were included in the data extraction and NMA, but comparisons of the most intensive intervention arm versus the least intensive arm were used for the aggregate meta-analysis. If data were not available in the study report, corresponding authors were contacted and the missing data items were requested.

Authors of studies included in the aggregate meta-analysis were informed that their study had been included in a systematic review and meta-analysis and were invited to participate in the IPD meta-analysis by contributing IPD. A list of the required data items was provided. The corresponding author was contacted via e-mail. If there was no response within 2–4 weeks, the lead, senior and other authors were contacted. If this was unsuccessful, authors were contacted via ResearchGate (Berlin, Germany) or contacted in person at conferences. If still unsuccessful, the head of the department at an author's institution and/or the editor of journals in which the paper was published was contacted.

In the first correspondence, a data use agreement (DUA) was sent to the author to be completed by the corresponding institution before data transfer occurred. On some occasions, institutions had their own ethics/legal procedures for sharing data. This was honoured by King's College London (KCL) and a senior contracts associate at KCL was involved to ensure that legal practices were adhered to. Once authors had agreed to participate and completed the DUA, data transfer could occur.

Data were requested in any format convenient to the author, including Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA), SPSS [Statistical Product and Service Solutions; SPSS Inc., Chicago, IL, USA (version 18 and below) or IBM Corporation, Armonk, NY, USA (IBM SPSS Statistics from version 19 onwards], SAS® (SAS Institute Inc., Cary, NC, USA), Stata® (StataCorp LP, College Station, TX, USA) or text. Fewer data items were requested for the IPD than were extracted for the aggregate meta-analyses. If study authors were unable to provide data, the reason given for not sharing data was recorded and authors were informed that their study would still be included in the aggregate meta-analysis. When data were received from study authors, they were checked against the study report and the data managed in SPSS version 15.

Data items

Data were extracted for the characteristics listed below for the main aggregate meta-analysis; all data items were considered to have the potential to influence efficacy and/or be potential effect modifiers in the aggregated meta-analysis. For the IPD meta-analysis, the items in italics were requested from the study research team for individual participants:

- Publication characteristics – year of publication, publication type (peer review or not), country of origin, health-care setting, language, funding source.

- Patient baseline characteristics – *participant identification (ID) (IPD only)*, *type of diabetes*, mean age, *age in years (IPD only)*, *gender*, *ethnicity*, clinical subgroup (e.g. *treatment type*, smoking status, BMI), *socioeconomic setting* (e.g. individual or family income, education), *duration of diabetes (years)* and *complication status*, receipt of structured education and *occupation status/type*.
- Intervention characteristics – type of therapy; number of therapy sessions; average number of sessions attended; duration of overall therapy; duration of therapy sessions; psychological theoretical framework or model; use of manual; specialty of therapist; training of therapist; fidelity assessment of therapist; description of techniques that aim to change emotional, cognitive and behavioural functioning (including adherence); format of delivery (face to face, online, telephone, text messaging); mode of delivery (one to one, group or family/couple); and use of booster or maintenance sessions.
- Control characteristics – the same data were extracted as for the intervention as applicable.
- Outcome characteristics –

    - Type of outcome included the primary outcome [change in glycaemic control (*HbA_{1c} level in % or mmol/mol*)] and secondary outcomes (change in self-reported self-management behaviour, change in self-reported psychological functioning, BMI).
    - Method of assessing the outcomes. For the primary outcome of HbA_{1c} level, this was an objective laboratory measurement. For the secondary outcomes, change in self-reported self-management behaviour was measured using validated measures [e.g. the Summary of Diabetes Self-Care Activities[69] measure], as was psychological functioning [e.g. depression was measured using the Patient Health Questionnaire-9 items (PHQ-9)[70]], the Center for Epidemiologic Studies Depression Scale (CES-D),[71] the Montgomery–Åsberg Depression Rating Scale,[72] the Beck Depression Inventory,[73] the Hospital Anxiety and Depression Scale[74] or the Symptom Checklist Depression Scale-20 items[75]] and QoL [measured using the World Health Organization (WHO) Quality of Life-BREF,[76] the Diabetes-specific QoL Measure,[77] Ferrans and Powers QoL Index,[78] the Short Form questionnaire-12 items or the EuroQol-5 Dimensions[79]]. Scores were standardised prior to analysis.
    - Time point of follow-up (post baseline or post treatment), *baseline and follow-up data* (or mean change).

For studies that were not reported in the English language, a restricted data extraction took place; for example, not all publication and patient characteristics were extracted. An example of data extracted from an Iranian study can be found in *Appendix 4*.

Individual patient data integrity

Data integrity was conducted. This involved an initial assessment of data completeness. Each data set received from the study authors was checked to determine the consistency of the main analysis with that in the published report.

Risk of bias in individual studies

The quality of RCTs was assessed using Cochrane Handbook Tool for Risk of Bias (RoB).[80] RoB assessment was carried out by two independent researchers (RU and KW); any disputes were resolved by a third researcher (KI). Studies were assessed as having a high, low or unclear RoB for the following domains: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data (for glycaemic control HbA_{1c}% or mmol/mol), selective outcome reporting and other potential threats to validity. This was used to generate a graph for data synthesis (study reference vs. RoB domain). Studies were not excluded from the meta-analyses based on RoB assessment; for example those rated as having a high RoB were not excluded.

Synthesis methods

Systematic review

A standardised structured synthesis of all studies included in the systematic review was conducted. If a study did not contain sufficient data to be pooled in the meta-analysis, it was summarised in a narrative synthesis.

Aggregate meta-analysis

The mean difference in change between baseline and follow-up (12 months or closest) scores between the two groups (psychological intervention vs. control group or least psychological intervention) was standardised by calculating Cohen's *d* for each of the included studies. The effect size was calculated from the raw published data or, if the necessary raw data were missing from publication, authors were contacted to provide data.

The standardised effects were pooled using a random-effects model and meta-analysis was performed in Stata 14 using the 'metan' command. The 'metainf' command was used to examine the influence of individual studies whereby meta-analysis estimates are computed omitting one study at a time. Publication bias was assessed using the Stata commands 'metabias' (Egger's test), 'metafunnel' (funnel plot) and 'metatrim' (fill and trim method for estimating missing studies). Any meta-regression was performed using the 'metareg' command. We conducted the meta-analyses only if there were five or more studies available because of problems to reliably estimate the between-studies variance of random-effects models.[81]

The combined data from previous systematic reviews[40,57] were aggregated with the current review to determine an overall effect size for change in glycaemic control. The findings of the current review were also reported separately.

Network meta-analysis

Organisations such as the NHS and the National Institute for Health and Care Excellence (NICE) need the synthesis of evidence from existing studies to inform their decisions. Meta-analysis methods combine evidence from related studies to produce results based on a whole body of research. However, relevant studies may not provide direct evidence about all the treatments or outcomes of interest. Often treatments are compared with different control treatments. NMA is a method to address this, using correlated or indirect evidence from such studies, alongside any direct evidence.[82]

Unlike standard meta-analyses that are based on combining results from the same or similar sets of treatments/and or controls, NMA allows simultaneous analysis of multiple treatments (and multiple outcomes) and, thus, allows the inclusion of all available information towards each outcome and treatment comparison. This is done by incorporating indirect evidence from related treatment comparisons (e.g. A–B and B–C allows one to infer an A–C comparison), in addition to any standard direct evidence. A treatment effect, therefore, can differ not only between studies (heterogeneity) but also by design (inconsistency). NMAs assume 'transitivity', which concerns mainly the validity of indirect comparisons. Transitivity refers to the assumption that it was equally probable that any patient in the network could have been given any of the treatments in the network. It is an assumption of balanced clinical and methodological study characteristics between the direct comparisons that make up an indirect comparison.[83]

In the first step, network plots of direct comparisons of all available studies for the NMA were assessed. Circles (nodes) represent the intervention type and lines that connect the interventions represent the direct comparisons available in the literature (see *Figures 18*, *21* and *22*). The width of the lines is proportional to the number of trials comparing each pair of treatments and the size of each node is proportional to the number of studies testing the specific treatment. The network pattern plot for all treatments was conducted to show which treatments were used in which studies.

In the main step, we performed network multivariate random-effects meta-analyses to perform frequentist estimation of meta-analyses models[84], which allows for both heterogeneity (variation in the true treatment effect between studies) and inconsistency (additional variation in the true treatment effect between different sets of treatments compared in a study). Inconsistency is modelled as a fixed effect using the design-by-treatment interaction model.[84,85]

Inconsistency in the contrasts between designs was assessed by comparing direct and indirect treatment effects of a contrast between two treatments and an overall Wald test of inconsistency treatment.[86]

If there was no evidence of inconsistency, a consistency model was fitted. Standardised mean differences (SMDs), using treatment as usual as control group, are presented in *Chapter 5*. The formulae for Hedges' *g* in White and Thomas[87] are used to estimate the SMD. These are unbiased estimators and involve corrections for small numbers of degrees of freedom.

In the last step, the performance of different treatments was assessed by estimating relative treatment rankings. Ranking probabilities for all treatments at each possible rank for each intervention are presented in *Chapter 5* as cumulative probability plots. The treatment hierarchy was established using the surface under the cumulative ranking (SUCRA) curve and mean ranks. SUCRA accounts for the location as well as the variance of all relative treatment effects. The larger the SUCRA value, the better the rank of the treatment.

Individual patient data meta-analysis

For the IPD meta-analysis, baseline variables were described using mean and standard deviation (SD) for continuous variables and frequencies and percentages for categorical variables.

For the outcome measure of HbA_{1c} level, we performed an IPD 'one-stage' meta-analysis. The one-stage was preferred to the 'two-stage' IPD meta-analysis because it is more suitable for exploring predictors and moderators of response (for reviews, see Simmonds *et al.*[88] and Debray *et al.*[89]). In addition, the one-stage approach uses a more exact likelihood function and, thus, does not rely on assumptions of within-study normality and known study variances.[90] The one-stage model uses a random effects model to account for the clustering of patients within studies.[91,92]

Data were analysed using the Stata commands 'mixed' and 'ipdforest', in accordance with the recommendations of guidelines for performing IPD one-stage meta-analysis in Stata.[93]

Participants with T1DM and T2DM were analysed separately. Of participants with T1DM, adolescents/children (< 18 years) and adults (≥ 18 years) were analysed separately.

We used linear regression models with HbA_{1c} level as outcome, and treatment type and baseline values of HbA_{1c} as fixed independent variables, with a random intercept for study and random treatment effect, and a random effect for baseline measures of HbA_{1c} levels. For adolescents/children with T1DM, only a random effect for treatment arm was included. The variance–covariance structure was considered to be independent; this structure allows a distinct variance for each random effect within a random-effects equation and assumes all covariances to be zero. The random effect structure was selected by model comparisons using the Bayesian information criterion.[94]

To identify moderators of improvement in HbA_{1c} levels, we ran several analyses, initially using only one predictor variable and its interaction with treatment arm at a time to avoid reducing sample size. The moderators considered included age, duration of diabetes and, for T2DM only, type of diabetes medication and gender. Non–significant interactions were removed and main effects were reported. In the last step, we assessed year of study as a potential confounder. Because not all variables were collected in all trials, sample sizes change between different studies. However, it can be assumed that data missing by design are missing completely at random, which does not produce any bias. Within studies, a complete-case analyses was performed, assuming that missingness is completely at random, unless a predictor of missingness is included as a covariate. In this case, missing at random is assumed.

The intraclass correlation for the random-effects study was presented as a measure of the correlation of patients in a cluster study site. We also present the estimate I^2 statistic to describe the percentage of variation across studies that is caused by heterogeneity rather than chance.

Risk of bias across studies

Publication bias was assessed by inspecting funnel plots and the effect of possible bias was assessed using the 'trim and fill' method in sensitivity analyses.[95] Meta-regression was used to investigate the possible effects of age of study and study quality, and compared with the data pooled for the previous T1DM and T2DM meta-analysis.[40,57]

Additional analyses

A meta-regression was conducted to determine whether or not factors such as country of study, number of therapy sessions, duration of therapy session, overall duration of treatment, control group and RoB were associated with changes in glycaemic control. Meta-regression was also performed to determine any difference between previous reviews[40,57] and the current review with regard to change in glycaemic control.

A network analysis was also undertaken including all arms of studies with more than two intervention arms. The NMAs allowed a comparison of results from two or more studies that have one treatment in common.

Confidence in synthesised evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used to determine the quality of the evidence of the outcomes under investigation and subsequent translational strength of recommendations for clinical practice.[96] The GRADE criteria were used to assess the quality of aggregate meta-analysis evidence for each outcome (primary and secondary) for T1DM and T2DM. The quality for each outcome was rated according to the following: RoB, inconsistency, indirectiveness, imprecision and publication bias. Each factor can be rated as not serious, serious or very serious. Overall evidence for each outcome can be rated as high (no problems in any factors), moderate (problem in one factor), low (problem in two factors or very serious problem in one factor) or very low (problem in three or more factors).

Part B: non-randomised controlled trial systematic review methods

Eligibility criteria

Eligibility criteria for the nRCT systematic review follows the same method as the RCT review (see *Part A: systematic review, randomised controlled trial meta-analysis, network meta-analysis and individual patient data meta-analysis methods*) for type of participants, types of intervention (health technologies) and types of outcome measures. Types of studies was also the same, except this review included published and unpublished non-randomised controlled studies of interventions to improve motivation for self-management rather than RCTs. Only reports of nRCTs written in English were selected.

Identification of studies

Information sources and search strategy

The following electronic databases were searched for nRCTs: EMBASE (2003 to January 2017), MEDLINE (2003 to January 2017) and PsycINFO (2003 to 16 January 2017). The search strategy for nRCTs used in EMBASE and MEDLINE were taken from Li *et al.*[97] and MEDLINE's nRCT search terms were used in PsycINFO to generate results (see *Appendix 6* for search terms for nRCTs).

Study selection and data collection process

Initially, one reviewer (AK) independently selected abstracts after running the searches in the electronic databases. In the following step, two reviewers (AK and RU) screened the full texts and made a decision to include studies that met the eligibility criteria. Any disagreement was resolved through discussion with a third researcher (KW). The inter-rater reliability was calculated using the Cohen's kappa. One reviewer (AK) extracted data from the articles that met all the inclusion criteria using a data extraction form (see *Appendix 7* for blank data extraction table for nRCTs).

Data items

Data were extracted for the characteristics listed below for the nRCT narrative synthesis:

- Publication characteristics – year of publication, country of origin, health-care setting, study design.
- Patient baseline characteristics – type of diabetes, number of participants screened/assessed for eligibility, inclusion/exclusion criteria, number of participants assigned to psychological intervention, number of participants assigned to control, number of participants lost to follow-up, reasons for loss to follow-up, mean age (years at baseline), mean duration of diabetes (years at baseline) and gender.
- Intervention and control characteristics – same as RCT systematic review reported in *Part A: systematic review, randomised controlled trial meta-analysis, network meta-analysis and individual patient data meta-analysis methods*.
- Outcome characteristics – outcome measure, method of assessing outcome, type of outcome (e.g. HbA_{1c} levels, change in psychological functioning, change in self-management behaviours, other), time point of follow-up, post-baseline or post-treatment findings, and other (e.g. any discussion points, notes about the study).

Risk of bias assessment

To assess the quality of studies, we used the Risk of Bias in Non-randomized Studies – of Interventions (ROBINS-I),[98] created by the Cochrane Methods Bias Group and Cochrane Non-Randomized Studies for Interventions Methods Group. The tool is designed to approximate the effectiveness of interventions that do not use randomisation to assign treatment groups to subjects. The tool includes seven domains to investigate bias in non-randomised studies. The first two domains are pre intervention and are used to determine confounding at baseline (prognostic factors that predict the outcome and/or predict the intervention received) and participant selection biases (exclusion of subjects who were eligible for the study). The third domain concerns bias when classifying the intervention, such as observer or measurement bias. The last four domains focus on the post-intervention period, addressing biases due to aberrations from the planned intervention, missing data, measurement issues or problems with the reporting of data. A study is said to have a low risk of bias when the study is similar to a well-conducted RCT across all the domains. Moderate risk denotes that a study is comparable to a thorough nRCT but not as good as a RCT. For serious risk, the study has some major issues and critical risk means that the study has too many problems and cannot provide any valuable information. 'No information' (NI) is assigned to studies when one or more domain is lacking information that makes decision-making regarding the risk difficult.

Synthesis methods

Systematic review

Structured narrative synthesis was used to evaluate the results of the review as the included studies were heterogeneous in nature and design. Results are reported by diabetes type, T1DM (including both adult and adolescent populations) and T2DM. The studies were systematically appraised by highlighting the similarities/dissimilarities between texts. The current review focused on the study characteristics, type of participants included, intervention and control designs, attendance and dropout rates, reporting of fidelity assessments in studies, types of outcome measures, methods of their assessment, risk of bias in studies and a summary of individual study results.

Part C: health economics methods

In this section, we report the methods for the literature reviews of health economic studies and an overview of the methods used to develop and adapt two existing health economic individual-level simulation models {the Sheffield Type 1 Diabetes Policy Model [Thokala P , Kruger J, Brennan A, Basarir H, Duenas A, Pandor A, *et al. The Sheffield Type 1 Diabetes Policy Model*. HEDS Discussion Paper 13/05. Sheffield; 2013 (unpublished)] and the School for Public Health Research [SPHR] Type 2 Diabetes Prevention Model[99]}, which were utilised in this study to address the research questions regarding the cost-effectiveness of psychological interventions. *Chapter 8* reports the detail of the health economic analyses undertaken.

Literature searching for previous economic evaluations

Methods

We undertook a process that involved:

- Web of Science citation-searching on the found articles in the clinical effectiveness systematic review.
- The reference lists of the articles were read to identify protocol articles.
- If protocol articles existed, they were also citation-searched.
- Known literature sources of health economic literature were examined, including studies on T1DM and T2DM.
- The Mount Hood website[100] was also searched.

This process was adopted so that the search for economic studies could use the studies found in the clinical review to find the articles that related to economic evaluations of psychological interventions.

The main inclusion criterion was an economic evaluation in which one arm was a psychological intervention. We did not exclude within-trial analyses, as they could provide useful costing information.

Results

One study was found, the ADaPT (A Diabetes and Psychological Therapies study) within-trial health economic analysis.[101] This was used to inform costings for psychological therapies (see *Chapter 8*).

Conclusions

A new health economic modelling exercise would be required for both T1DM and T2DM.

Literature searching for long-term effectiveness studies

Methods

- Web of Science citation searching on the found articles in the clinical effectiveness systematic review.
- The reference lists of the articles were read to identify protocol articles.

Results

Only one relevant paper was found. The ADaPT long-term follow-up[101] report. This has been used in *Chapter 8* to estimate longer-term HbA_{1c} level trajectories after 12 months.

Overview of the health economic analyses undertaken

In this subsection, we summarise the new health economic modelling work undertaken for this report using the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist framework.[102]

The CHEERS checklist items are as follows.

Present the study question and its relevance for health policy or practice decisions

We undertook two main studies to examine the cost-effectiveness of psychological interventions versus usual care: one for adults with T1DM and one for adults with T2DM. The interventions chosen were those interventions identified in the NMA results for interventions with more than two studies. Attention control was not included as a comparator arm, as this was not a psychological intervention. Psychotherapy was not assessed for adults with T2DM, as the *p*-value was very close to 1 ($p = 0.98$).

- Cost-effectiveness of CBT versus counselling versus usual care in adults with T1DM.
- Cost-effectiveness of CBT versus counselling versus usual care in adults with T2DM.

Target population and subgroups
The target populations were adults with T1DM and adults with T2DM. No further subgroup analyses were undertaken because of limited evidence on subgroup effectiveness differences, that is the evidence was too limited to enable NMAs by subgroups. We did not model cost-effectiveness for adolescents with T1DM because the NMAs for adolescents (see *Chapter 5*) showed only non-significant differences, with *p*-values typically ranging from 0.4 to 0.9.

Setting and location
The studies were set in the UK.

Study perspective
The perspectives used were the NHS and Personal Social Services (PSS).

Comparators
The comparators were CBT versus counselling versus usual care in adults with T1DM, and CBT versus counselling versus usual care in adults with T2DM.

Time horizon
A lifetime time horizon was used.

Discount rate
A discount rate of 3.5% per annum was applied.

Choice of health outcomes
HbA_{1c} effects in year 1 and HbA_{1c} longer-term trajectories evidence were used as input to the individual-level simulation models, which then analysed the numbers of clinical events. For T1DM, the clinical events included were nephropathy, neuropathy, retinopathy, macular oedema, myocardial infarction, stroke, heart failure, angina, severe hypoglycaemia and DKA. For T2DM, the clinical events included were kidney disease, ulcer, amputation and blindness, cardiovascular disease (CVD), congestive heart failure, osteoarthritis, depression and breast or colon cancer.

Measurement of effectiveness
Quality-adjusted life-years (QALYs) were used as the measure of effectiveness.

Measurement and valuation of preference-based outcomes
Quality-adjusted life-years were based on utility values for health states from published literature and previous studies using the models and life expectancy (see *Appendix 16* for the utilities used in the T1DM analyses).

Estimating resources and costs
Resource use associated with model health states was estimated based on published literature and previous studies using the economic models. Costing of psychological interventions was undertaken based on their description in clinical studies and liaison with UK experts in the project team.

Currency, price date and conversion
Costs were inflated to 2015/16 Great British pound (GBP) values.

Choice of model
Two previously used individual-level simulation models were extended and adapted to incorporate evidence on psychological interventions.

Assumptions
Assumptions are reported in detail in *Chapter 8* (for T1DM and T2DM populations). The key assumptions in relation to this particular study relate to the evidence to be utilised for the long-term trajectory of HbA_{1c} levels for people who receive a psychological intervention versus those who do not.

Analytic methods
Analytic methods are reported in detail in *Chapter 8* (for T1DM and T2DM populations).

Study parameters
Study parameters are reported in detail in *Chapter 8* (for T1DM and T2DM populations).

Incremental costs and outcomes
Lifetime discounted costs and QALYs for each comparator are used to quantify incremental cost-effectiveness ratios (ICERs) (incremental cost/incremental QALYs) and net monetary benefit (QALYs × £20,000 – costs).

Characterising uncertainty
A probabilistic sensitivity analysis (PSA) was undertaken using uncertainty on all parameters. A total of 500 samples of the parameters were used; for each sample, 5000 individual patients were simulated in each arm of the model. We used the Sheffield Accelerated Value of Information (SAVI) online tool to calculate the expected value of perfect information (EVPI) to quantify overall decision uncertainty. Expected value of perfect parameter information (EVPPI) analysis was also used to identify key uncertainties to inform priorities for further research in terms of reducing uncertainty about the quantitative effects of psychological interventions.

Characterising heterogeneity (e.g. subgroup differences)
No further subgroup analyses were undertaken because of limited evidence on subgroup effectiveness differences.

The reporting of both models in this report have been compared to the Palmer *et al.*[103] checklist for the reporting model inputs in diabetes simulation models. These checklists are provided separately for the modelling of psychological interventions for people with T1DM and people with T2DM in *Appendix 16*.

Part D: patient and public involvement methods
We used qualitative methods to determine the views of people with diabetes with regard to the initial findings of this systematic review and meta-analysis.

Aims
The aims of the focus groups were to:

- determine patient views on the preliminary findings of the RCT systematic review and meta-analysis
- discuss the best ways to inform patients and the public regarding the review findings.

Participants, recruitment and setting
People with T1DM and people with T2DM were identified from London and Sheffield and surrounding areas to take part in a focus group. The focus groups were advertised via NHS England, Diabetes UK local groups, Twitter (Twitter, Inc., San Francisco, CA, USA; www.twitter.com), Lay ADvice for Diabetes and Endocrine Research (LADDER) patient and public involvement (PPI) panel in Sheffield, and patient information boards in diabetes clinics.

The focus group in London was held in a conference room at KCL, and the Sheffield focus group was held at the University of Sheffield. The focus groups were facilitated by the principal investigator (KW), PhD student (RU), and a MSc Health Psychology student [Sophie Fawson (SF)].

Focus group meetings were held in March 2017 for the London and Sheffield groups. Participants were offered up to £50 in travel expenses and £75 for their time on the day. Lunch was also provided.

Procedure

Focus group participants were provided with a formal invite and information sheet prior to the focus group meeting. The information sheet detailed what the review involved, a definition of a psychological intervention and what we aimed to achieve through this research.

On the day of the focus groups, participants consented to the session being audio-taped and transcribed, and consented to the use of unattributed quotations in the report.

Kirsty Winkley introduced the research team and initiated participant introductions and discussion. Participants were first asked: 'What three things do you feel would improve your diabetes care from hospital/general practice?' Each member of the focus group was given the opportunity to answer this question, which prompted everyone in the group to speak.

Rebecca Upsher presented preliminary findings of the research using mini posters (see *Appendix 8*), which also included characteristics of the studies included in the review, for example intervention facilitators, mode of delivery, type of psychological intervention and format of delivery. Kirsty Winkley then asked the group questions based on these findings. This was split into three phases, to present findings and ask questions based on studies of adolescents/children with T1DM, adults with T1DM and T2DM. Following this, participants were then asked questions regarding their views on how the findings of the research should be disseminated.

Focus groups lasted ≈2 hours.

Focus group questions

These questions followed the presentation of findings:

- What are your impressions of these findings for T1DM/T2DM?
- What are your thoughts on the delivery of psychological interventions for T1DM/T2DM?
- Do you feel that psychological interventions can help better manage your diabetes? How/why not?
- In your opinion, what components of a psychological intervention are important to help improve T1DM/T2DM management?
- What types of psychological support for T1DM/T2DM would you like to see offered?
- Do these findings convince you that psychological interventions are important in T1DM/T2DM? How so/why not?

Dissemination

- How do you access information about diabetes-related research?
- Where would you like to see the results of our research published?
- If you were to see our research published, what pieces of information are most important to you to inform you about the literature of psychological interventions in diabetes care?

Synthesis of focus group findings

Sophie Fawson took notes during the focus group sessions, listened to interview transcripts and summarised findings detailing participant views of research findings and views of the best methods to disseminate findings.

Chapter 4 Results

Study selection and individual patient data obtained

Literature searches identified 24,694 citations (*Figure 1*). There were 16,705 citations after removing duplicates; titles/abstracts were screened for eligibility. A total of 259 articles were assessed for full-text eligibility, conducted per protocol. A total of 182 studies were excluded based on the full-text screening. No unpublished studies were identified. Fourteen studies were included in qualitative analysis for adults with T1DM and seven were included in the aggregate meta-analysis (three studies[104–106] were from papers that included a T1DM and T2DM population, and separate analysis per diabetes type was provided by the author). Eighteen studies were included in the qualitative analysis for adolescents/children with T1DM and 14 studies were included in the aggregate meta-analysis. Fifty-six studies were included in the qualitative analysis for adults with T2DM and 40 studies were included in the aggregate meta-analysis (three studies[104–106] were from papers that included a T1DM and T2DM population, and separate analysis per diabetes type was provided by the author). Eleven studies included in the qualitative analysis included a T1DM and T2DM population; for eight of these studies, no separate analysis per diabetes type could be provided for the aggregate meta-analysis.

In the re-screen, 19 new studies were identified: (see *Figure 1*) 11 adult T2DM studies (nine for the aggregate meta-analysis) and four studies on T1DM in adolescents/children (all with sufficient data for the aggregate meta-analysis) and four studies with an adult T1DM and T2DM population (all with sufficient data for the qualitative synthesis).

For the IPD (*Figure 2*), 58 study authors included in the aggregate meta-analysis were contacted (from studies identified prior to re-screening of study abstracts) and 41 responded (70.69%); 29 provided data (50%), (adults with T1DM: $n = 6$ studies, 751 participants; adolescents/children with T1DM: $n = 9$ studies, 1392 participants; adults with T2DM: $n = 19$ studies, 3639 participants; note that five studies included people with T1DM and people with T2DM). Twelve study authors responded but declined to forward data for the following reasons: three authors and/or their research team had no access to data, two authors were not interested in participating, two could not provide data, citing ethical reasons, and five did not have time to find the data set within the given time frame. The total number of participants for the IPD data set was 5823. Authors of studies identified when we re-screened study titles and abstracts were not contacted because of insufficient time.

Type 1 diabetes mellitus adult study characteristics

For the qualitative synthesis for adults with T1DM, 18 studies were included; 13 studies had a mixed T1DM and T2DM population. Studies are described qualitatively and a summary of study characteristics for each is reported in *Table 1*. Details of psychological interventions, control groups and interventionist categories are included in *Appendix 5*.

Study location

Twelve studies were conducted in Europe (Denmark, $n = 3$;[165,166,178] Germany, $n = 3$;[105,106,190] the Netherlands, $n = 3$;[104,164,197] Sweden, $n = 1$;[162] the UK, $n = 1$;[163] and Norway, $n = 1$[188]), one in Australia[108] and five in North America.[187,192,193,195,196]

Participant characteristics

The total sample size for all adult T1DM studies was 1457 ($n = 13$; five studies with a mixed T1DM and T2DM population did not provide sample size per diabetes type). Across studies, the sample size ranged from 11 to 315 participants.

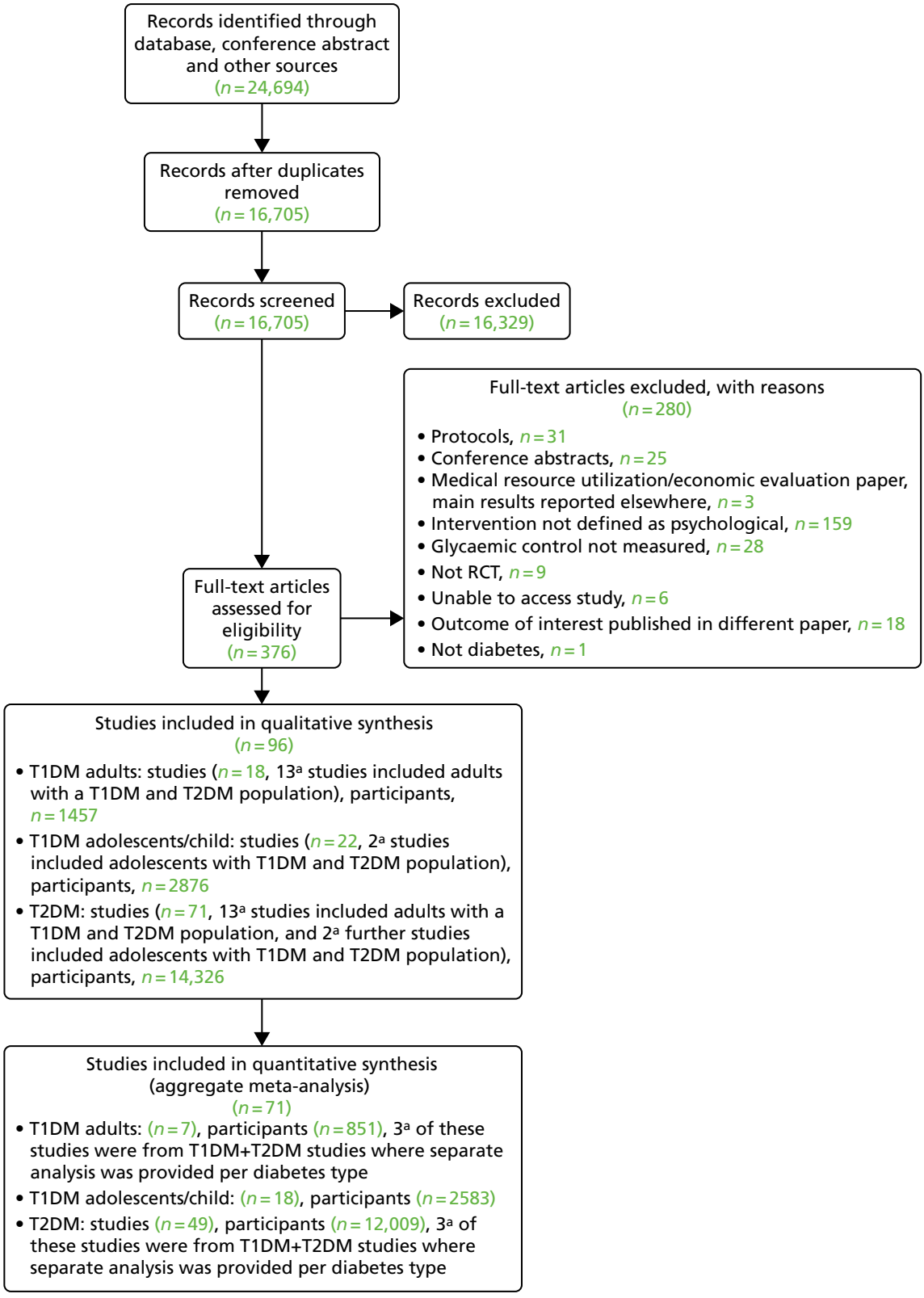


FIGURE 1 The PRISMA flow diagram for all studies (including re-screened studies) for the qualitative synthesis and aggregate meta-analysis. a, Same studies.

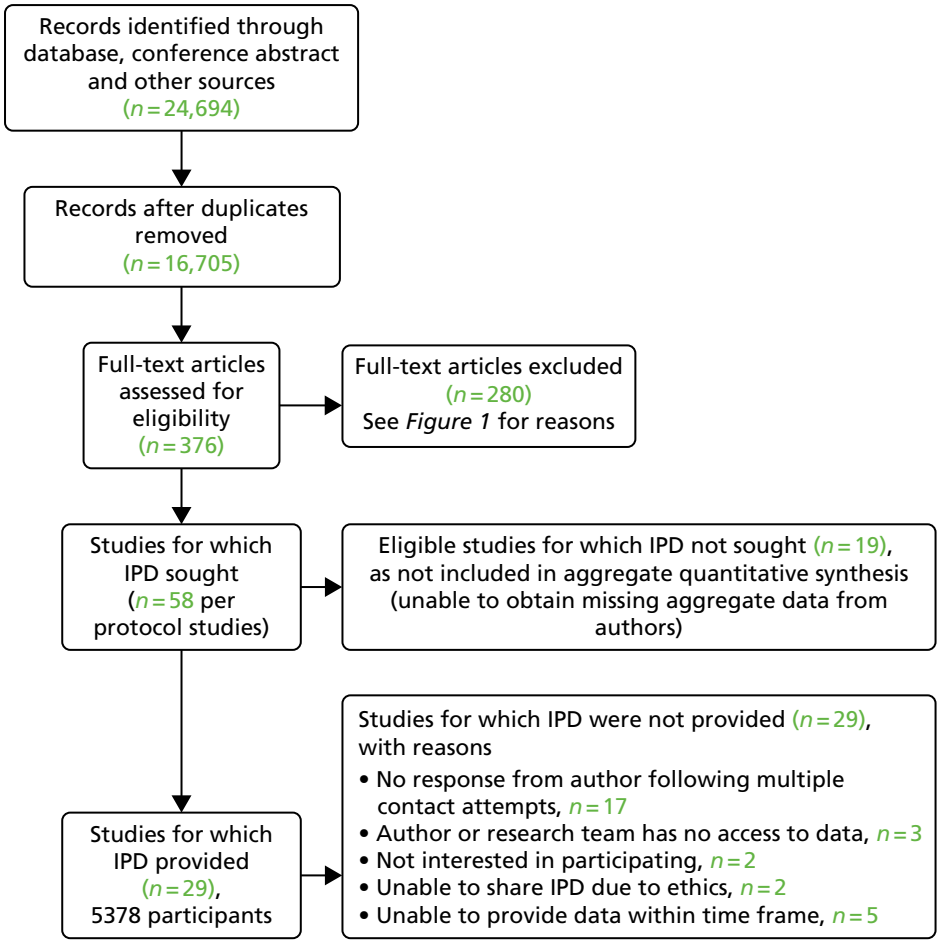


FIGURE 2 The IPD PRISMA flow diagram.

Intervention characteristics

Most studies tested a CBT intervention ($n = 9$),[104–106,162–164,188,192,197] followed by counselling ($n = 7$)[108,165,166,190,191,193,196] and collaborative care, including elements of psychotherapy ($n = 2$).[188,195] Studies were delivered by non-diabetes specialists, including psychologists, primary care physicians and peers ($n = 8$)[104–106,164,191,195–197] and diabetes specialists (i.e. diabetes nurses, diabetes educators) ($n = 10$).[108,162,163,165,166,187,188,190,192,193] The mode of delivery was mostly face to face ($n = 15$),[104–106,162–166,187,188,190–192,195,197] with two intervention studies delivered via telephone.[193,196] One study was delivered face to face and by telephone.[108] Most studies were delivered in a group setting ($n = 9$);[104–106,162,164–166,188,192] the rest were delivered one to one ($n = 9$).[108,163,187,190,191,193,195–197] The number of psychological therapy sessions ranged from 5 to 14, and sessions lasted between 45 minutes and 2 hours. The total duration of therapy ranged from 1.5 to 20 months.

Control characteristics

Control groups were categorised into two different types: usual care and attention control (matched with the intervention in frequency and length). Fourteen studies[104,106,108,162,163,165,166,187,188,191,193,195–197] delivered usual diabetes care as a control, and four studies[105,164,190,192] delivered attention control; this included blood glucose awareness training (BGAT) ($n = 1$)[164] and diabetes education ($n = 2$).[105,192] One study[190] delivered peer support to the control participants; this was coded as attention control.

Primary outcome

The primary outcome was HbA_{1c} level (measured as % or mmol/mol). The mean difference was calculated from baseline to 12 months' follow-up (or the closest measurement to 12 months) for the intervention and control groups. The time between HbA_{1c} level follow-up measurements between studies ranged from 2 to 18 months for adult T1DM studies.

TABLE 1 Summary of characteristics for RCTs in the systematic review and meta-analysis for all studies

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
T2DM studies included in the meta-analysis									
2004, the USA, Whittemore[107]	49	All: 57.6 (10.9)	T2DM, 30–70 years, HbA_{1c} level of > 7%	2.7 (3.0)	Counselling	6	Nurse-coaching intervention, nurses, face to face, individual	Usual care	6 months
2012, the USA, Williams[108]	293	• Intervention: 70.1 (6.9) • Control: 70.3 (7.1)	T2DM, > 60 years	NR	Collaborative care (including psychotherapy)	6–8	Collaborative care (depression treatment including problem-solving treatment); depression clinical specialist plus GP; face to face; individual	Usual care	12 months
2006, Germany, Siebolds[109]	223	• Intervention: 58.7 (7.6) • Control: 60.5 (6.6)	T2DM	• Intervention: 65.5 (57.2) • Control: 62.6 (47.3)	Counselling	4	Counselling, physician, face to face, individual	Dietary counselling, physician, face to face, individual	6 months
2006, Thailand, Keeratiyutawong[110]	90	27–60	T2DM for < 10 years; OADs only; fasting blood glucose of > 130 mg/dl on at least two occasions	NR	CBT	5	Self-management group; psychology researcher; face to face; group	Diabetes education; diabetes health-care team; face to face; individual	6 months
2007, the USA, Gregg[111]	81	• Intervention: 51.9 • Control: 49.8	T2DM	• Intervention: 5.3 • Control: 6.6	Counselling	1	ACT, psychologist, face to face, group	Diabetes education, psychology masters-level students, face to face, group	3 months
2007, the USA, West[112]	217	• Intervention: 54 (10) • Control: 52 (10)	T2DM, treated with OADs, not insulin; overweight	• Intervention: 5.8 (6.5) • Control: 4.9 (5)	Counselling	5	MI; clinical psychologists; face to face; individual	Diabetes education; health educators; face to face; individual	12 months
2009, the UK, Dale[113]	231	*n* (%) • Intervention 1: < 50 years = 6 (14.3); 51–69 years = 25 (59.5); > 70 years = 11 (26.2) • Intervention 2: < 50 years = 17 (19.3); 51–69 years = 46 (52.3); > 70 years = 25 (28.4) • Control: < 50 years = 12 (13.5); 51–69 years = 54 (60.7); > 70 years = 23 (25.8)	T2DM, not treated with insulin, HbA_{1c} level of > 8%	• Intervention 1: < 1 year = 6 (14.3); 1–15 years = 30 (71.4); > 15 years = 6 (14.3) • Intervention 2: < 1 year = 16 (18.2); 1–15 years = 65 (73.9); > 15 years = 7 (8.0) • Control: < 1 year = 12 (13.6); 1–15 years = 72 (18.8); > 15 years = 4 (4.6)	Counselling	6	• Telephone support (MI); nurses; telephone; individual • Telephone support (MI); peers; telephone; individual	Usual care	6 months

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2009, Iran, Davazdah[114]	40	35–60	T2DM	NR	CBT	12	CBT, trained researcher, face to face, group	Waiting list; see intervention description	3 months
2009, the USA, Sacco[115]	62	52 (8.6) for all participants	T2DM; HbA_{1c} level of > 6.5%	9.5 (7.2) for all participants	Counselling	18	Telephone 'coaching' intervention; undergraduates in psychology; telephone; individual	Usual care	6 months
2010, Australia, Evans[116]	60	57.1 (22–84) for all participants	T2DM	14.3 (1–45) for all participants	CBT	7	CBT; face to face; group	Waiting list (usual care for 3 months, then intervention)	3 months
2010, the USA, Wolever[117]	56	• Intervention: 53.1 (8.29) • Control: 52.8 (7.64)	T2DM for > 1 year, OADs for > 1 year	• Intervention: 11.8 (8.5) • Control:10.6 (6.43)	Counselling	14	Integrative health coaching; coaches (masters-level degrees in social work or psychology); telephone; individual	Usual care	6 months
2010, the USA, D'Eramo Melkus[118]	109	• Intervention: 47 (9) • Control: 45 (10)	T2DM; black women; did not require insulin, BMI of < 37 kg/m^2	NR	CBT	11	CBT + DSMT + CST; nurse; face to face; group	Diabetes education; nurse; face to face; group	3 months
2010, Belgium, De Greef[119]	41	• 35–54 years (*n*): intervention – 6; control – 3 • 55–75 years (*n*): intervention – 35; control – 18	T2DM for ≥ 6 months	• 1–5 years (*n*): intervention – 16; control – 8 • > 5 years (*n*): intervention – 25; control – 13	CBT	5	cognitive–behavioural pedometer-based group intervention; coaches (degree in PE, movement sciences or clinical psychology); face to face; group	Usual care	52 weeks
2010, the USA, Hawkins[120]	66	• Intervention: 64 • Control: 65.8 (10.4)	T2DM, ≥ 60 years	• Intervention: < 1 year – 7 (26.5); 1–5 years – 10 (29.4); 6–10 years – 9 (26.5); > 10 years – 6 (17.6) • Control: < 1 year – 3 (9.3); 1–5 years – 15 (46.9); 6–10 years – 6 (18.8); > 10 years – 8 (25)	CBT	12	MI video call; nurses, telephone, individual	Attention control telephone support (no MI); nurses; telephone; individual	6 months

continued

TABLE 1 Summary of characteristics for RCTs in the systematic review and meta-analysis for all studies (*continued*)

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2010, the USA, Osborn[121]	185	• Intervention: 56.9 (11.3) • Control: 58.4 (10.1)	T2DM for > 1 year; Puerto Rican ethnicity	• Intervention: 13.2 (12) • Control: 12.3 (9.4)	Counselling	1	Culturally tailored diabetes self-care intervention; bilingual medical assistant of Puerto Rican heritage; face to face; individual	Usual care	3 months
2011, Chile, García-Huidobro[122]	167	• Intervention: 53.4 (8.1) • Control: 53.5 (9.8)	T2DM, 18–70 years, HbA_{1c} level of ≥ 7%	NR	Family therapy	4	Family intervention, health-care team, face to face, family	Usual care	6 months
2011, Ireland, Keogh[123]	121	• Intervention: 59.96 (11.67) • Control: 57.29 (11.34)	T2DM for > 1 year, having at least two of their last three HbA_{1C} readings at ≥ 8.0%	• Intervention: 9.17 (7.1) • Control: 9.65 (6.45)	Counselling	3	Family-based intervention; health psychologist; face to face; family	Usual care	6 months
2011, Belgium, De Greef[124]	67	• Intervention 1: 70 (6.3) • Intervention 2: 66.6 (9.5) • Control: 66 (11.1)	T2DM for ≥ 6 months, aged ≤ 80 years, BMI of 25–35 kg/m^2, HbA_{1c} level of ≤ 12%, pharmaceutically treated for T2DM	< 5 years (%) • Intervention 1: 68.5% • Intervention 2: 66.7% • Control: 59.1% > 5 years: • Intervention 1: 31.6% • Intervention 2: 33.3% • Control: 40.9%	Counselling	3	• Group behavioural intervention; clinical psychologist; face to face; group • Individual consultation; GP, face to face, individual	Usual care	12 weeks
2011, Iran, Hamid[125]	46	32–65	T2DM	NR	CBT	12	CBT, trained researcher, face to face, group	Waiting list, see intervention description	6 months
2011, the USA, Piette[126]	291	• Intervention: 55.1 (9.4) • Control: 56 (10.9)	T2DM, ≥ 21 years; antihyperglycaemic medication; depressed, as measured by the PHQ-9	NR	CBT	12	Telephone-delivered CBT; nurses; telephone; individual	Enhanced usual care (usual care + copy of self-help book based on CBT for depression)	12 months
2011, the Netherlands, Lamers[127]	70	• Intervention: 70.7 (6.6) • Control: 69.7 (6.6)	T2DM; depressed, as3 measured by the PHQ-9; ≥ 60 years	• Intervention: 8.2 (8.8) • Control: 9.8 (9.1)	CBT	4	Minimal psychological intervention; nurses; face to face; individual	Usual care	9 months

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2011, the USA, Welch[128]	119	• Intervention 1: 56.1 (10.4) • Intervention 2: 54.9 (9.3) • Control 1: 57.2 (10.9) • Control 2: 54.4 (10.3)	T2DM, 30–70 years, (HbA_{1c} levels of ≥ 7.5%)	• Intervention1: 9.8 (8) • Intervention 2: 9 (7.3) • Control 1: 7 (6.5) • Control 2: 7.1 (5.8)	Counselling	4	• MI + computerised self-management: diabetes educator; face to face; individual • MI alone; diabetes educator; face to face; individual	• Diabetes education alone; diabetes educator; face to face; individual • Computer self-management alone; computer; individual	6 months
2011, the USA, Ell[129]	229	All: 54 (8.7)	T1DM or T2DM; ≥ 18 years; depressed, as measured by the PHQ-9	NR	Collaborative care (elements of psychotherapy)	NR	Socioculturally adapted collaborative care: primary care physicians/graduate social workers/diabetes depression clinical specialists; face to face/ telephone; individual	Enhanced usual care (usual care + prescribed antidepressant medication and provided counselling or refer to community mental health care)	12 months
2012, the UK, Farmer[130]	211	• Intervention: 62.5 (11) • Control: 64.1 (10.3)	T2DM, ≥ 18 years, HbA_{1c} levels of ≥ 7.5%	• Intervention: 6.7 (4.8) • Control: 6.9 (5.3)	Counselling	1	Consultation-based intervention, clinical nurses, face to face, individual	Usual care	8 weeks
2012, the USA, Penckofer[131]	74	• Intervention: 54.8 (8.8) • Control: 54 (8.4)	T2DM for > 6 months; ≥ 18 years; depressed, as measured by the CES-D	• Intervention: 10.5 (8.2) • Control: 10 (6.5)	CBT	8	Psychoeducation: nurses; face to face, group	Usual care	6 months
2012, Germany, Hartmann[132]	110	• Intervention: 58.7 (7.4) • Control: 59.3 (7.8)	T2DM, albuminuria	• Intervention: 11 (7.5) • Control: 12.2 (7.6)	Counselling	8	Mindfulness-based intervention: psychologist and a resident in internal medicine; face to face; group	Usual care	12 months
2012, Taiwan, Chen[133]	215	• Intervention: 59.19 (10.24) • Control: 58.67 (10.23)	T2DM for > 3 months, aged > 18 years	• Intervention: 7.98 (7.57) • Control: 7.91 (6.95)	Counselling	NR	MI: nurses; face to face; individual	Diabetes education; nurse/diabetes educator; face to face; group	3 months

continued

TABLE 1 Summary of characteristics for RCTs in the systematic review and meta-analysis for all studies (*continued*)

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2013, Canada, Plotnikoff[134]	287	• Intervention: 62.3 (11.1) • Control 1: 61 (11.7) • Control 2: 61.4 (12.6)	T2DM, > 18 years	• Intervention: 8.8 (7) • Control 1: 11.7 (9.9) • Control 2: 10.7 (9.9)	Counselling	22	Telephone counselling (MI): five individuals with relevant degree qualifications related to physical activity promotion and/or counselling; telephone; individual	1. Diabetes education; educational materials 2. Printed materials (relates to transtheoretical model)	12 months
2013, the Netherlands, Welschen[135]	154	• Intervention: 60.5 (9.4) • Control: 61.2 (8.8)	T2DM, 18–75 years, HbA_{1c} level of ≥ 52 mmol/mol (7.0%) and/or BMI of 27.0 kg/m^2 and/or smoking	• Intervention: 7.6 (5) • Control: 7.8 (6.1)	CBT	3–6	CBT; diabetes nurse and dietitian; face to face; individual	Usual care; dietitian/ diabetes nurse; face to face; individual	12 months
2013, the USA, Mandel[136]	131	• Intervention: 58 (11.29) • Control 1: 57.1 (9.67) • Control 2: 58.9 (10.76)	T2DM, 30–85 years, enrolled in diabetes education programme	• Intervention: 3.22 (5.94) • Control 1: 2.32 (6.1) • Control 2: 3.78 (7.06)	Creative therapy	4	Music therapy; music therapy clinician; face to face; group	1. Diabetes education; diabetes educator/ dietitian; face to face; group 2. Music relaxation CD	3 months
2013, the Netherlands, Jansink[137]	521	• Intervention: 64.1 (8.9) • Control: 63.9 (9.8)	T2DM, < 80 years, HbA_{1c} level of > 7%, BMI of > 25 kg/m^2	• Intervention: 7.5 (6.0) • Control: 7.8 (5.8)	Counselling	5–8	MI; nurse; face to face; individual	Usual care	14 months
2014, Denmark, Juul[138]	3946	• Intervention: 60.2 (8.2) • Control: 60.7 (8.6)	T2DM	• Intervention: 8 • Control: 8	Counselling	Variable	Nurse-led diabetes consultations, GP & nurses, face to face, individual	Usual care	18 months
2014, the UK, Steed[139]	124	• Intervention: 59.2 (8.8) • Control:60.3 (8.6)	T2DM, < 75 years	• Intervention: 10.7 (7.5) • Control: 10.9 (7.9)	Counselling	5	Self-management intervention, diabetes specialist nurse & dietitian, face to face, group	Usual care	3 months
2014, the USA, Safren[140]	87	• Intervention: 55.44 (8.72) • Control: 58.31 (7.41)	T2DM; 18–70 years; HbA_{1c} level of > 52 mmol/mol (7.0%); depressed, as measured by the DSM-IV	NR	CBT	9–12	CBT-AD: therapist; face to face; individual	Enhanced usual care; nurse/dietitian; face to face; individual	4 months

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2014, Portugal, Gois[141]	22	• Intervention: 56.82 (4.25) • Control: 53.81 (7.04)	T2DM for > 6 months, aged 18–65 years	• Intervention: 13.12 (4.85) • Control: 11.63 (6.68)	Psychotherapy	12	Interpersonal psychotherapy, psychiatry, face to face, individual	Medical care and sertraline	6 months
2014, China, Li[97]	101	• Intervention: 58.5 (5) • Control: 59.2 (5.2)	T2DM for 1–2 years, aged 40–70 years, HbA_{1c} level of ≥ 9%	• Intervention: 1.3 (0.5) • Control: 1.2 (0.4)	Counselling	4	MI; therapist; face to face; individual	Diabetes education; face to face; individual	6 months
2014, the UK, Griffin[142]	478	• Intervention: 59.5 (7.5) • Control:59.8 (7.5)	T2DM clinical diagnosis within previous 3 years, aged 40–69 years	NR	Counselling	8	Intensive plus behavioural intervention: lifestyle facilitators; face to face/ telephone; individual	Enhanced usual care; GP; face to face; individual	12 months
2014, Australia, Eakin[143]	277	• Intervention: 57.7 (8.1) • Control: 58.3 (9.0)	T2DM, 20–75 years, inactive, BMI of ≥ 25 kg/m^2	Median (quartiles): • Intervention: 4 (2, 7) • Control: 5 (2, 10)	Counselling	27	Telephone counselling (MI): trained researchers (degree nutrition or dietetics); telephone; individual	Usual care	6 months
2014, the Netherlands, van Son[104]	83	• Intervention: 56 (13) • Control: 57 (13)	T1DM or T2DM, of emotional well-being (WHO-5)	NR	CBT	8	Mindfulness cognitive-based therapy; psychologist; face to face; group	Usual care	6 months
2015, the USA, Kim[144]	209	• Intervention: 59.1 (8.4) • Control: 58.3 (8.5)	T2DM, ≥ 35 years, HbA_{1c} level of ≥ 7.0%	In months: • Intervention: 105.3 (87.6) • Control: 99.3 (84.8)	Counselling	6	Self-management intervention, nurses and community health workers, face to face, group	Diabetes education, face to face, group	12 months
2015, the USA, Chlebowy[145]	62	• Intervention: 55.8 (2.1) • Control: 53 (2.25)	T2DM, ≥ 18 years, African American, prescribed oral antihyperglycaemic agents and/or insulin	NR	Counselling	4	MI: nurses; face to face; individual	Usual care	3 months
2015, the USA, Pladevall[146]	1692	• Intervention: 64.5 (10.5) • Control 1: 64.9 (11.5) • Control 2: 63.3 (10.9)	T2DM, ≥ 18 years, HbA_{1c} level of ≥ 7%, LDL-C ≥ 100 mg/dL	NR	Counselling	6	MI and adherence information: nurses and pharmacists; face to face/ telephone; individual	• Usual care • Adherence information; clinicians; face to face; individual	12 months
2015, Germany, Hermanns[105]	60	• Intervention: 34.2 (14.9) • Control: 43.4 (13.8)	T1DM or T2DM; depressed, as measured by the CES-D; 18–70 years	• Intervention: 14.2 (10.3) • Control: 14.2 (10.7)	CBT	5	DIAMOS: psychologists, face to face; group	Diabetes education; diabetes educators; face to face; group	12 months

continued

TABLE 1 Summary of characteristics for RCTs in the systematic review and meta-analysis for all studies (*continued*)

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2015, Croatia, Pibernik-Okanović[147]	121	• Intervention: 57.7 (6.2) • Control: 58.2 (5.6)	T2DM for at least 1 year, aged 18–65 years	• Intervention: 11.4 (9.1) • Control: 10.5 (6.9)	CBT	6	Psychoeducation: psychologist; face to face; group	Diabetes education; diabetologist; face to face; group	12 months
2015, Germany, Petrak[106]	53	• Intervention: 49 (10.6) • Control: 47.9 (12.8)	T1DM or T2DM, insulin treated, 21–69 years, major depression DSM-IV, HbA_{1c} level of > 7.5% (58 mmol/mol)	• Intervention: 15.7 (10.4) • Control: 15.0 (10.6)	CBT	10	CBT, clinical psychologists, face to face, group	Usual care and antidepressants	12 months
2016, Taiwan, Huang[148]	61	• Intervention: 55.06 (10.44) • Control: 57.83 (10.38)	T2DM; ≥ 20 years; depressed, as measured by the CES-D	Months: • Intervention: 44.32 (21.59) • Control: 45.7 (18.06)	CBT	12	MET + CBT: psychotherapist/clinical nurse; face to face; group	Usual care	90 days
2016, China, Browning[149]	682	• Intervention: 63.7 (7.6) • Control: 64 (9)	T2DM, ≥ 50 years	• Intervention: 10 (6.5) • Control: 9.6 (6.6)	Counselling	9	Health coaching: clinicians (doctors, nurses and psychologists; face to face/telephone; individual	Usual care	12 months
2016, the Netherlands, Kasteleyn[150]	161	• Intervention: 66 (9.3) • Control: 65.6 (9.4)	T2DM for > 1 year, aged > 35 years	Mean (IQR): • Intervention: 7 (2.8–16) • Control: 8.5 (5–15)	Counselling	3	MI: nurses; face to face; individual	Less intensive psychological intervention; nurse, telephone; individual	5 months
2016, Taiwan, Chiu[151]	174	• Intervention: 64.78 (0.3) • Control: 64.59 (0.4)	T2DM, ≥ 50 years, minor depressive symptoms	• Intervention: 10 (0.6) • Control: 10.58 (0.2)	Counselling	4	Minimal psychological intervention: psychology assistants; telephone; individual	Usual care	10 weeks
Studies in systematic review only (not included in meta-analysis) of T2DM									
2004, the UK, Clark[152]	100	All: 59.5 (NR)	T2DM, 40–70 years, BMI of > 25 kg/m^2	NR	Counselling	1	Self-management intervention: interventionist (trained in MI); face to face; individual	Usual care	12 months
2006, the USA, Hokanson[153]	114	• Intervention: 54 (9) • Control: 53 (9)	T2DM, smokers	NR	Counselling	4–7	Smoking cessation MI, research staff, telephone, individual	Usual care	6 months

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2010, the Netherlands, Heinrich[154]	537	All: 59 (5.27)	T2DM for ≤ 5 years, aged 40–70 years	26.4% were diagnosed with diabetes ≤ 1 year previously; 47.0% were diagnosed 2–3 years previously; and 26.6% were diagnosed 4–5 years previously	Counselling	8	MI; nurses; face to face; individual	Usual care	12 months
2010, Iran, Pourisharif[155]	41	NR	T2DM, 30–75 years, diagnosed in the preceding 12 months	NR	Counselling	4	1. CBT; face to face; group 2. MI; face to face; group	Usual care	9 weeks
2011, Italy, Castelnuovo[156]	34	• Intervention: 59.19 (10.24) • Control: 58.67 (10.23)	T2DM	• Intervention: 7.98 (7.57) • Control: 7.91 (6.95)	CBT	Variable	TECNOB: clinical psychologist; face to face/ telephone/online and text messaging; individual/ group	Usual care	12 months
2012, the USA, Waker[157]	154	• Intervention: 60.35 (NR) • Control: 58.67 (NR)	T2DM, HbA_{1c} level of ≥ 6.5%	• Intervention: 13.1 (NR) • Control: 13.28 (NR)	Counselling	2	MI: researcher; face to face; individual	Usual care	3 months
2013, the USA, Gabbay[158]	545	• Intervention: 58 (11) • Control: 58 (11)	T2DM, HbA_{1c} level of > 8.5%	NR	Counselling	8	MI: nurses; face to face; individual	Usual care	12 months
Jiang 2014[159]	52	Cannot access paper for this information	T2DM	Cannot access paper for this information	Psychotherapy	Cannot access paper for this information	Psychotherapy, face to face, group	Usual care plus paroxetine	6 months
2015, the USA, Inouye[160]	207	• Intervention: 57 (11.1) • Control: 57.8 (10.8)	T2DM, 18–76 years, received diabetes education	NR	CBT	6	CBT: research assistants; face to face; group	Diabetes education; research assistants; face to face; group	12 months
2016, the USA, Fitzpatrick[161]	182	• Intervention 1: 58.72 (11.21) • Intervention 2:54.82 (9.31) • Control 1: 54.51 (10.34) • Control 2: 60.57 (10.27)	T2DM, ≥ 25 years, black/African American	NR	Counselling	9	1. DECIDE group, graduate assistant, face to face, group 2. DECIDE individual, graduate assistant, face to face, individual	1. Enhanced usual care (usual care + education materials), face to face/mail, individual 2. DECIDE self-study; mail; individual	20 weeks

continued

TABLE 1 Summary of characteristics for RCTs in the systematic review and meta-analysis for all studies (*continued*)

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
Studies included in meta-analysis of adults with T1DM									
2009, Sweden, Amsberg[162]	74	• Intervention: 41.1 (11.7) • Control: 41.4 (12.9)	T1DM for ≥ 2 years, aged 18–65 years, BMI of < 30 kg/m^2, HbA_{1c} level of > 7.5%	• Intervention: 19.9 (9.4) • Control: 23.2 (11.8)	CBT	8	CBT-based intervention; diabetes specialist nurse and psychologist; face to face; group	Waiting list	48 weeks
2008, the UK, Ismail[163]	344	• Intervention 1: 37.2 (9.9) • Intervention 2: 35.6 (9.6) • Control: 36.4 (11.3)	T1DM for ≥ 2 years, two records of HbA_{1c} levels of between 8.2% and 15% (within 12 months), aged 18–65 years	• Intervention 1: 18.7 (9.2) • Intervention 2: 17.3 (9.6) • Control: 19.5 (10.4)	CBT	1. 12 2. 4	1. MET + CBT; nurse; face to face; individual 2. MET; nurse; face to face; individual	Usual care	12 months
2008, the Netherlands, Snoek[164]	86	All: 37.8 (10.6)	T1DM for ≥ 1 year, HbA_{1c} level of ≥ 8.0% on two occasions, multiple daily insulin injections (≥ 2) or continuous subcutaneous insulin infusion	All: 18 (10.4)	CBT	6	Cognitive–behavioural group training; psychologist; face to face; group	BGAT; psychologist; face to face; group	12 months
2015, Germany, Hermanns[105]	114	• Intervention: 34.2 (14.9) • Control: 43.4 (13.8)	T1DM and T2DM; depressed, as measured by the CES-D; 18–70 years	• Intervention: 14.2 (10.3) • Control: 14.2 (10.7)	CBT	5	DIAMOS: psychologists, face to face; group	Diabetes education; diabetes educators; face to face; group	12 months
2015, Denmark, Zoffmann[165]	200	• Intervention: 25.9 (5) • Control: 25.3 (5.2)	T1DM for ≥ 1 year, aged 18–35 years, HbA_{1c} level of ≥ 64 mmol/mol	• Intervention: 13.8 (6.9) • Control: 13.7 (6.8)	Counselling	14	Flexible GSD; nurses; face to face; group	Waiting list	12 months
2014, the Netherlands, Van Son[104]	83	• Intervention: 56 (13) • Control: 57 (13)	T1DM and T2DM, low level of emotional well-being (WHO-5)	NR	CBT	8	Mindfulness cognitive-based therapy; psychologist; face to face; group	Usual care	6 months
2015, Germany, Petrak[106]	53	• Intervention: 49 (10.6) • Control: 47.9 (12.8)	T1DM and T2DM, insulin treated, 21–69 years, major depression DSM-IV, HbA_{1c} level of 7.5% (58 mmol/mol)	• Intervention: 15.7 (10.4) • Control: 15.0 (10.6)	CBT	10	CBT, clinical psychologists, face to face, group	Usual care and antidepressants	12 months
Studies in systematic review only (not included in meta-analysis) of adults with T1DM									
2006, Denmark, Zoffmann[166]	50	• Intervention: 36.8 (1.7) • Control: 35.7 (2.1)	T1DM, 18–49 years, HbA_{1c} level of ≥ 8.0%	NR	Counselling	8	GSD; nurses; face to face; group	Waiting list	12 months

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
Studies included in meta-analysis of adolescents/children with T1DM									
2005, Norway, Graue[167]	83	• Intervention: 14.5 (1.6) • Control: 14.3 (1.6)	T1DM, 11–17 years	• Intervention: 6.7 (3.3) • Control: 6.9 (4.3)	Counselling	3	Structured educational and counselling programme, physician/ diabetes specialist nurse/ clinical psychologist/ dietitian/social worker, face to face, group	Usual care	15 months
2007, the UK, Channon[168]	66	• Intervention: 15.3 (0.97) • Control: 15.4 (1.19)	T1DM for ≥ 1 year; aged 14–17 years	• Intervention: 9.2 (1.96) • Control: 9.1 (1.47)	Counselling	4	MI; nurse; face to face; individual	Non-directive psychological support; nurse; face to face; individual	12 months
2007, the USA, Ellis[169]	127	• Intervention: 13.4 (1.9) • Control: 13.1 (2)	T1DM for ≥ 1 year; HbA_{1c} level of ≥ 8%, 10–17 years	• Intervention: 5.3 (3.9) • Control: 5.2 (4.8)	Family therapy	NR	MST; therapist; face to face; family	Usual care	6 months
2007, the USA, Nansel[170]	81	• Intervention: 13.6 (1.9) • Control: 13.9 (1.6)	T1DM for ≥ 1 year; aged 11–16 years	• Intervention: 7.5 (3.4) • Control: 7.8 (4)	Counselling	6	Diabetes personal trainer intervention; trained non-professional (MI training); face to face/telephone; family/individual	Diabetes education; educational booklet; family	12 months
2009, the USA, Grey[171]	82	• Intervention: 9.91 (1.48) • Control: 9.91 (1.4)	T1DM for ≥ 6 months; 8–12 years; treated with insulin	• Intervention: 3.66 (2.75) • Control: 3.8 (3.2)	CBT	6	CST; mental health professional; face to face; group	Diabetes education; nurse; face to face; group	12 months
2010, the USA, Wang[172]	44	• Intervention: 15.3 (1.4) • Control: 15.6 (1.7)	T1DM for > 1 year; aged 12–18 years; HbA_{1c} level of ≥ 9%	• Intervention: 6.7 (3.4) • Control: 7.6 (4.7)	Counselling	2	MI; diabetes educators; face to face; group	Diabetes education; diabetes educator; face to face; group	9 months
2010, the USA, Lehmkuhl[173]	32	• Intervention: 13.72 (2.67) • Control: 13.43 (2.17)	T1DM for ≥ 6 months; HbA_{1c} level of > 9%	NR	Family therapy	36	Telehealth behaviour therapy; clinical psychologists or clinical psychology interns; telephone; family	Waiting list control	12 weeks
2012, the UK, Robling[174]	689	• Intervention: 10.4 (2.8) • Control: 10.7 (2.8)	T1DM for ≥ 12 months, aged 4–15 years	• Intervention: 5.2 (2.8) • Control: 5.0 (2.7)	Counselling	Variable	DEPICTED, health-care professionals, face to face, individual	Usual care	12 months
2012, Germany, Sassmann[175]	33	• Intervention: 6.4 (2.3) • Control: 5.8 (1.9)	T1DM, aged 2–10 years	• Intervention: 2.6 (1.6) • Control: 2.6 (1.9)	CBT	5	DELFIN, psychologist, face to face, group	Waiting list	3 months

continued

TABLE 1 Summary of characteristics for RCTs in the systematic review and meta-analysis for all studies (*continued*)

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2012, the USA, Nansel[176]	390	• Intervention: 12.5 (1.8) • Control: 12.4 (1.7)	T1DM for ≥ 3 months, with at least two or more daily injections or use of an insulin pump; aged 9–14.9 years; HbA_{1c} level of > 6%	• Intervention: 4.8 (3.3) • Control: 4.9 (3.2)	Family therapy	9	Family behavioural intervention; health advisors; face to face/ telephone; family	Usual care	12 months
2013, Iran, Najmi[177]	85	• Intervention 1: 15.1 (1.9) • Intervention 2: 15.3 (1.8) • Intervention 3: 14.1 (1.8) • Control: 15.2 (1.7)	T1DM for > 1 year; aged 12–18 years	NR	CBT	8	1. CBT + CST; psychiatrist; face to face; family 2. CBT; psychiatrist; face to face; family 3. CST; psychiatrist; face to face; family	Usual care	3 months
2014, Denmark, Husted[178]	71	• Intervention: 14.9 (1.5) • Control: 14.6 (1.3)	T1DM for > 1 year, aged 13–18 years,	• Intervention: 6.1 (3.0) • Control: 5.3 (3.4)	Counselling	8	GSD, physicians/diabetes nurses/dietitian, face to face, individual	Usual care	12 months
2014, the USA, Jaser[179]	40	• Intervention: 15.3 (1.4) • Control: 15 (1.6)	T1DM for ≥ 6 months; aged 13–17 years	• Intervention: 7.3 (4.3) • Control: 6.5 (3.5)	Counselling	4	Positive affect; trained research assistant; telephone; family	Diabetes education; education materials; mail; individual	6 months
2014, the USA, Katz[180]	153	• Intervention 1: 12.7 (2.2) • Intervention 2: 12.5 (2.3) • Control: 13.4 (2.4)	T1DM for ≥ 6 months; aged 8–16 years	• Intervention 1: 6.5 (3.8) • Intervention 2: 6.8 (3.2) • Control: 5.7 (3.5)	Family therapy	Variable	1. Care ambassador ultra; research assistant; face to face; family 2. Care ambassador; research assistant; telephone or e-mail; family	Usual care	12 months
2014, the UK, Christie[181]	315	• Intervention: 13.1 (2.1) • Control: 13.2 (2.1)	T1DM for ≥ 12 months; aged 8–16 years; mean 12-month HbA_{1c} value of ≥ 8.5%	• Intervention: 5.7 (3.2) • Control: 6.1 (3.3)	Counselling	4	CASCADE (psychoeducation); paediatric diabetes specialist nurse and another health-care professional; face to face; group	Usual care	12 months
2015, the USA, Harris[182]	90	• Intervention: 15.04 (1.79) • Control: 14.94 (1.77)	T1DM for ≥ 1 year; aged 12–19 years; HbA_{1c} level of ≥ 9.0%	• Intervention: 6.51 (3.24) • Control: 6.56 (3.77)	Family therapy	10	BFST-D via clinic; therapist; face to face; family	BFST-D via Skype™ (Microsoft Corporation, Redmond, WA, USA); therapist; Skype; family	3 months

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2015, the USA, Nansel[183]	136	• Intervention: 12.6 (2.7) • Control: 13 (2.5)	T1DM for ≥ 1 year; aged 8–16.9 years; most recent HbA_{1c} level of between 6.5% and 10.0%	• Intervention: 5.6 (2.5) • Control: 6.3 (3.6)	Family therapy	6	Family intervention; research assistant; face to face; family	Care ambassador; research assistant; face to face; family	18 months
2016, Australia, Serlachius[184]	147	• Intervention: 14.36 (1.07) • Control: 14.31 (1.12)	T1DM; aged 13–16 years	• Intervention: 5.63 (3.33) • Control: 6.12 (3.8)	CBT	5	The BOC; health psychologist; face to face; group	Usual care	12 months
Studies in systematic review only (not included in meta-analysis) of adolescents/children with T1DM									
2014, the USA, Holmes[185]	40	• Intervention: 12.95 (1.24) • Control: 12.73 (1.23)	T1DM for > 1 year; aged 11–14 years	• Intervention: 4.93 (2.95) • Control: 5.15 (3.16)	Family therapy	4	CST; interventionist; face to face; family	Diabetes education; BA-level facilitators; face to face; family	3 months
2008, the USA, Wysocki[186]	104	• Intervention: 13.9 (1.9) • Control 1: 14.4 (1.9) • Control 2: 14.2 (1.9)	T1DM or insulin-treated T2DM for ≥ 2 years; aged 11–16 years; HbA_{1c} level of ≥ 8%	• Intervention: 5.1 (3) • Control 1: 5.5 (3.2) • Control 2: 5.9 (4)	Family therapy	12	BFST-D; therapist; face to face; family	1. Usual care 2. Educational support; face to face; family	12 months
Studies of people with T1DM and T2DM (included in systematic review only, as separate analysis T2DM not available)									
2004, the USA, Katon[187]	329	• Intervention: 58.6 (11.8) • Control: 58.1 (12)	T2DM or T1DM	• Intervention: 9.6 (8.8) • Control: 10.2 (10.1)	Collaborative care (including psychotherapy)	Variable	Pathways study, nurses/ psychiatrists/primary care physician, face to face/ telephone, individual	Usual care	12 months
2004, Norway, Karlsen[188]	63	• Intervention: 49.2 (24.7) • Control: 48.6 (10.3)	T1DM or T2DM	NR	CBT	9	Group-based counselling; nurse; face to face; group	Waiting list	6 months
2006, the USA, Wysocki[189]	104	• Intervention: 13.9 (1.9) • Control 1: 14.2 (1.9) • Control 2: 14.4 (1.9)	T1DM or T2DM for ≥ 2 years; aged 11–16 years; HbA_{1c} level of ≥ 8%	• Intervention: 5.1 (3.0) • Control 1: 5.9 (4.0) • Control 2: 5.5 (3.2)	Family	12	Behavioural family systems therapy; psychologists; face to face; family	1. Usual care 2. Educational support; nurses; face to face; family	6 months
2010, Germany, Heisler[190]	244	• Intervention: 62.3 (6.6) • Control: 61.8 (6.1)	T2DM or T1DM	NR	Counselling	Variable	Nurse case management, nurses, face to face and telephone, individual	Reciprocal peer support, care manager, face to face, group	6 months
2011, Denmark, Rosenbek Minet[191]	349	• Intervention: 57.1 (12.6) • Control: 55.8 (11.6)	T1DM or T2DM, aged > 18 years	• Intervention: 4.7 (6.9) • Control: 4.7 (6.5)	Counselling	5	MI; health-care professionals (nurse, dietitian, physiotherapist or psychologist); face to face; individual	Usual care	12 months

continued

TABLE 1 Summary of characteristics for RCTs in the systematic review and meta-analysis for all studies (*continued*)

Year, country, first author	Total number of participants	Mean age (SD or range) (years)	Clinical subgroup (inclusion criteria for individual studies)	Mean (SD or range) duration of diabetes, years in intervention/control	Type of psychological intervention	Number of sessions in intervention	Intervention description (intervention name, facilitator, format, individual/group)	Control description (control category, facilitator, format, individual/group)	Follow-up, up to 12 months
2011, the USA, Weinger[192]	222	Median (range) • Intervention: 51.8 (23.7–74.2) • Control 1: 54.7 (25–75.1) • Control 2: 56.2 (21.6–74.8)	T1DM or T2DM for ≥ 2 years, aged 18–70 years, HbA_{1c} levels of > 7.5%	Median (range) • Intervention: 14.9 (1.3–66.1) • Control 1: 15 (2.6–48.5) • Control 2: 16.8 (2.2–45.7)	CBT	5	Structured behavioural group; diabetes educators; face to face, group	1. Group attention control; diabetes educators; face to face, group 2. Individual control; diabetes educators; face to face; individual	12 months
2012, Australia, Williams[108]	80	• Intervention: 68 (8.3) • Control: 66 (10.8)	T2DM or T1DM	NR	Counselling	Variable	Self-management intervention, nurse, face to face and telephone, individual	Usual care	9 months
2012, the USA, Fischer[193]	762	• Intervention: 58.5 (12.4) • Control: 58.3 (12.1)	T2DM or T1DM, aged > 17 years	NR	Counselling	Variable	Telephone-based outreach, nurses, telephone, individual	Usual care	18 months
2012, the USA, Ellis[194]	146	• Intervention: 14.2 (2.2) • Control: 14.1 (2.4)	T1DM or T2DM for ≥ 1 year; aged 10–18 years; HbA_{1c} level of ≥ 8%	• Intervention: 4.7 (3.2) • Control: 4.6 (2.9)	Family	Variable	MST; therapist; face to face; family	Telephone support; therapist; telephone; individual	12 months
2014, the USA, Lin[195]	NR	• Intervention: 57.4 (10.5) • Control: 56.3 (12.1)	T1DM or T2DM, depression (score of > 10 points on the PHQ-9)	NR	Collaborative care (including psychotherapy)	Variable	Collaborative care; primary care physician and nurse and psychiatrist and psychologist; face to face; individual	Usual care	12 months
2015, the USA, Safford[196]	NR	• Intervention: 59.2 (11.8) • Control: 61.1 (12.4)	T1DM or T2DM	NR	Counselling	Variable	MI; peers, telephone; individual	Diabetes education; face to face; individual	12 months
2015, the Netherlands, Schroevers[197]	24	• Intervention: 54.9 (10.3) • Control: 55.9 (8.2)	T1DM or T2DM, 18–70 years	• Intervention: 16.6 (14.4) • Control: 20.5 (13.7)	CBT	8	Mindfulness-based cognitive therapy; clinical psychologist; face to face; individual	Waiting list	8 weeks

ACT, acceptance and commitment therapy; BA, Bachelor of Arts; BFST-D, Behavioural Family Systems Therapy for Diabetes; BGAT, blood glucose awareness training; BOC, Best of Coping; CASCADE, Child and Adolescent Structured Competencies Approach to Diabetes Education; CBT-AD, cognitive–behavioural therapy for adherence and depression; CST, coping skills training; DECIDE, Decision-making Education for Choices In Diabetes Everyday; DELFIN, Das Elterntraining für Eltern von Kindern mit Diabetes Typ 1 (The parenting programme for parents of children with diabetes type 1); DEPICTED, Development and Evaluation of a Psychosocial Intervention in Children and Teenagers Experiencing Diabetes; DIAMOS, Diabetes Motivational Strengthening; DSM-IV, *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition; DSMT, diabetes self-management training; GP, general practitioner; GSD, guided self-determination; IQR, interquartile range; LDL-C, low-density lipoprotein cholesterol; MET, motivational enhancement therapy; MST, multisystemic therapy; NR, not reported; PE, physical education; TECNOB, TEChnology for Obesity; WHO-5, the World Health Organization – Five Well-Being Index.

Secondary outcomes

There were insufficient data (i.e. fewer than five studies) to conduct meta-analyses on secondary outcomes for changes in psychological functioning ($n = 4$ studies) or change in self-management behaviour ($n = 2$ studies).

Results of individual studies of adults with type 1 diabetes mellitus

All studies included in the systematic review are listed in *Table 1*.

Synthesis of results

Primary outcome: glycated haemoglobin level

Seven adult T1DM studies[104–106,162–165] (total participants, $n = 851$) had HbA_{1c} level data available to conduct a meta-analysis. A random-effects meta-analysis demonstrated a pooled mean difference of –0.13 [95% confidence interval (CI) –0.33 to 0.07], a non-significant decrease in HbA_{1c} level in favour of psychological intervention (*Figure 3*). This was a small effect size and equates to –0.18 change in % of HbA_{1c} level (a reduction of ≈2 mmol/mol). There was low heterogeneity ($I^2 = 43.8\%$; $p = 0.099$). Egger's test demonstrated little evidence of publication bias ($p = 0.889$) (see *Appendix 9*, *Figure 30*). The trim-and-fill method for correcting publication bias found no missing studies.

When the main outlier, Hermanns *et al.*,[105] was removed from the meta-analysis, there was a statistically significant (but not a clinically significant) decrease in HbA_{1c} level in favour of psychological intervention (SMD –0.20, 95% CI –0.37 to –0.02, equivalent to a –0.25 change in % HbA_{1c} level or a reduction of ≈3 mmol/mol). There was little influence when any other single study was removed. Hermanns *et al.*'s[48] study is one of two studies that compared an intervention with an attention control group (diabetes education); the other, Snoek *et al.*,[164] used BGAT. When both studies were removed, there was a statistically significant (but not clinically significant) decrease in HbA_{1c} level in favour of the psychological intervention groups (SMD –0.25, 95% CI –0.41 to –0.09, equivalent to a –0.31 change in % HbA_{1c} level, or a reduction of ≈3–4 mmol/mol).

In a meta-regression, there was no statistically significant difference between different group of psychological interventions (CBT vs. counselling, $p = 0.985$) and HbA_{1c} level, or between type of interventionists delivering

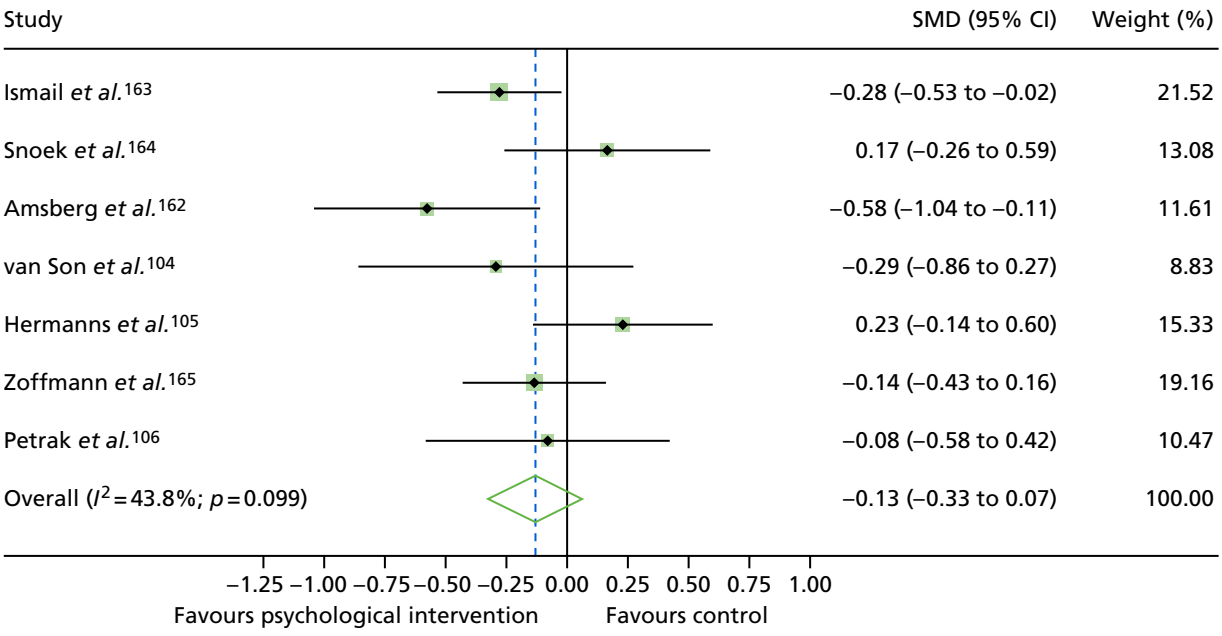


FIGURE 3 A meta-analysis of SMD in HbA_{1c} level in the psychological intervention group compared with the control group for adults with T1DM.

the psychological intervention (nurses vs. psychologists, $p = 0.074$) and HbA_{1c} level. There was no association between the number of therapy sessions ($p = 2.98$), therapy session duration ($p = 0.894$) or duration of therapy ($p = 0.643$) and HbA_{1c} level. There was a statistically significant difference between the type of control group ($p = 0.04$) and HbA_{1c} level, with a larger treatment effect (coefficient of 0.45) for the attention control group than the usual care group.

Combining the results with those of the previous review of studies of adults with type 1 diabetes mellitus

For adults with T1DM, data from this review ($n = 7$ trials) and our previous review[57] ($n = 11$ trials with a total of 516 participants) were combined (*Figure 4*). For these 18 trials (a total of 1367 participants), a random-effects meta-analysis demonstrated a non-statistically significant decrease in HbA_{1c} level in favour of psychological intervention versus control (SMD –0.12, 95% CI –0.29 to 0.04). Both the current review (SMD –0.13, 95% CI –0.33 to 0.07) and the previous review (SMD –0.17, 95% CI –0.45 to 0.10) reported a non-statistically significant decrease in HbA_{1c} levels; a meta-regression demonstrated a non-statistically significant difference in HbA_{1c} change between both reviews ($p = 0.927$).

Risk of bias within studies

Overall, the RoB for the studies of adults with T1DM was rated as 'unclear' to 'low'. All domains of RoB were also rated as 'unclear' to 'low'. Of the studies included in the meta-analysis, four[104,106,163,164] were rated as being at a 'low' RoB and three[105,162,165] were rated as being at an 'unclear' RoB (see *Appendix 9*, *Figure 29*). There were not enough studies to perform a subgroup analysis of HbA_{1c} level by RoB rating.

Risk of bias across studies

For 'selective reporting' and 'other bias' domains, 100% of bias was rated as being at a 'low' RoB across studies (*Figure 5*). For studies rated as having an 'unclear' RoB, this was usually in the 'random sequence generation' and 'blinding of participants and personnel' domains.

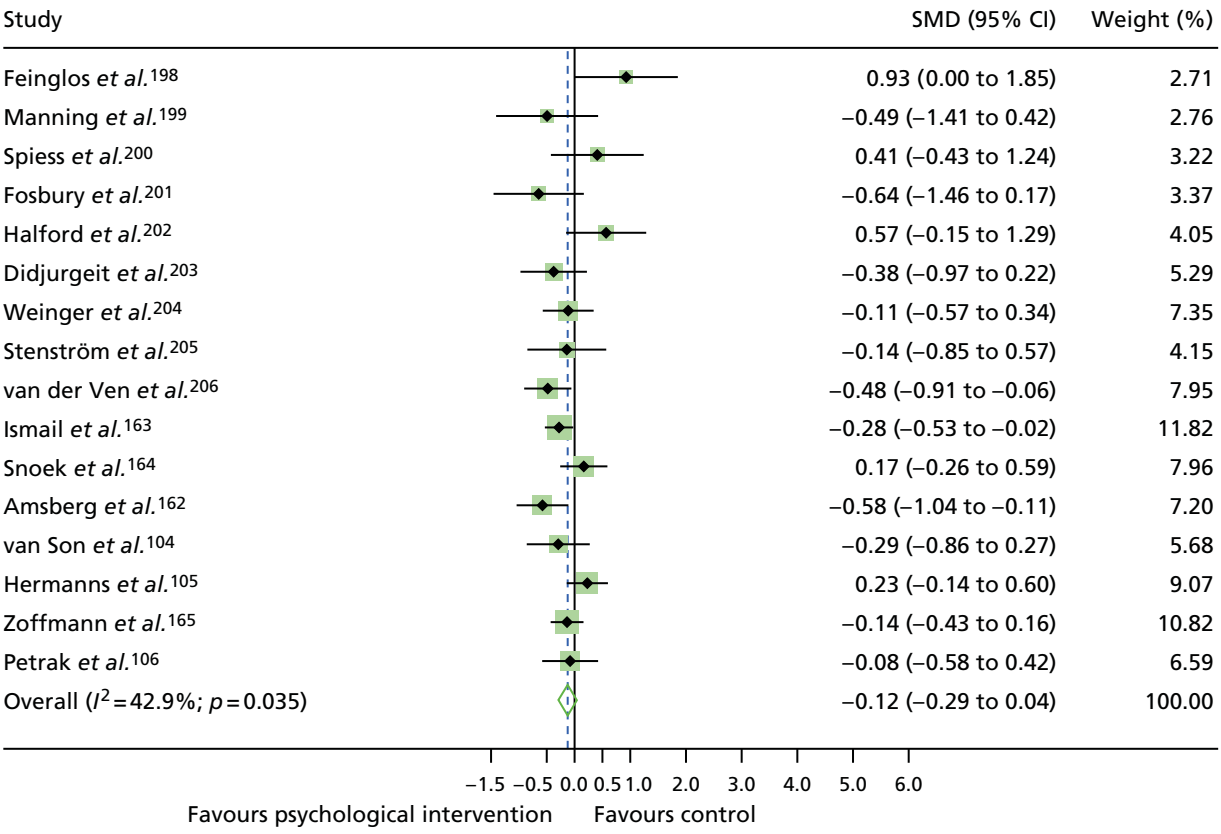


FIGURE 4 A meta-analysis of SMD in HbA_{1c} level in psychological intervention groups compared with control groups for adults with T1DM, combined studies from current and previous review.

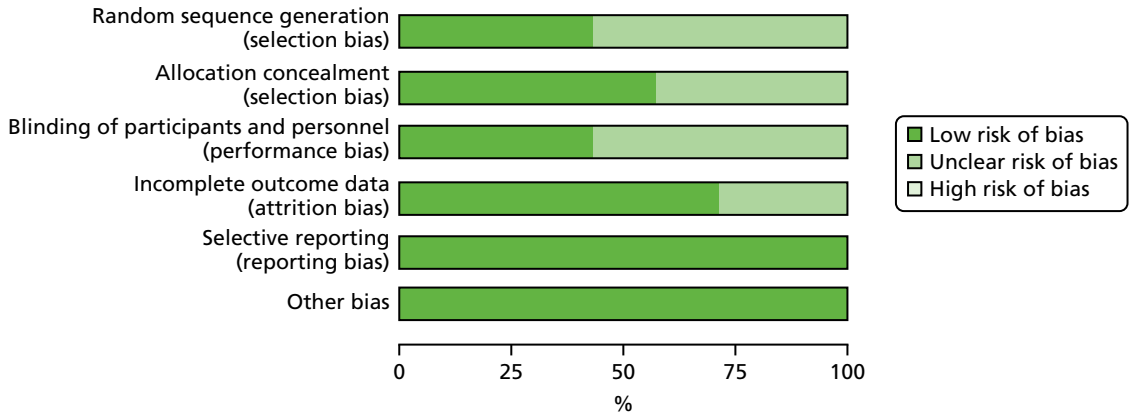


FIGURE 5 Risk of bias across studies of adults with T1DM.

Characteristics of studies on adolescents/children with type 1 diabetes mellitus

A total of 22 studies involving adolescents/children with T1DM were included in the qualitative synthesis; two of these studies had a mixed T1DM and T2DM adolescent/child population. A summary of study characteristics for each study is reported in *Table 1*.

Study location

Most studies of adolescents/children with T1DM were conducted in the USA ($n = 14$);[169–173,176,179,180,182,183,185,186,189,194] the remaining studies were conducted in the UK ($n = 3$, including re-screening),[168,174,181] Europe (non-UK, $n = 3$),[167,175,178] Asia ($n = 1$)[177] and Australia ($n = 1$).[184]

Participant characteristics

The total sample size for all studies of adolescents/children with T1DM was 2876 participants ($n = 22$ studies; two studies included a T1DM and T2DM population and did not report the sample size per diabetes type). Sample sizes ranged from 32 to 390 participants.

Intervention characteristics

Psychological interventions were categorised into three types: CBT ($n = 4$),[171,175,177,184] counselling ($n = 10$)[167,168,170,172–174,178,179,181,185] and family therapy ($n = 8$).[169,176,180,182,183,186,189,194] The interventions were delivered by diabetes specialists [$N = 5$; made up of diabetes nurses ($n = 4$)[167,168,178,181] and diabetes educators ($n = 1$)[172]], psychology professionals [$N = 10$; made up of clinical psychologists ($n = 4$),[173,175,186,189] therapists ($n = 3$),[169,182,194] mental health professionals ($n = 1$),[171] psychiatrists ($n = 1$)[177] and health psychologists ($n = 1$)[184]] and other [$N = 7$; made up of a health advisor ($n = 1$),[176] a health-care professional ($n = 1$),[174] a trained non-professional ($n = 1$)[170] and research assistants ($n = 4$)[179,180,183,185]].

Most psychological interventions were delivered face to face ($n = 18$);[167–169,171,172,174,175,177,178,180–186,189,194] the others were delivered via telephone ($n = 2$)[173,179] or via a combination of face to face and telephone ($n = 2$).[170,176] Therapy sessions were administered to individuals ($n = 3$),[168,174,178] groups ($n = 6$),[167,171,172,175,181,184] families ($n = 12$)[169,173,176,177,179,180,182,183,185,186,189,194] or families and individuals ($n = 1$).[170] The number of therapy sessions ranged from 2 to 36. The duration of therapy sessions ranged from 5 minutes to 2 hours. The total duration of therapy ranged from 5 weeks to 2 years.

Control characteristics

The control groups were categorised as follows: usual care ($n = 13$),[167,169,173–178,180,181,184,186,189] attention control [$N = 7$, made up of diabetes education ($n = 5$),[170–172,179,185,194] care ambassador case management ($n = 1$)[183] and telephone support ($n = 1$)[194]] and less intensive psychological intervention [$n = 2$; made up of Behavioral Family Systems Therapy for Diabetes (BFST-D) via Skype ($n = 1$)[182] and non-directive psychological support ($n = 1$)[168]].

Primary outcome

The primary outcome was HbA_{1c} level. The mean difference was calculated from baseline to 12-month follow-up (or closest measurement to 12 months) for the intervention and control groups. The follow-up period for HbA_{1c} level ranged from 3 months to 18 months.

Secondary outcomes

There were insufficient data (i.e. secondary outcomes in five or more studies) to conduct a meta-analysis on secondary outcomes for changes in psychological functioning ($n = 4$) or in self-management behaviour ($n = 2$).

Results of individual studies of adolescents/children with type 1 diabetes mellitus

All studies included in the systematic review are listed in *Table 1*.

Synthesis of results

Eighteen studies (with a total of 2583 participants) were identified that had enough data to include in a meta-analysis. A random-effects meta-analysis demonstrated a pooled mean difference of 0.00 (95% CI –0.18 to 0.18) (*Figure 6*), equating to no change in HbA_{1c} level (% or mmol/mol). Study heterogeneity was high ($I^2 = 77.3\%$; $p < 0.001$), and may reflect the variation in the categories of interventions tested. There was little influence on the removal of any individual study. There was little evidence of publication bias according to Egger's test ($p = 0.45$). No studies were estimated as missing according to the trim-and-fill method for correcting publication bias.

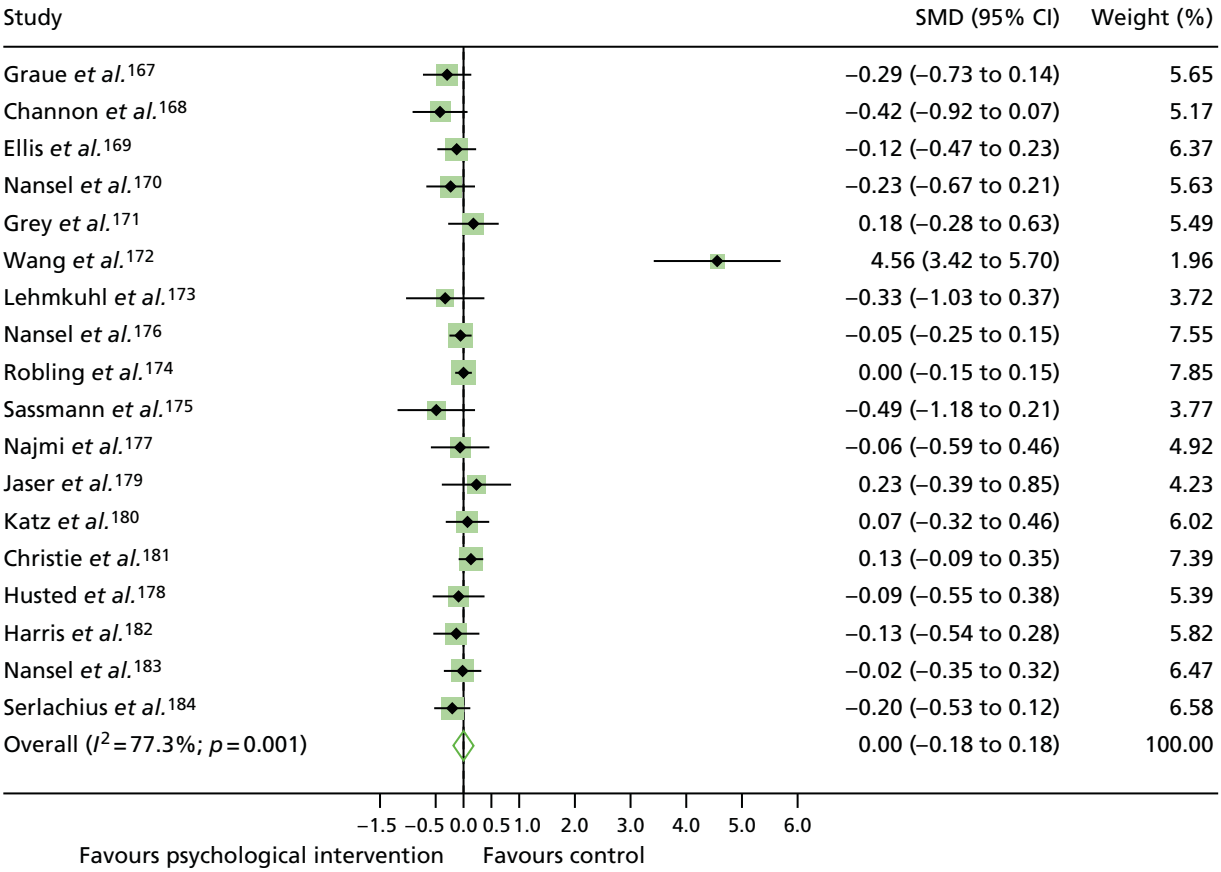


FIGURE 6 A meta-analysis of the SMD in HbA_{1c} level in the psychological intervention group compared with the control group for adolescents/children with T1DM.

Subgroup analysis of glycated haemoglobin levels by psychological intervention category

A subgroup analysis was conducted for the psychological intervention categories of counselling ($n = 8$)[167,168,170,172,174,178,179,181] and family therapy ($n = 6$)[169,173,176,180,182,183] [there were too few CBT studies ($n = 4$) to include in the analysis]. There was no statistically significant difference in HbA_{1c} level for counselling studies (SMD 0.23, 95% CI –0.17 to 0.63) or family therapy studies (SMD –0.06, 95% CI –0.19 to 0.07); see *Appendix 10*, *Figure 33*. Study heterogeneity was high and statistically significant for counselling studies ($I^2 = 89.8\%$; $p < 0.001$), but low for family therapy studies ($I^2 = 0\%$; $p = 9.4$). There was no evidence of publication bias ($p = 0.39$) for counselling studies or family therapy studies ($p = 0.40$), and no studies were estimated as missing according to the trim-and-fill method.

Subgroup analysis of glycated haemoglobin levels by interventionist category

A subgroup analysis by interventionist revealed no statistically significant difference in HbA_{1c} levels for psychological interventions delivered by psychology professionals (SMD –0.13, 95% CI –0.3 to 0.06), diabetes specialists (SMD 0.57, 95% CI –0.24 to 1.38) or 'other' interventionists (SMD –0.02, 95% CI –0.12 to –0.03). There was no statistically significant difference ($p = 0.47$) between interventionist groups; see *Appendix 10*, *Figure 34*. Study heterogeneity was high for diabetes specialists ($I^2 = 94\%$; $p < 0.001$), but low for psychology professionals ($I^2 = 0\%$; $p = 0.76$) and 'other' interventionists ($I^2 = 0\%$; $p = 0.86$). There was no evidence of publication bias for interventions delivered by psychology professionals ($p = 0.55$) or diabetes specialists ($p = 0.41$), and no studies were estimated as missing according to the trim-and-fill method. There was little evidence of publication bias according to Egger's test ($p = 0.84$) for interventions delivered by 'other' interventionists; however, one study was estimated to be missing according to the trim-and-fill method.

Meta-regression

There was no association between the number of therapy sessions ($p = 0.44$), therapy session duration ($p = 0.60$) or duration of overall therapy ($p = 0.92$) and HbA_{1c} levels. There was no statistically significant difference between types of control groups ($p = 0.13$) and HbA_{1c} levels.

Combining the results with the previous review of studies on adolescents/children with type 1 diabetes mellitus

For adolescents/children with T1DM, data from this review ($n = 18$) and the previous review were combined[57] ($n = 8$ studies with a total of 543 participants) (*Figure 7*). For the combined 26 trials (with a total of 3126 participants), a random-effects meta-analysis demonstrated a non-statistically significant decrease in HbA_{1c} levels for psychological intervention groups versus control groups (SMD –0.07, 95% CI –0.25 to 0.10). The current review reported no change in HbA_{1c} levels (SMD 0.00, 95% CI –0.18 to 0.18), whereas the previous review reported a statistically significant decrease in HbA_{1c} levels (SMD –0.35, 95% CI –0.66 to –0.48; change in % HbA_{1c} level: a reduction of ≈5 mmol/mol). The difference in the change in HbA_{1c} levels between reviews was non-statistically significant ($p = 0.38$).

Risk of bias in studies

Overall, the risk of bias in studies of adolescents/children with T1DM was rated as being unclear to low (see *Appendix 10*, *Figure 32*). For studies included in the meta-analysis, 10 studies[167–170,173,174,178,181,183,184] were rated as having a 'low' risk of bias and eight studies[171,172,175–177,179,180,182] were rated having an 'unclear' risk of bias. In a subgroup analysis of HbA_{1c} levels by risk of bias (see *Appendix 10*, *Figure 31*), HbA_{1c} levels reduced non-statistically significantly in studies rated as having a 'low' risk of bias (SMD –0.05, 95% CI –0.15 to 0.04) and increased non-statistically significantly for studies rated as having an 'unclear' risk of bias (SMD 0.35, 95% CI –0.14 to 0.83), although the difference between these risk-of-bias categories was not statistically significant ($p = 0.245$).

Risk of bias across studies

The risk of bias for the 'other' bias domains was rated as being 100% low across studies (*Figure 8*). Risk of bias was rated as being most unclear for the 'blinding of participants and personnel' domain.

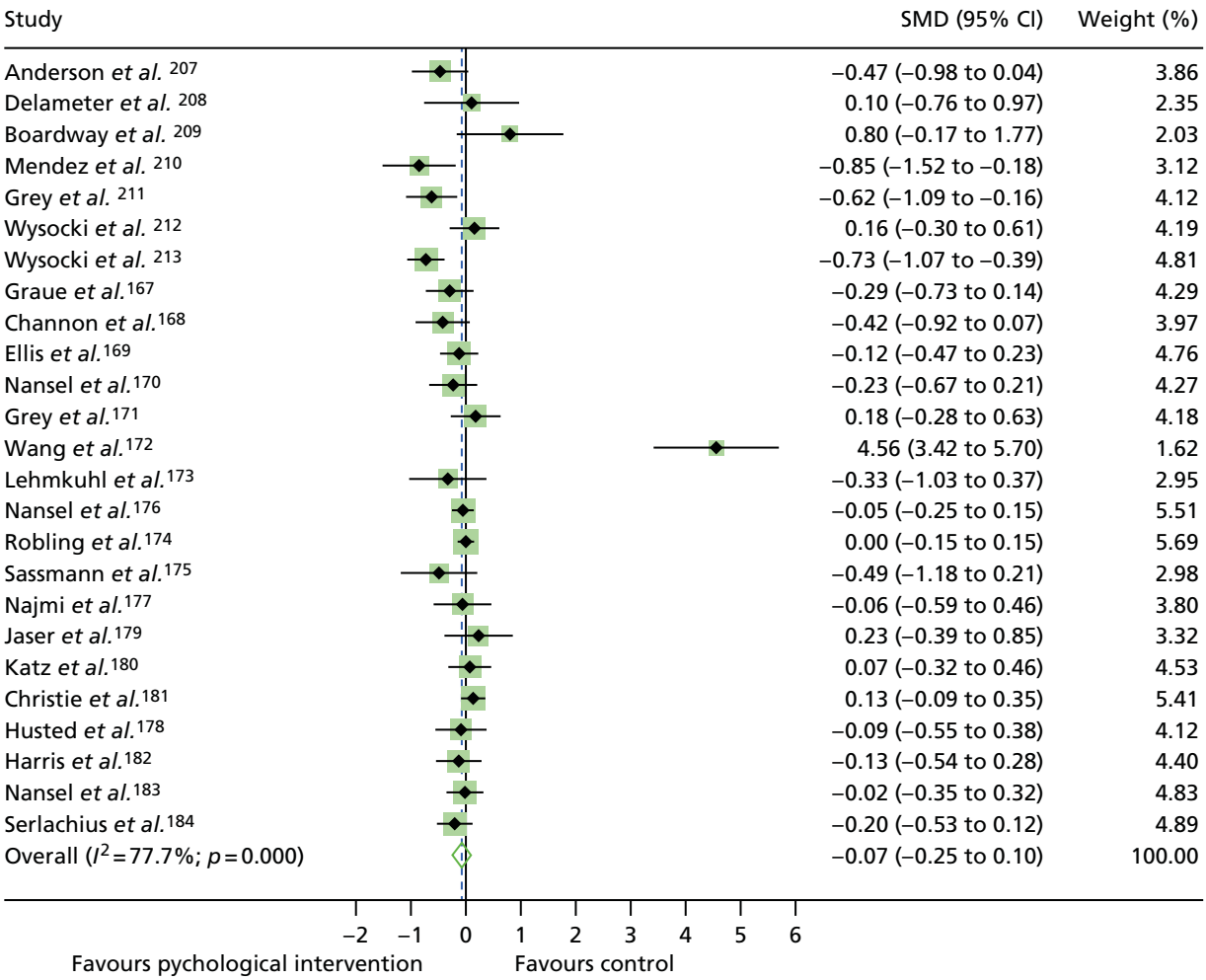


FIGURE 7 A meta-analysis of the SMD in HbA_{1c} levels in psychological intervention groups compared with control groups in studies of adolescents/children with T1DM, combining the current and previous reviews.

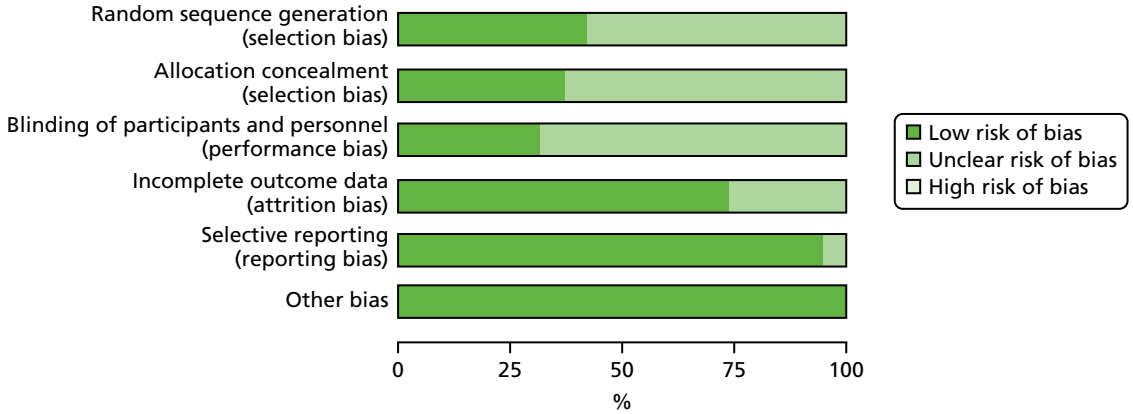


FIGURE 8 Risk of bias across studies of adolescents/children with T1DM.

Characteristics of the studies of adults with type 2 diabetes mellitus

For the T2DM qualitative synthesis, 71 T2DM studies were included; 13 of these had a mixed T1DM and T2DM population. A summary of the study characteristics for each study is reported in *Table 1*.

Study location

These studies were published in Europe [Belgium ($n = 2$),[119,124] Ireland ($n = 1$),[123] the Netherlands ($n = 7$),[104,127,135,137,150,154,197] Germany ($n = 5$),[105,106,109,132,190] Croatia ($n = 1$),[147] Italy ($n = 1$),[156] Norway ($n = 1$),[188] Denmark ($n = 2$),[138,191] Portugal ($n = 1$)[141] and the UK ($n = 5$)[113,130,139,142,152]], North America ($n = 31$),[107,111,112,115,117,118,120,121,126,128,129,131,134,136,140,144–146,153,157,158,160,161,187,189,192–196,214] Asia ($n = 10$),[59,110,114,125,133,148,149,151,155,159] Australia ($n = 3$)[108,116,143] and Chile ($n = 1$).[122]

Participant characteristics

The total number of adults with T2DM included in the qualitative synthesis was 14,326 ($n = 71$ studies; two studies[195,196] did not report number of participants per diabetes type). The sample size per study ranged from 13 to 3946 participants. Two studies[189,194] included adolescent populations with T2DM.

Fifteen studies included a mixed T1DM and T2DM population. In three of these studies,[104–106] a separate analysis per diabetes type was provided, so T2DM data were included in the meta-analysis. For eight studies,[12,188,189,191,192,194,195,197] a separate analysis per diabetes type was not available; these studies were included in the qualitative synthesis only.

Studies stipulated various inclusion criteria to study subgroups of people with T2DM. For example, some studies included people with T2DM with suboptimal glycaemic control, which was defined as HbA_{1c} levels of > 6.5%,[115,157] > 7%,[135,140,146] > 7.5%,[106,128,192] > 8%,[113,123,189,194] > 8.5%[158] and > 9%.[97] One study required patients to have glycaemic control of < 12.5%.[124] Studies focused on populations with differing duration of T2DM, for example having T2DM for < 10 years,[110] ≤ 5 years,[154] ≤ 3 years,[142] < 1 year,[155] > 3months,[133] ≥ 6 months,[119,124,131] > 1 year[117,121,123,147,150,194] and ≥ 2 years.[192] Other studies defined a particular age group for participants: ≥ 20 years,[148] ≥ 25 years,[161] > 35 years,[150] 40–70 years,[152,154] ≥ 60 years,[120,126,214] ≥ 50 years,[149,151] ≤ 70 years[105,192,197] and < 80 years.[124,137] Some studies included only people of a particular ethnicity, for example black women,[118] Puerto Rican[121] and African American.[145,161] There were criteria for BMI values for some RCTs, for example > 25 kg/m^2.[124,135,137,143,152] Ten studies defined the population as depressed.[105,106,126,127,129,131,140,148,151,195]

Intervention characteristics

Psychological interventions were categorised into five therapy types according to which psychological model underpinned treatment: CBT ($n = 21$),[104–106,110,114,116,118,119,125–127,131,135,140,147,148,156,160,188,192,197] counselling ($n = 40$),[59,107–109,111–113,115,117,120,121,123,124,128,130,132–134,137–139,142–146,149–155,157,158,161,190,191,193,196] collaborative care (including elements of psychotherapy; $n = 6$),[129,141,159,187,195,214] creative therapy (i.e. music therapy, $n = 1$)[136] and family therapy ($n = 3$).[122,189,194]

Control conditions were categorised into three main types: usual care [$N = 51$ – waiting list ($n = 5$),[114,116,125,188,197] usual care ($n = 41$)[104,106–108,113,115,117,119,121,122,124,126,127,129–132,135,137–139,142,143,145–149,151–159,187,189,191,193,195,214] and enhanced usual care ($n = 5$)[110,134,141,150,161]], attention control [$N = 16$ – dietary counselling ($n = 1$),[109] diabetes education ($n = 11$),[59,105,111,112,118,128,133,136,144,160,196] attention control ($n = 2$),[120,192] peer support ($n = 1$)[190] and telephone support ($n = 1$);[194] these matched the intervention in duration and frequency] and a less intensive psychological intervention ($n = 1$).[140]

Interventionists who delivered the psychological therapies were categorised as follows: diabetes specialists ($n = 32$),[107–110,113,118,120,126–131,133,135,137–139,144–146,149,150,154,158,187,188,190–193,195] psychology professionals ($n = 20$)[59,104–106,111,112,123,124,132,140,141,147,148,151,156,157,189,194,197,214] and other ($n = 16$).[114,115,117,119,121,122,125,134,136,142,143,152,153,160,161,196]

Psychological interventions were delivered face to face ($n = 56$),[59,104–107,109–112,114,116–119,121–125,127,128,130–133,135–141,144,145,147,148,150,152,154–161,187–192,194,195,197,214] by telephone ($n = 10$),[113,115,120,126,134,143,151,153,193,196] or by telephone and face to face ($n = 5$).[108,129,142,146,149] Most studies delivered psychological interventions in an individual ($n = 42$)[59,107–109,112,113,115,117,120,121,126–130,133–135,137,138,140–143,145,146,149–154,157,158,187,190,191,193,195–197,214] or group format ($n = 25$);[104–106,110,111,114,116,118,119,124,125,131,132,136,139,144,147,148,155,156,159–161,188,192] four interventions were delivered to families.[122,123,189,194]

The mean number of psychological sessions was 7.40 (range 1–27 sessions). The mean overall duration of interventions was 6.67 months (range 30 minutes to 2 years). The mean duration of a psychological intervention session was 1.22 hours (range 15 minutes to 3 hours per session).

Primary outcome

In all studies, HbA_{1c} level (in % or mmol/mol) was assessed at baseline and follow-up. In the meta-analysis, data on HbA_{1c} levels were extracted for 12 months or closest to 12 months. The mean length of follow-up was 7.78 months (range 2–18 months).

Secondary outcomes

The following secondary outcomes were assessed: change in psychological outcomes (i.e. depression and quality of life), change in self-management behaviour (i.e. dietary behaviour), BMI (in kg/m^2) and blood pressure (in mmHg).

Results of individual studies of adults with type 2 diabetes mellitus

All studies included in the systematic review are listed and described in *Table 1*.

Synthesis of results

Data on HbA_{1c} levels for adults with T2DM were available for 49 studies (with a total of 12,009 participants). In a pooled random-effects meta-analysis, the SMD in HbA_{1c} levels was statistically significantly lower for adults with T2DM who received a psychological intervention than for those who received a control condition (SMD –0.21, 95% CI –0.31 to –0.10) (*Figure 9*), equivalent to –0.33 change in % HbA_{1c} level (a reduction of ≈3.5 mmol/mol). Study heterogeneity was large: $I^2 = 93.9\%$; $p < 0.001$.

Removal of any of the individual studies from the meta-analysis had little or no impact on HbA_{1c} levels. There was little evidence of publication bias according to Egger's test ($p = 0.80$); see *Appendix 11*, *Figure 37*. The trim-and-fill method for correcting publication bias did not estimate any missing studies.

Subgroup analysis of glycated haemoglobin levels by psychological intervention category

A subgroup analysis of HbA_{1c} levels by psychological intervention category was conducted (see *Appendix 11*, *Figure 38*) for CBT ($n = 16$)[104–106,110,114,116,118,119,125–127,131,135,140,147,148] and counselling ($n = 28$) studies.[59,107,109,111–113,115,117,120,121,123,124,128,130,132–134,137–139,142–146,149–151] There were too few psychotherapy ($n = 3$),[129,141,214] creative therapy ($n = 1$)[136] and family therapy ($n = 1$)[122] studies to conduct subgroup analyses. CBT studies (SMD –0.25, 95% CI –0.42 to –0.09; –0.44 change in % HbA_{1c} levels, a reduction of ≈4 mmol/mol) and counselling studies (SMD –0.24, 95% CI –0.39 to 0.00; –0.33 change in % HbA_{1c} levels, a reduction of ≈3–4 mmol/mol) demonstrated statistically significant reductions in HbA_{1c} levels compared with controls, although the difference in effect size between psychological intervention categories was not statistically significant ($p = 088$). The heterogeneity in CBT studies was moderate and statistically significant ($I^2 = 54\%$; $p = 0.005$). There was some evidence of publication bias for CBT studies ($p = 0.03$), although, the trim-and-fill method for correcting publication bias did not estimate any missing studies. The heterogeneity in counselling studies was high ($I^2 = 89.1\%$; $p < 0.001$). There was no evidence of publication bias for counselling studies ($p = 0.12$), and the trim-and-fill method revealed no missing studies.

Subgroup analysis of glycated haemoglobin levels by interventionist category for counselling studies only

In a non-prespecified subgroup analysis of counselling studies by interventionist, heterogeneity remained high for counselling interventions delivered by diabetes specialists ($I^2 = 94.1\%$; $p < 0.001$), with a significant reduction in HbA_{1c} levels in favour of counselling (SMD –0.35, 95% CI –0.59 to –0.11; 0.49 change in % HbA_{1c} levels, a reduction of ≈5 mmol/mol). Study heterogeneity was low for counselling interventions

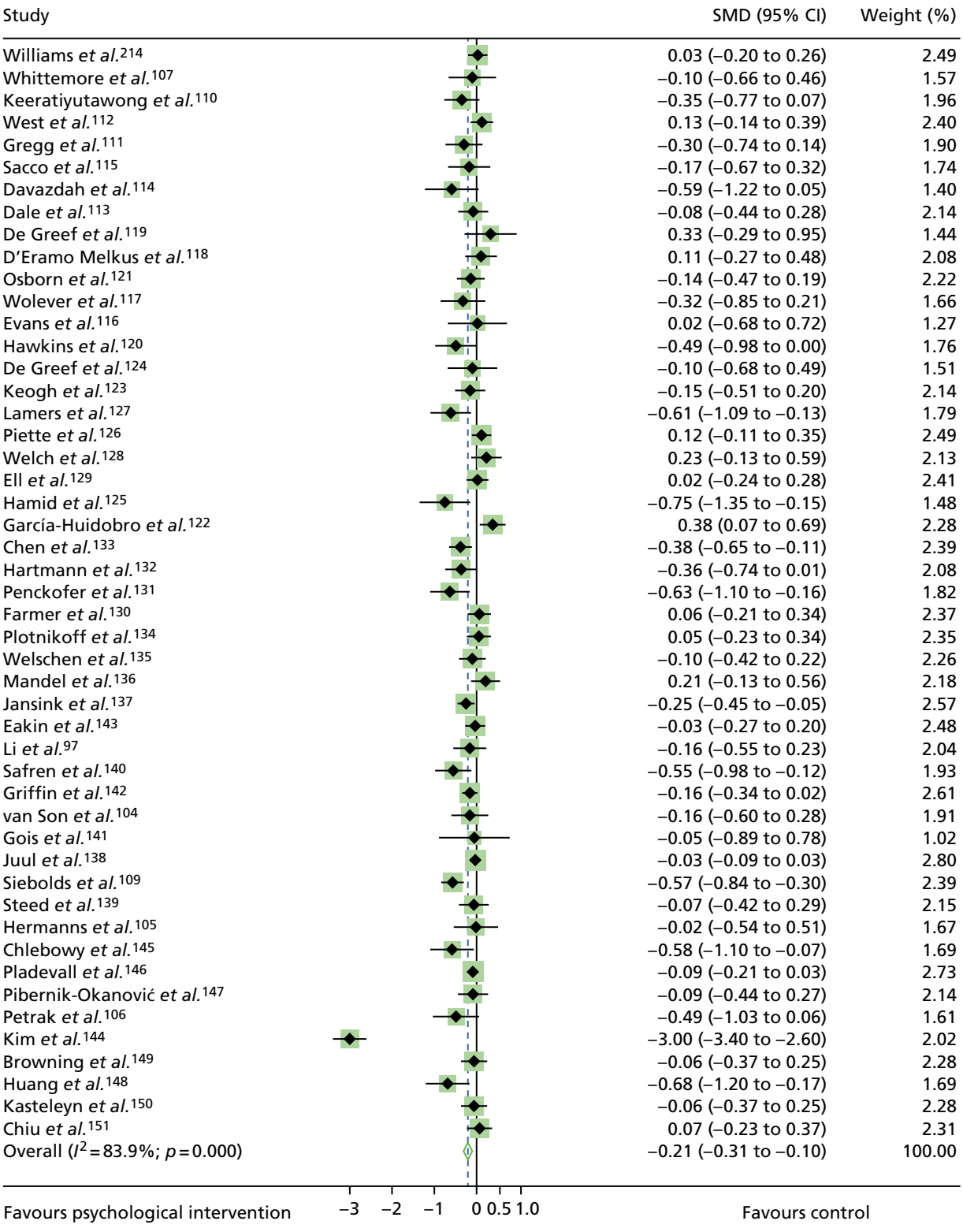


FIGURE 9 A meta-analysis of the SMD in HbA_{1c} levels in the psychological intervention groups compared with the control groups for studies of adults with T2DM.

delivered by psychological professionals (I^2 = 11%; p = 0.35) and 'other' interventionists (I^2 = 0%; p = 0.75), and there was a non-statistically significant decrease in HbA_{1c} levels for both categories of interventionists (psychology professionals, SMD –0.08, 95% CI –0.23 to 0.02; 'other' interventionists, SMD –0.10, 95% CI –0.22 to 0.01).

Subgroup analysis of glycated haemoglobin levels by interventionist category

A subgroup analysis of HbA_{1c} levels by interventionist category (see *Appendix 11*, *Figure 39*) for all psychological intervention categories demonstrated that HbA_{1c} levels were significantly lower in intervention than control groups for psychological interventions delivered by psychology professionals ($n = 15$,[59,104–106,111,112,123,124,132,140,141,147,148,151,214] SMD –0.15, 95% CI –0.26 to –0.03; –0.26 change in % HbA_{1c} levels, a reduction of ≈3 mmol/mol) and diabetes specialists ($n = 22$,[107,109,110,113,118,120,126–131,133,135,137–139,144–146,149,150] SMD –0.30, 95% CI –0.48 to –0.11; –0.47 change in % HbA_{1c} levels, a reduction of ≈5 mmol/mol). HbA_{1c} levels were non-statistically significantly lower in intervention than control groups for psychological interventions delivered by 'other' interventionists ($n = 11$,[114,115,117,119,121,122,125,134,136,142,143] SMD –0.06, 95% CI –0.22 to 0.11; –0.10 change in % HbA_{1c} levels, a reduction of ≈1 mmol/mol), although there were no statistically significant differences between interventionist groups ($p = 0.49$). In studies for which the intervention was delivered by a diabetes specialist, heterogeneity was high and statistically significant ($I^2 = 91.8\%$; $p < 0.001$). There is no evidence of publication bias in studies in which the intervention was delivered by a diabetes specialist ($p = 0.19$); in addition, the-trim and-fill method for correcting publication bias did not estimate any missing studies. In studies for which the intervention was delivered by a psychology professional, heterogeneity was low but non-significant ($I^2 = 27.3\%$; $p = 0.156$). There was some evidence of publication bias in these studies ($p = 0.02$); however, the trim-and-fill method for correcting publication bias did not estimate any missing studies. Heterogeneity was moderate and statistically significant in studies for which the intervention was delivered by 'other' interventionists ($I^2 = 56.2\%$; $p = 0.01$). There was no evidence of publication bias in study interventions delivered by 'other' interventionists ($p = 0.60$), supported by the trim-and-fill method, which did not estimate any missing studies.

Subgroup analysis of glycated haemoglobin levels by the primary outcome of individual studies

A subgroup analysis of HbA_{1c} levels by primary outcome variable was conducted (see *Appendix 11, Figure 40*). The primary outcome per study could be categorised into three groups:

1. glycaemic control ($n = 24$)[106,107,109–112,114,116,118,120,122,123,125,126,128,133,136–138,144,146,148,149]
2. self-management [$N = 13$[59,115,117,119,121,124,130,134,139,140,142,143,145] – adherence ($n = 3$); medication use, glucose monitoring and physical activity ($n = 1$); physical activity ($n = 5$); self-management behaviours ($n = 2$); diet adherence ($n = 1$); and medication adherence ($n = 1$)]
3. psychological [$N = 12$[104,105,113,127,129,131,132,141,147,150,151,214] – depression ($n = 8$), distress ($n = 2$), self-efficacy ($n = 1$) and stress ($n = 1$)].

When glycaemic control was the main outcome of the study, there was a statistically significant improvement in HbA_{1c} levels (SMD –0.28, 95% CI –0.46 to –0.10). For studies in which self-management was the main outcome, there was a statistically significant improvement in HbA_{1c} levels (SMD –0.11, 95% CI –0.21 to –0.01). When psychological outcomes were the main outcome of the study, there was a non-statistically significant improvement in HbA_{1c} levels (SMD –0.12, 95% CI –0.24 to 0.01). There were no statistically significant differences between these groups ($p = 0.63$). Study heterogeneity was high and statistically significant for studies in which glycaemic control was the primary outcome ($I^2 = 91.5\%$; $p < 0.001$), but low and not statistically significant for studies in which the primary outcomes were psychological ($I^2 = 25.6\%$; $p = 0.19$) or self-management ($I^2 = 12.0\%$; $p = 0.33$). There is no evidence of publication bias in studies for which the primary outcome was glycaemic control ($p = 0.13$), self-management ($p = 0.47$) or psychological outcome ($p = 0.06$); in addition, the trim-and-fill method for correcting publication bias did not estimate any missing studies for any of these groups.

Meta-regression

Studies conducted in Asia compared with those conducted in the Western world (i.e. Europe, the UK, North America, Australia) demonstrated a greater reduction in HbA_{1c} levels ($p = 0.05$). There was no association between HbA_{1c} levels and the number of therapy sessions ($p = 0.81$), the length of therapy sessions ($p = 0.23$) or the type of control group ($p = 0.14$).

Secondary outcomes

Depression

Fourteen studies[109,115,126,131,132,135,140,141,144,147,148,150,160,214] of T2DM (with a total of 2075 participants) had outcome data for depression (see *Appendix 12*, *Figure 41*). There was a non-statistically significant decrease in depression for psychological intervention groups compared with control groups (SMD –0.28, 95% CI –0.63 to 0.06) (*Figure 10*). Study heterogeneity was high: $I^2 = 93.1\%$; $p < 0.001$). If the Kim *et al.*[144] study was removed from the analysis, there was a statistically significant decrease in depression in favour of psychological interventions (SMD –042, 95% CI –0.61 to –0.23). Removal of any other individual studies from the meta-analysis had little or no impact on HbA_{1c} levels. There was little evidence of publication bias, demonstrated by the Egger test ($p = 0.72$), as displayed in *Appendix 12*, *Figure 41*. The trim-and-fill method for correcting publication bias did not estimate any missing studies.

Quality of life

A random-effects meta-analysis was conducted on 13 studies[59,109,110,117,131,134,135,137,139,141,144,147,149] (with a total of 2354 participants) reporting QoL measures (*Figure 11*). Psychological therapies were associated with statistically significant improved QoL compared with control groups (SMD 0.66, 95% CI –0.08 to 0.24). Heterogeneity was high: $I^2 = 96.9\%$; $p = < 0.001$). Removal of the Kim *et al.*[144] study did not affect QoL. Removal of any other individual studies from the meta-analysis had little or no impact on QoL. Egger's test indicated some evidence of publication bias ($p = 0.048$). The trim-and-fill method estimated five missing studies.

Body mass index

Twelve studies[107,119,123,124,134,136,137,142,145,148,149,152] (with a total of 2254 participants) provided BMI outcome data (*Figure 12*). The pooled mean difference was –0.08 (95% CI –0.16 to 0.00), indicating a non-statistically

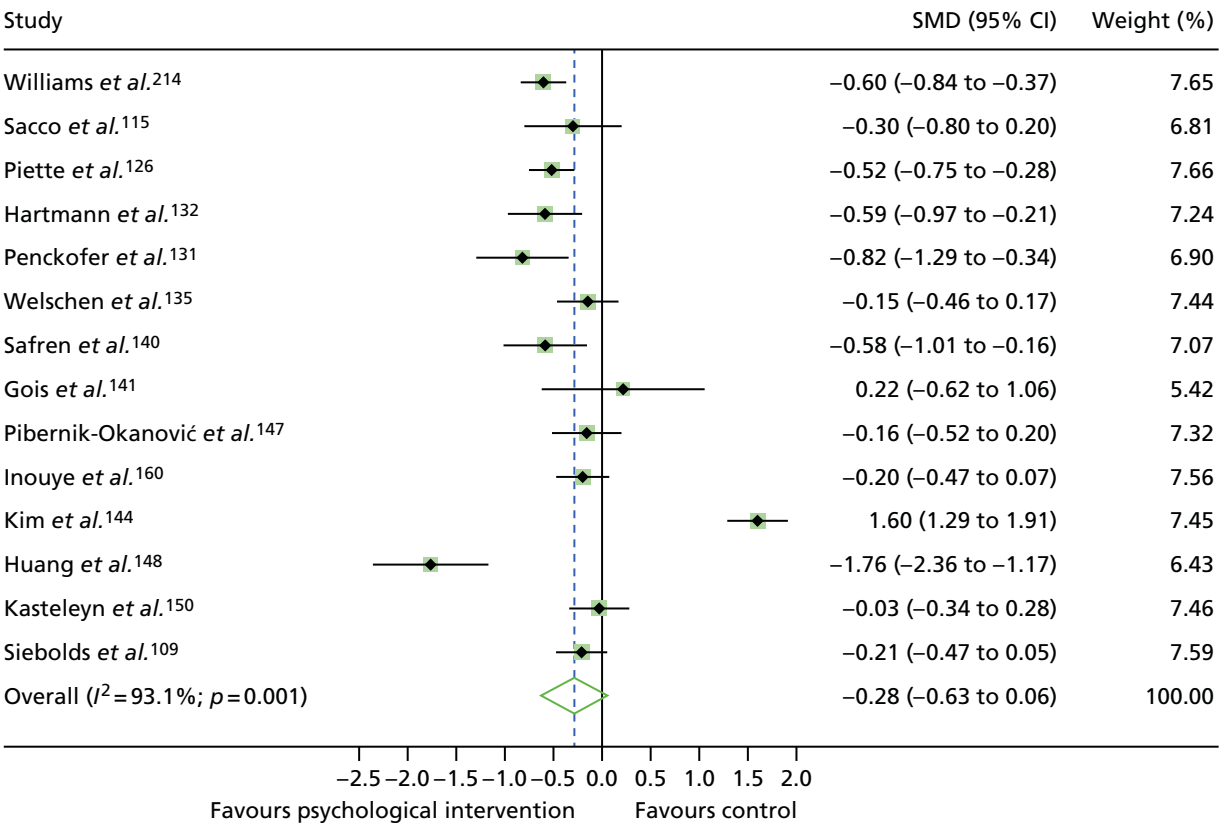


FIGURE 10 A meta-analysis of the SMD in depression in psychological intervention groups compared with control groups for studies of adults with T2DM.

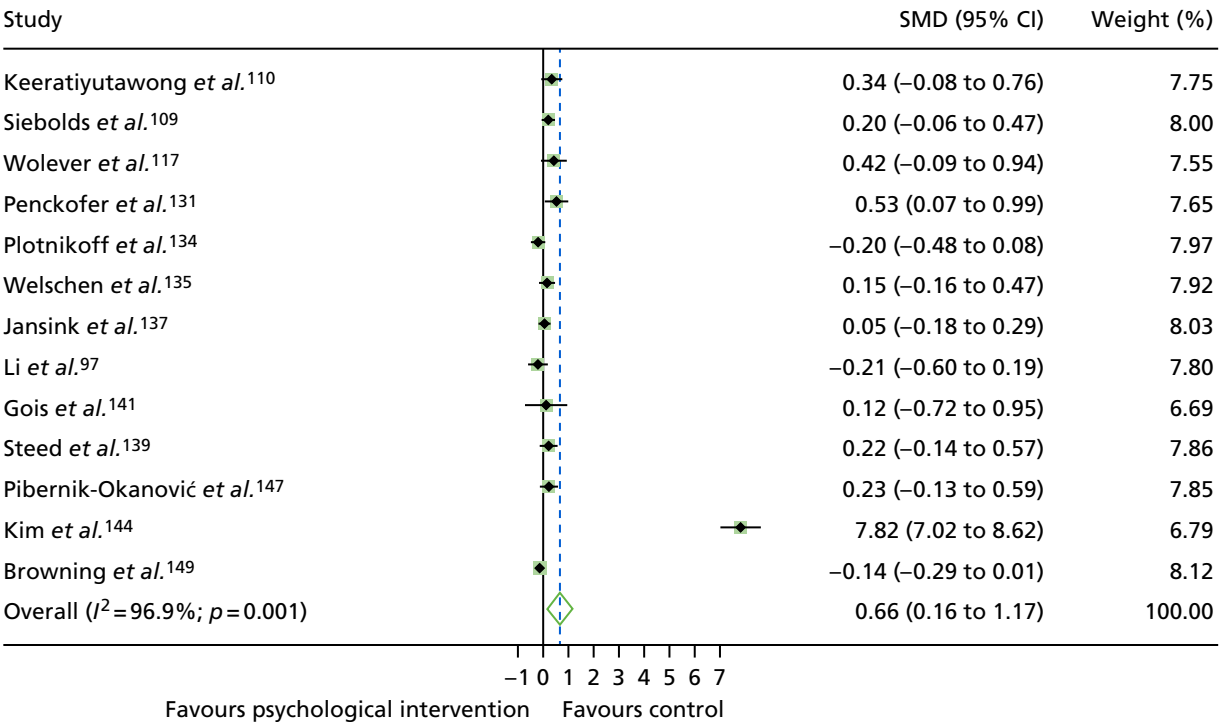


FIGURE 11 A meta-analysis of the SMD in QoL in psychological intervention groups compared with control groups for studies of adults with T2DM.

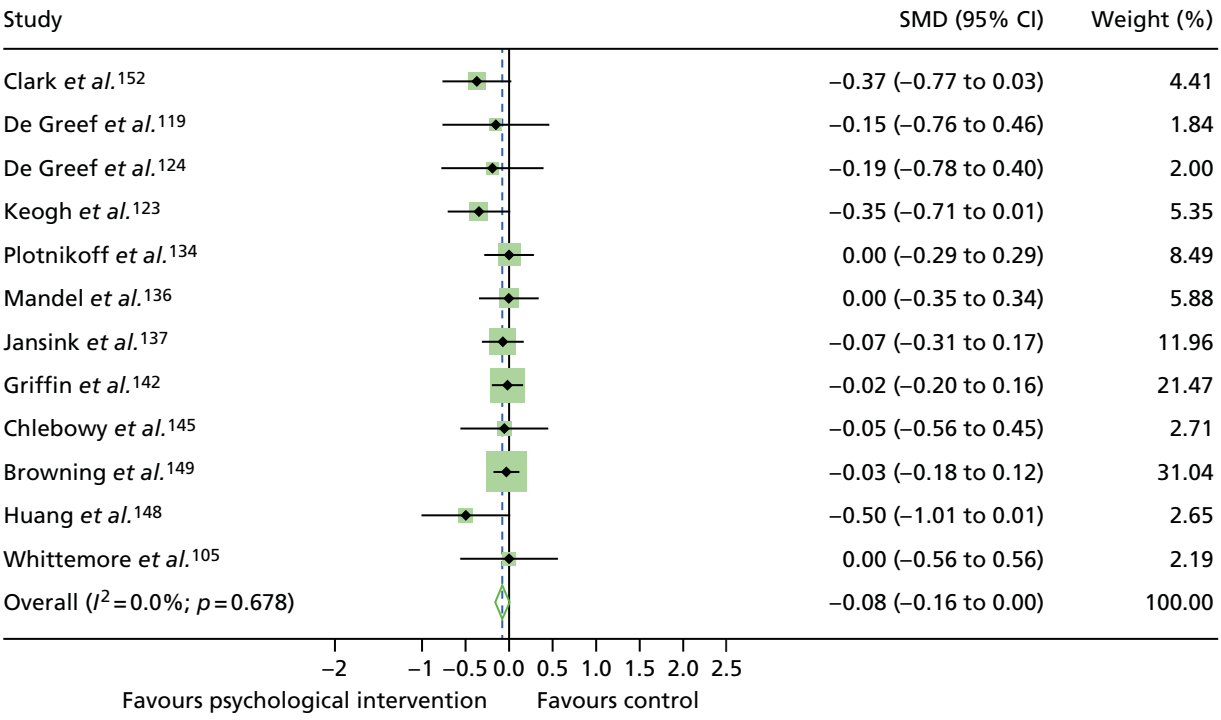


FIGURE 12 A meta-analysis of the SMD in BMI in psychological intervention groups compared with control groups for studies of adults with T2DM.

significant decrease in BMI. Removal of the Griffin *et al.*[142] study reveals a significant reduction in BMI (SMD –0.09, 95% CI –1.19 to –0.001; equivalent to a change in BMI of –0.80 kg/m^2). Heterogeneity was low but not statistically significant (I^2 = 0%; p = 0.678). There is little evidence of publication bias (Egger's test, p = 0.68); see *Appendix 12*, *Figure 43*. The trim-and-fill method for correcting publication bias did not estimate any missing studies.

Blood pressure per protocol

Blood pressure outcomes were available for six studies.[119,123,136,137,142,149] In a pooled random-effects meta-analysis, the mean systolic blood pressure (SBP) (*Figure 13*) and diastolic blood pressure (DBP) (*Figure 14*) values were non-statistically significantly lower in psychological intervention groups than control groups. Pooled mean differences were –0.11 for SBP (95% CI –0.26 to 0.04; a reduction of 1.97 mmHg) and –0.04 for DBP (95% CI –0.16 to 0.08; a reduction of 0.39 mmHg). Heterogeneity was high for SBP (I^2 = 51.5%; p = 0.067) and low for DBP (I^2 = 27.6%; p = 0.228). There was little influence of omission of individual studies from the random-effects meta-analysis: the pooled mean difference remained non-statistically significantly lower for SBP and DBP. There was no evidence of publication bias for SBP (p = 0.33) or DBP (p = 0.92); see *Appendix 12*, *Figures 44* and *45*, respectively. The trim-and-fill method for correcting publication bias did not estimate any missing studies for SBP. However, for DBP, the trim-and-fill method estimated two missing studies.

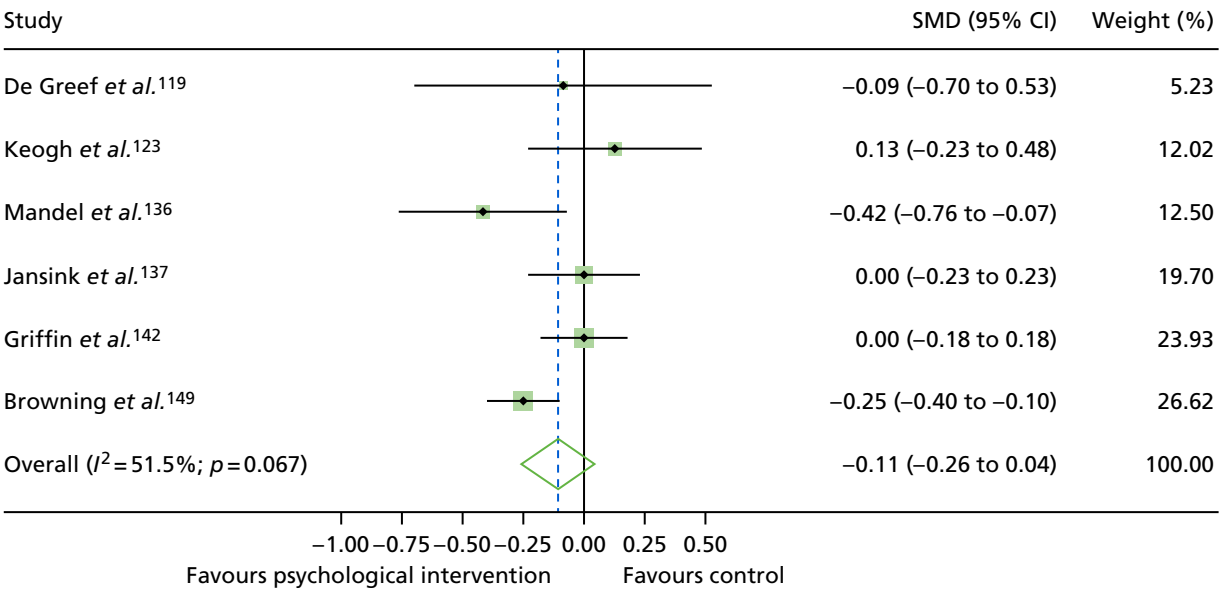


FIGURE 13 A meta-analysis of the SMD in SBP in psychological intervention groups compared with control groups for studies of adults with T2DM.

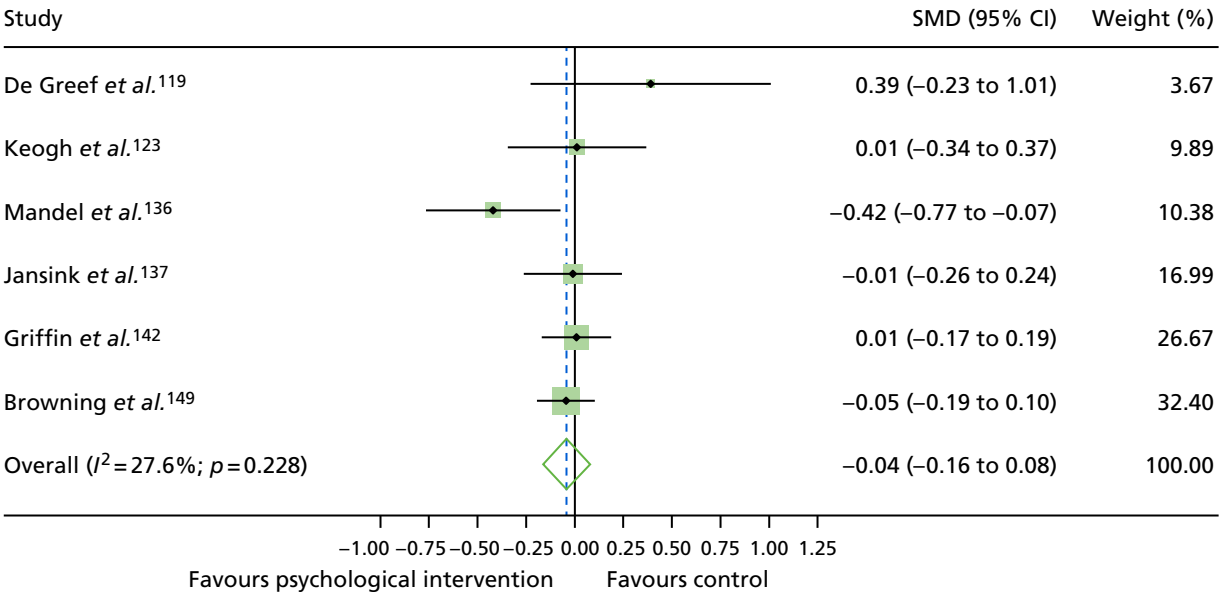


FIGURE 14 A meta-analysis of the SMD in DBP in psychological intervention groups compared with control groups for studies of adults with T2DM.

Changes in self-management behaviours

Eight studies[111,115,123,139,149,152,157,214] (with a total of 1608 participants) had data available to conduct a meta-analysis for dietary self-management (*Figure 15*), measured by the SDSCA. A random-effects meta-analysis demonstrated no improvement in general dietary behaviour (SMD 0.47, 95% CI –0.28 to 1.23). High significant heterogeneity was found: $I^2 = 97.8\%$; $p < 0.001$. There was little change on effect size following removal of individual studies. There was little evidence of publication bias ($p = 0.18$); see *Appendix 12, Figure 46*. The trim-and-fill method for correcting publication bias did not estimate any missing studies.

Combining the results with those of the previous review of studies of adults with type 2 diabetes mellitus

In our previous review,[40] data on HbA_{1c} levels for 12 trials (with a total of 510 participants) were available for meta-analysis (studies from 1991–2003). Combining data from both reviews (n = 61 studies, with a total of 12,519 participants), a random-effects meta-analysis demonstrated that the SMD in HbA_{1c} levels was statistically significantly lower for people with T2DM in receipt of a psychological intervention than those in a control condition (SMD –0.22, 95% CI –0.32 to –0.12; equivalent to a –0.35 change in % HbA_{1c} levels, a reduction of ≈4 mmol/mol) (*Figure 16*). The effect size was larger in the previous review (SMD –0.32, 95% CI –0.57 to –0.07; equivalent to a –0.76 change in % HbA_{1c} levels, a reduction of ≈8 mmol/mol) than the current review (SMD –0.21, 95% CI –0.31 to –0.10; equivalent to a –0.33 change in % HbA_{1c} levels, a reduction of ≈3.5 mmol/mol), although the difference between reviews was not statistically significant ($p = 0.53$).

Risk of bias in studies

Of the studies included in the meta-analysis, 23 studies[104,106,111,119,120,123,124,126,127,129–131,134,136,138,140–143,147,149,214] were rated as having a 'low' RoB, 25studies[59,105,107,109,110,112–118,121,125,128,132,133,137,139,144–146,148,150,151] were rated as having an 'unclear' RoB and one study[122] was rated as having a 'high' RoB (see *Appendix 11, Figure 35*). In a subgroup analysis of HbA_{1c} levels by risk of bias (see *Appendix 11, Figure 36*), HbA_{1c} levels reduced more in studies rated as having an 'unclear' RoB (SMD –0.32, 95% CI –0.53, –0.11) than those rated as having a 'low' RoB (SMD –0.08, 95% CI –0.16 to –0.01), although the difference between these RoB categories was not statistically significant ($p = 0.178$).

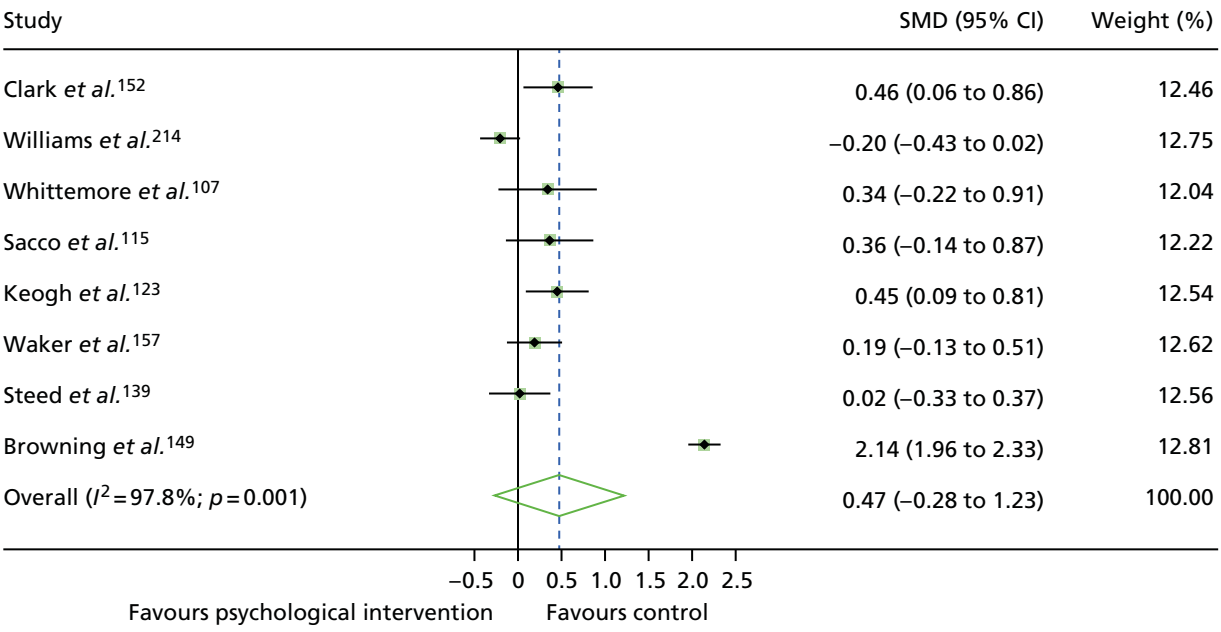


FIGURE 15 A meta-analysis of the SMD in general diet behaviour in psychological intervention groups compared with control groups for studies of adults with T2DM.

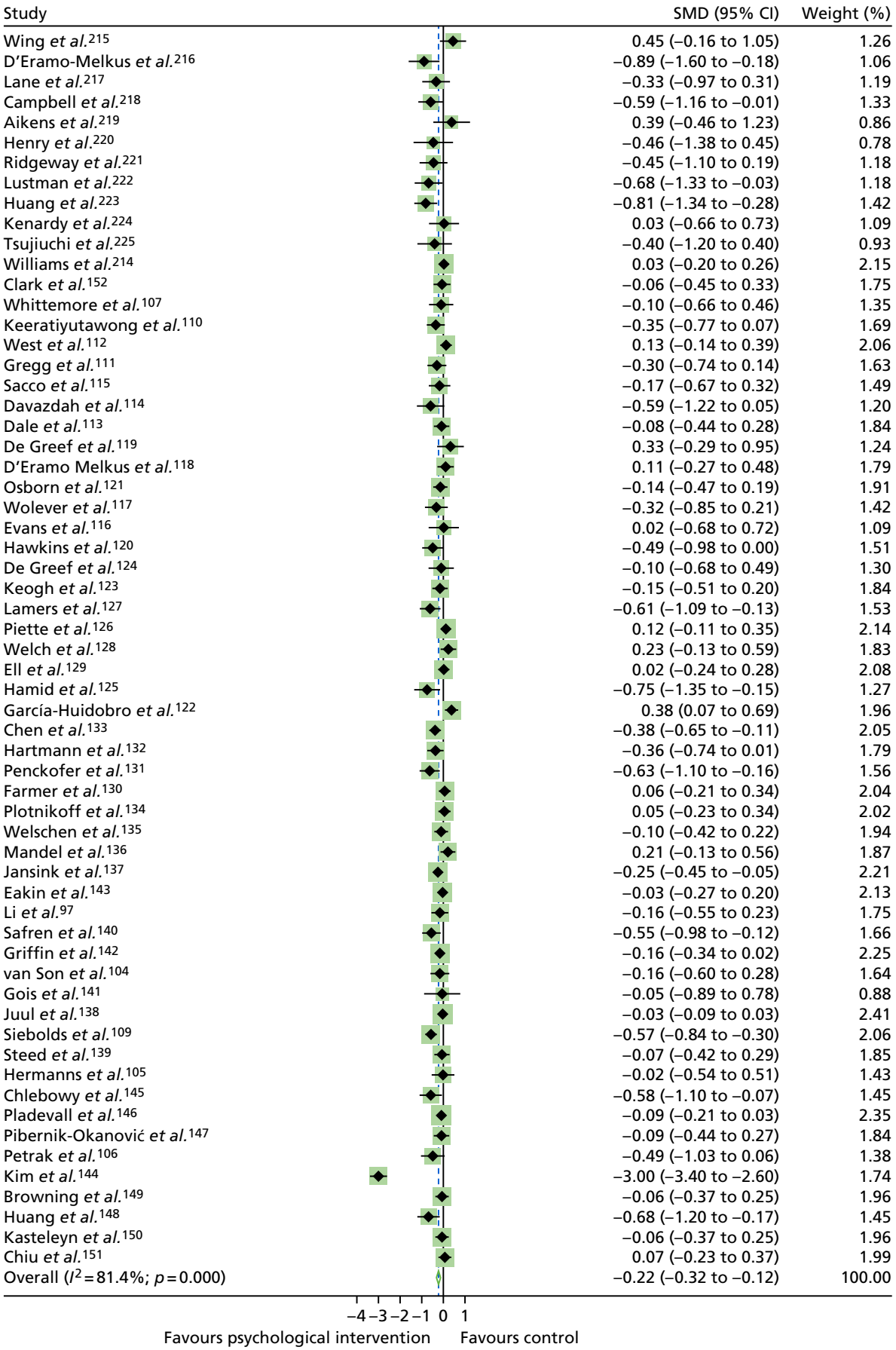


FIGURE 16 A meta-analysis of the SMD in HbA_{1c} levels in psychological intervention groups compared with control groups for studies of adults with T2DM, combining the current and previous reviews.

Risk of bias across studies

For RoB across studies, the RoB was lowest for the 'other bias' domain. The RoB was most unclear in the 'blinding of outcome assessment domain'; *Figure 17*.

GRADE assessment

The primary outcome, HbA_{1c} levels, was rated as being of 'high quality' for studies of adults with T1DM and studies of adolescents/children with T1DM, as there were no problems with any factors (*Table 2*). Heterogeneity for the outcome of HbA_{1c} levels in studies of adolescents/children with T1DM was high; however, a prespecified subgroup analysis by interventionist revealed low heterogeneity in interventionist groups (i.e. psychology professionals and 'other'). This meant that a 'no serious inconsistency' rating could be allocated to HbA_{1c} levels for this analysis. A 'high-quality' rating indicates confidence that the effect size found is close to the true effect.

For studies of adults with T2DM, the outcomes of HbA_{1c} levels was rated as being at a moderate risk of bias, as the inconsistency factors were graded 'serious' because heterogeneity was large for this outcome ($I^2 \geq 50\%$).

Meta-analyses were conducted for secondary outcomes in T2DM only. Secondary outcomes assessed as being of 'high quality' included BMI and blood pressure, with no problems in either factor.

Depression, QoL and general dietary behaviour (measured by the SDSCA scale) outcomes were rated as being of 'low quality', as the inconsistency factor was rated as 'very serious'; heterogeneity was very large for these outcomes ($I^2 \geq 75\%$). In addition, for the QoL outcome, publication bias was rated as 'serious' because the trim-and-fill method estimated five missing studies. Subanalyses were not conducted for secondary outcomes, and could account for high heterogeneity.

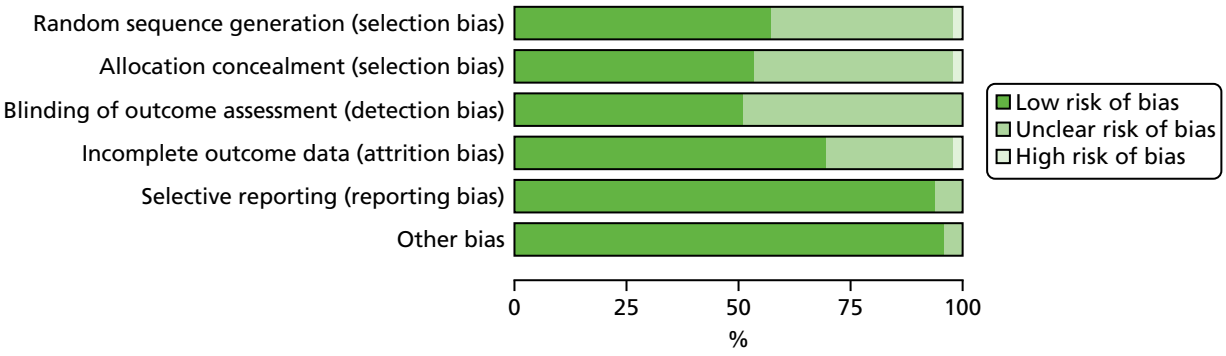


FIGURE 17 The RoB across studies of adults with T2DM.

TABLE 2 The GRADE evidence profile for the impact of psychological interventions for T1DM and T2DM from systematic review and meta-analysis of RCTs of psychological interventions to improve motivation for self-management in diabetes

Quality assessment								Summary of findings	
Type of diabetes	Number of studies (design)	Risk of bias	Inconsistency	Indirectiveness	Imprecision	Publication bias	Quality	Total number of participants	SMD (95% CI)
Primary outcome									
HbA_{1c} levels									
T1DM in adults	7 (RCTs)	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	No serious publication bias	High	851	–0.13 (–0.33 to 0.07)
T1DM in adolescents/ children	18 (RCTs)	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	No serious publication bias	High	2583	0.00 (–0.18 to 0.18)
T2DM	49 (RCTs)	No serious risk of bias	Serious	No serious indirectness	No serious imprecision	No serious publication bias	Moderate	12,009	–0.21 (–0.31 to –0.10)
Secondary outcomes									
Depression									
T2DM	14 (RCTs)	No serious risk of bias	Very serious	No serious indirectness	No serious imprecision	No serious publication bias	Low	1390	–0.28 (–0.63 to 0.06)
QoL									
T2DM	13 (RCTs)	No serious risk of bias	Very serious	No serious indirectness	No serious imprecision	Serious publication bias	Low	2354	0.66 (–0.08 to 0.24)
BMI									
T2DM	12 (RCTs)	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	No serious publication bias	High	2254	–0.08 (–0.16 to 0.00)
Blood pressure									
T2DM	6 (RCTs)	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	No serious publication bias	High	1768	• SBP: –0.11 (–0.26 to 0.04) • DBP: –0.04 (–0.16 to 0.08)
General diet behaviour									
T2DM	8 (RCTs)	No serious risk of bias	Very serious	No serious indirectness	No serious imprecision	No serious publication bias	Low	1608	0.47 (–0.28 to 1.23)

Chapter 5 Network meta-analysis results

Network meta-analysis of studies of adults with type 1 diabetes mellitus

Descriptives

In our meta-analyses, we retrieved data from seven studies with two different psychological intervention types and two types of control groups. In addition, one of these studies, Ismail *et al.*,[163] had two treatment arms (CBT and counselling).

A total of seven studies with 15 treatment or control arms were included in the meta-analyses, with a total sample size of 968 participants (*Table 3*). CBT ($n = 6$)[104–106,162–164] and counselling ($n = 2$)[163,165] were offered as interventions, and usual care ($n = 5$)[104,106,162,163,165] and attention control ($n = 2$)[105,164] were the control groups. The sample size and the number of studies using counselling and attention control are, thus, limited.

Given that we had four conditions, six contrasts were possible. *Figure 18* shows the network plots of evidence for all studies. The plots reflect the number of patients for each arm (size of circles), the observed contrasts (lines) and the amount of evidence for a contrast (width of line). The plot shows that five contrasts were investigated. The two control arms, attention control and usual care, were not directly assessed.

Table 4 shows that the estimated direct and indirect effects between interventions did not differ significantly. The non-significant chi-squared test for inconsistency [$\chi^2(2) = 0.05$; $p = 0.98$, $I^2 = 0$] supports the conclusion of model consistency. *Table 5* shows the results of the consistency NMAs comparing treatments with usual care. Only CBT and attention control showed significant reduction in treatment outcome compared with usual care. Effect sizes were moderate (for CBT) or medium (for attention control). A summary of pairwise comparisons of treatment effect can be found in *Appendix 13*, *Table 28*.

The rankogram graph (*Figure 19*) shows that attention control has an 88.9% probability of being the best treatment whereas CBT has only a 7.6% probability of being the best treatment; the probabilities of the other two interventions being best are negligible. An assessment of the rescaled mean rank (SUCRA) showed that attention control is certain to be the best treatment, followed by CBT (SUCRA = 0.7) and counselling (0.3), with usual care (0.0) most likely to be the worst therapy (see *Appendix 13*, *Table 26*).

TABLE 3 Number of studies and arms included in the NMAs of studies of adults with T1DM

Treatment	Studies (*n*)	Studies (%)	Arm	Sample size (*n*)
CBT	6	40.0	T	292
Counselling	2	13.3	T	251
Usual care	5	33.3	C	322
Attention control	2	13.3	C	103
Total	15	100		968

C, arm was defined as control group in original study; T, arm was defined as treatment arm.

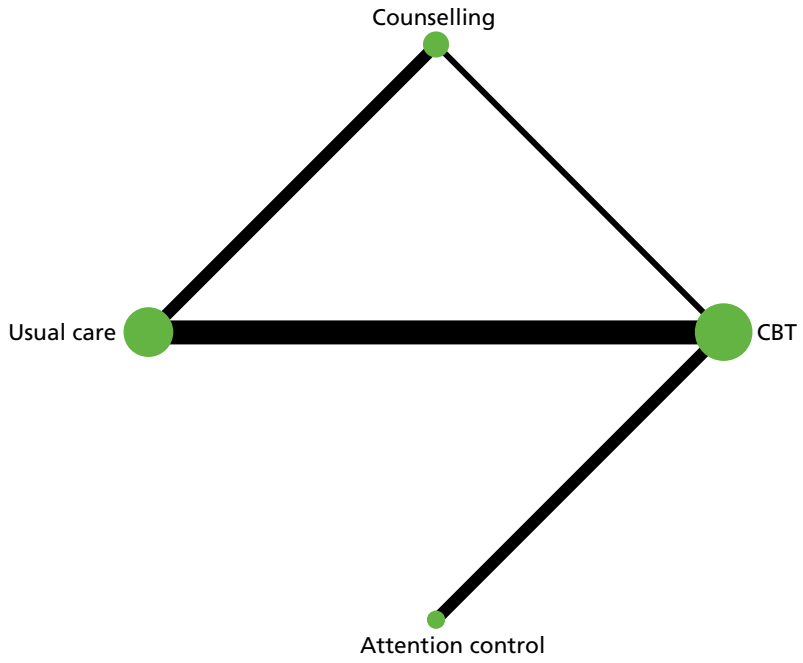


FIGURE 18 Network plots of direct comparisons for the NMA of studies of adults with T1DM. The width of the lines is proportional to the number of trials comparing each pair of treatments and the size of each node is proportional to the number of studies testing the specific treatment. It shows, roughly, how much information is available for each treatment and for each treatment comparison.

TABLE 4 Direct and indirect treatment effects (where indirect treatment effects were available) and the difference between them, including significance test for difference, in studies of adults with T1DM

Treatment comparison	Side	Direct		Indirect		Difference		
		Coefficient	SE	Coefficient	SE	Coefficient	SE	$p > z$
CBT	Usual care	0.309	0.098	0.356	0.376	–0.047	0.388	0.90
CBT	Counselling	0.191	0.131	0.195	0.212	–0.004	0.249	0.99
CBT	Attention control	–0.200	0.142	0.629	44.652	–0.829	44.652	0.99
Counselling	Usual care	0.117	0.098	0.173	0.375	–0.056	0.387	0.88

SE, standard error.

Note

The large SE of 44.6 for the comparison between CBT and attention control suggests an unidentified model; therefore, the conclusion about homogeneity should be treated with care.

TABLE 5 A summary of the treatment effects compared with TAU, assuming a common heterogeneity estimate for all treatment design comparisons, for studies of adults with T1DM

Treatment	b	95% CI	SE	*z*-value	*p*-value
Usual care	0				
CBT	–0.312	(–0.499 to –0.126)	0.095	–3.29	0.001
Counselling	–0.121	(–0.307 to 0.066)	0.095	–1.27	0.21
Attention control	–0.513	(–0.848 to –0.177)	0.1701	–3.00	0.003

SE, standard error.

Note

Supported by the non-significant test for inconsistency ($\chi^2 = 0.05$; $p = 0.98$) and non-significant differences between direct and indirect treatment effects. 'b' is the SMD using TAU as the control group. The formulas for Hedges' *g* in White and Thomas[87] are used.

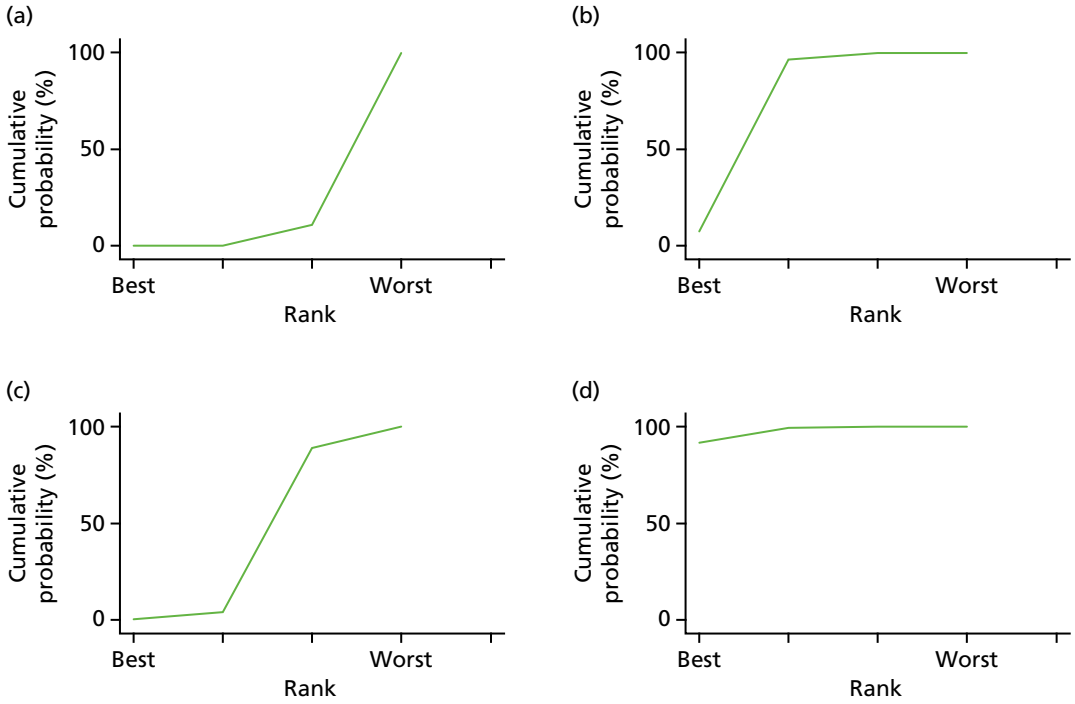


FIGURE 19 Rankogram for all treatments in studies of adults with T1DM. (a) Usual care; (b) CBT; (c) counselling; and (d) attention control. The plot shows the surface under the cumulative ranking curves for all treatments. For example, usual care has a very low probability of being among the best treatments, but a very high probability of being one of the worst.

Network meta-analysis results for studies of adolescents/children with type 1 diabetes mellitus

Descriptives

We retrieved data from a total of 18 studies of adolescents/children with T1DM. Two studies had more than one treatment arm (main arm: CBT, extra arm: CBT2;[177] main arm: family therapy, extra arm: family therapy via telephone[180]). However, because the two treatments in each study shared the same category of treatment, one treatment needed to be excluded (i.e. the least intensive).

All studies included

A total of 18 studies with 18 treatment and 18 control arms were included in the meta-analyses, with a total sample size of 2583 participants (see *Appendix 13*, *Table 29*). Family therapy ($n = 6$)[169,173,176,180,182,183] and counselling ($n = 8$)[167,168,170,172,174,178,179,181] were offered most often as interventions; usual care ($n = 11$)[167,169,173–178,180,181,184] and attention control ($n = 5$)[170–172,179,183] were mainly offered as control groups.

Given that we had six conditions, 15 contrasts were possible. *Appendix 13*, *Figure 47*, shows the network plots of evidence for all studies. The plot shows that eight contrasts were investigated.

Table 6 shows that the estimated direct and indirect effects between interventions did not differ significantly. The non-significant chi-squared test for inconsistency [$\chi^2(3) = 1.19$; $p = 0.76$, $I^2 = 0$] supports the conclusion of model consistency. *Table 7* shows the results of the consistency NMAs comparing treatments with usual care. No treatment showed a statistically significant reduction of treatment outcome compared with usual care. The observed effect sizes of the two arms with small sample sizes, coping skills training and attention control, were medium to large. *Appendix 13*, *Table 32*, reports pairwise comparisons of treatment effect.

TABLE 6 Direct and indirect treatment effects (where indirect treatment effects were available) and the difference between them, including the significance test for difference, for studies of adolescents/children with T1DM

Side comparison		Direct		Indirect		Difference		
Intervention	Control	SMD	SE	SMD	SE	SMD	SE	*p*-value
CBT	Usual care	0.241	0.557	0.718	1.136	–0.477	1.265	0.71
CBT	Attention control	–0.177	0.955	–0.654	0.830	0.478	1.265	0.71
Counselling	Usual care	0.058	0.453	–0.984	0.928	1.042	1.033	0.31
Counselling	Attention control	–1.227	0.571	–0.184	0.862	–1.043	1.033	0.31
Family therapy	Usual care	0.100	0.465	1.033	1.102	–0.932	1.196	0.44
Family therapy	Attention control	0.017	0.918	–0.916	0.766	0.933	1.196	0.44

SE, standard error.

TABLE 7 Summary of treatment effects compared with TAU, assuming a common heterogeneity estimate for all treatment design comparisons, for studies of adolescents/children with T1DM

Treatment	b	95% CI	SE	*z*-value	*p*-value
Usual care	0				
CBT	–0.33	–1.248 to 0.589	0.469	–0.7	0.59
Counselling	0.141	–0.635 to 0.917	0.396	0.36	0.92
Family therapy	–0.24	–1.045 to 0.565	0.411	–0.58	0.57
Attention control	–0.767	–1.757 to 0.222	0.505	–1.52	0.22

SE, standard error.
Note
'b' is the SMD using TAU as the control group. The formulas for Hedges' *g* in White and Thomas[87] are used.

The rankogram graph (*Figure 20*) shows that attention control has a 66.6% probability of being the best treatment, followed by CBT with an 18.5% probability of being the best; all others have a probability of < 8% of being the best treatment. An assessment of the rescaled mean rank (SUCRA) shows that attention control is most likely to be the best treatment (SUCRA = 0.9), followed by CBT and family therapy (SUCRA = 0.6 and 0.5, respectively), and that less intensive psychological intervention and counselling are least likely to be the best ones (SUCRA = 0.3) (see *Appendix 13*, *Table 27*).

Analyses of studies with more than two sites

Only less intensive psychological intervention was studied fewer than three times. A total of 16 studies with treatment and control arms with five types of treatment (CBT, counselling, family therapy, attention control and usual care) were included in the meta-analyses, with a total sample size of 2427 participants (*Table 8*).

Given that we had five conditions, 10 contrasts were possible. *Figure 21* shows the network plots of evidence for all studies. The plot shows that six contrasts were investigated.

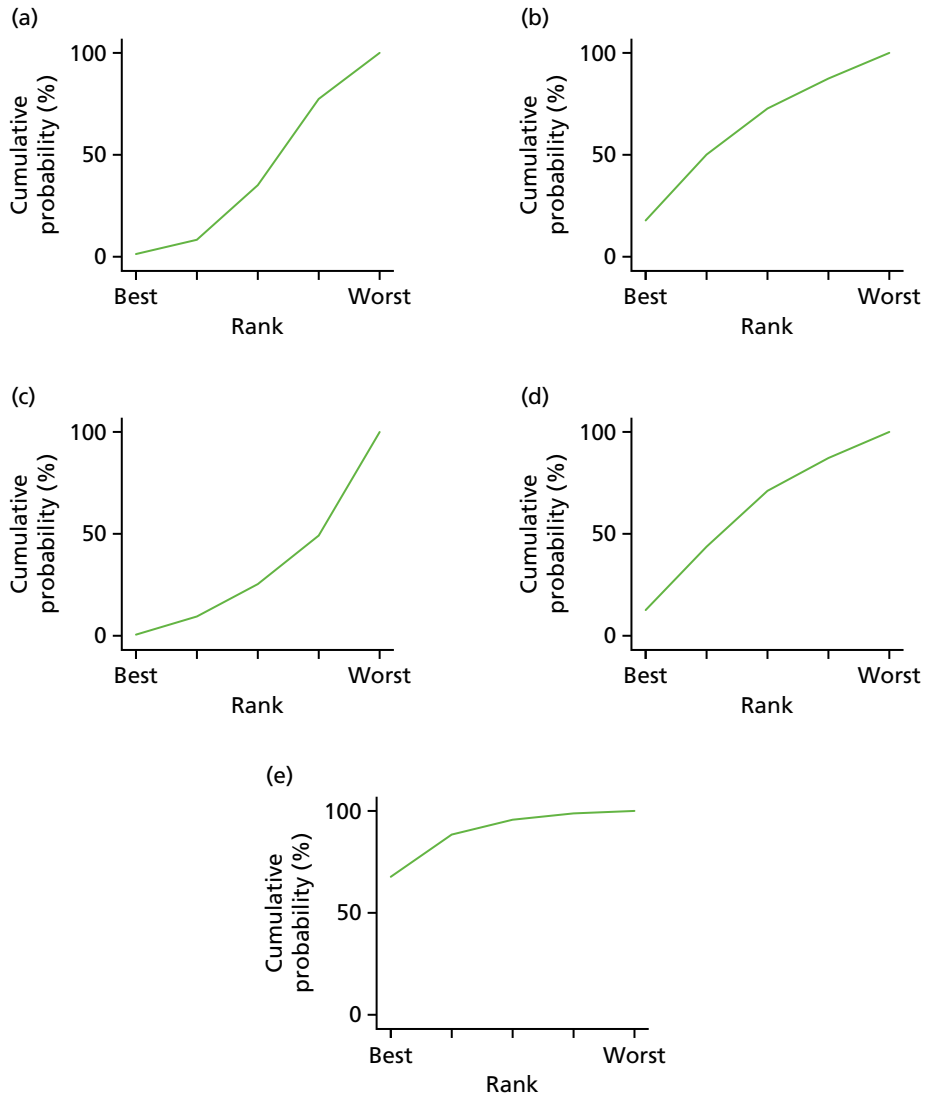


FIGURE 20 Rankogram for all treatments in studies of adolescents/children with T1DM. (a) Usual care; (b) CBT; (c) counselling; (d) family therapy; and (e) attention control. The plot shows the SUCRA curves for all treatments. For example, usual care has a very low probability of being among the best treatments, but a very high probability of being one of the worst.

TABLE 8 Number of studies and arms included in the NMAs for studies of adolescents/children with T1DM

Treatment	Studies (*n*)	Studies (%)	Arm	Sample size (*n*)
CBT	4	11.8	T	167
Counselling	7	23.5	T	676
Family therapy	5	17.6	T	399
Usual care	11	32.4	C	1002
Attention control	5	14.7	C	183
Total	32	100		2427

C, arm was defined as control group in original study; T, arm was defined as treatment arm.

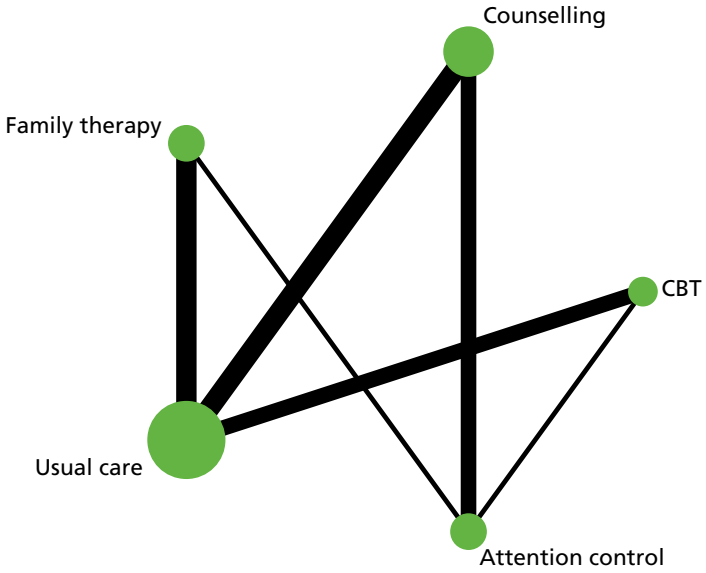


FIGURE 21 Network plots for all studies. Network plots of direct comparisons for the NMA for studies of adolescents/children with T1DM. The width of the lines is proportional to the number of trials comparing each pair of treatments and the size of each node is proportional to the number of studies testing the specific treatment. It shows, roughly, how much information is available for each treatment and for each treatment comparison.

Table 9 shows that the estimated direct and indirect effects between interventions did not differ significantly. The non-significant chi-squared test for inconsistency [$\chi^2(2) = 0.98$; $p = 0.61$, $I^2 = 0$] supports the conclusion of model consistency. *Table 10* shows the results of the consistency NMAs comparing treatments with usual care. No treatment showed a statistically significant reduction of treatment outcome compared with usual care. *Appendix 13*, *Table 33*, reports pairwise comparisons of treatment effect.

TABLE 9 Direct and indirect treatment effects (if indirect treatment effects were available) and the difference between them for studies of adolescents/children with T1DM

Side comparison		Direct		Indirect		Difference		
Treatment	Control	Coefficient	SE	Coefficient	SE	Coefficient	SE	*p*-value
CBT	Usual care	0.241	0.526	0.721	1.072	–0.480	1.194	0.69
CBT	Attention control	–0.177	0.901	–0.657	0.784	0.481	1.194	0.69
Counselling	Usual care	0.058	0.438	–0.559	0.775	0.617	0.890	0.49
Counselling	Attention control	–1.198	0.541	–0.129	0.780	–1.069	0.949	0.26
Counselling	Less intensive psychological intervention	0.416	0.899	–0.253	1.036	0.670	1.372	0.63
Family therapy	Usual care	0.100	0.448	0.513	0.868	–0.412	0.977	0.67
Family therapy	Attention control	0.017	0.857	–0.969	0.682	0.986	1.095	0.37
Family therapy	Less intensive psychological intervention	0.128	0.888	0.797	1.045	–0.670	1.372	0.63

SE, standard error.
Note
Includes significance test for difference.

TABLE 10 Summary of treatment effects compared with TAU, assuming a common heterogeneity estimate for all treatment design comparisons, for studies of adolescents/children with T1DM

Treatment	b	95% CI	SE	*z*-value	*p*-value
Usual care	0				
CBT	–0.329	–1.198 to 0.539	0.443	–0.74	0.54
Counselling	0.088	–0.621 to 0.797	0.362	0.24	0.8
Family therapy	–0.184	–0.917 to 0.549	0.374	–0.49	0.55
Attention control	–0.768	–1.704 to 0.169	0.478	–1.61	0.17
Less intensive psychological intervention	0.22	–1.076 to 1.516	0.661	0.33	1.52

SE, standard error.
Note
b is the SMD using TAU as the control group. The formulas for Hedges' *g* in White and Thomas[87] are used. These are unbiased estimators and involve corrections for small numbers of degrees of freedom.

Network meta-analysis results for studies of adults with type 2 diabetes mellitus

Descriptives

In our meta-analyses, we retrieved data from 49 studies of adults with T2DM that had five different psychological intervention types and five main types of control groups. In addition, four studies[128,134,136,146] had two control groups and three studies had two treatment groups. However, two of those had the same treatment arm (counselling) and only one control group. We had to remove one of the two counselling groups as the network analyses algorithms did not allow the inclusion of two treatment arms of the same type in a study. One study[128] had two treatment and control substudies. These were separated into two separate studies in the NMAs.

A total of 50 studies with 103 treatment or control arms were thus included in the meta-analyses, with a total sample size of 12,409 participants (*Table 11*). Four studies[128,134,136,146] provided more than two arms to the NMAs.[128,134,136,146] CBT (used in 53.7% of studies) and counselling (used in 39% of studies) were the

TABLE 11 Number of studies and arms included in the NMAs for studies of adults with T2DM

Arm	Studies (*n*)	%	Arm	Sample size (*n*)
CBT	16	15.53	T	717
Counselling	29	28.16	T	4636
Psychotherapy	3	2.91	T	268
Creative therapy	1	0.97	T	67
Usual care	37	35.92	T	5050
Attention control	12	11.65	C	796
Computerised material	2	1.94	C	666
Printed material	1	0.97	C	68
Music relaxation CD	1	0.97	C	58
Family therapy	1	0.97	T	83
Total	103	100		12,409

C, arm was defined as control group in original study; CD, compact disc; T, arm was defined as treatment arm.

interventions most often studied. Usual care (used in 70.4% of studies) was used most often as control arm, followed by attention control (used in 20.4% of studies). Other intervention and control arms were offered only once or twice.

Descriptive information and the coding of variables for each of the studies are provided earlier in the report (see *Chapter 3* and *Table 1*).

Given that we had 10 conditions, 45 contrasts were possible. *Figure 49* shows the network plots of evidence for all studies. The plot shows that only 12 contrasts were investigated and only five conditions had at least moderate sample size, based on more than two studies.

To reduce the overestimation of treatment effects due to publication bias and to obtain robust findings, we performed two NMAs. First, all available studies were analysed. Second, we then restricted our main analyses to five conditions (CBT, counselling, attention control, psychotherapy and usual care).

Results of all available studies

Table 12 shows that the estimated direct and indirect effects between interventions did not differ significantly. The non-significant chi-squared test for inconsistency [$\chi^2(2) = 2.55$; $p = 0.28$, $I^2 = 0$] supports the conclusion of model consistency. Although there was no significant difference between direct and indirect treatment effects, it should be noted that some direct and indirect effects show opposite treatment effects, that is CBT shows a significant positive treatment effect in direct comparison with usual care (–0.292, 95% CI –0.56 to –0.024) but a (non-significant) worsening effect when looking at the indirect evidence (0.277, 95% CI –0.389 to 0.943).

Table 13 shows the results of the consistency NMAs comparing treatments with usual care. No therapy shows a significant reduction of treatment outcome compared with usual care. Only music therapy showed a moderate treatment standardised effect size. *Appendix 13*, *Table 35*, presents pairwise comparisons of treatment effect.

The rankogram graph (see *Appendix 13*, *Figure 50*) shows that music therapy has a 62.5% probability of being the best treatment, whereas computerised material treatment has only a 14.9% probability of being the best treatment; the probabilities for all other studies are < 10%. An assessment of the rescaled mean rank (SUCRA) shows that music therapy [music relaxation compact disc (CD)] is potentially the best

TABLE 12 Direct and indirect treatment effects (where indirect treatment effects were available) and the difference between them for adults with T2DM, including significance test for difference

Comparison		Direct		Indirect		Difference		
Treatment	Control	SMD	SE	SMD	SE	SMD	SE	*p*-value
Usual care	Computerised material	–0.087	0.314	–0.395	0.583	0.309	0.662	0.64
CBT	Usual care	0.292	0.134	–0.277	0.333	0.569	0.359	0.11
CBT	Family therapy	0.153	0.274	0.722	0.233	–0.569	0.359	0.11
Counselling	Usual care	0.121	0.101	0.690	0.345	–0.569	0.359	0.11
Counselling	Family therapy	0.551	0.161	–0.019	0.321	0.569	0.359	0.11
Counselling	Computerised material	–0.059	0.314	0.250	0.583	–0.309	0.662	0.64
Counselling	Music relaxation CD	–0.395	0.464	0.336	63.250	–0.731	63.252	0.99
Creative therapy	Family therapy	–0.221	0.459	0.538	63.247	–0.759	63.249	0.99
Family therapy	Printed material	0.103	0.459	–0.656	63.256	0.759	63.258	0.99

CD, compact disc; SE, standard error.

TABLE 13 Summary of treatment effects compared with TAU, assuming a common heterogeneity estimate for all treatment design comparisons, for studies of adults with T2DM

Treatment	b	(95% CI)	SE	*z*-value	*p*-value
Usual care	0				
CBT	–0.213	–0.461 to 0.035	0.126	–1.68	0.09
Counselling	–0.166	–0.36 to 0.027	0.099	–1.68	0.09
Psychotherapy	0.009	–0.535 to 0.553	0.277	0.03	0.97
Creative therapy	0.491	–0.464 to 1.446	0.487	1.01	0.31
Attention control	0.27	–0.051 to 0.591	0.164	1.65	0.1
Computerised material	–0.156	–0.69 to 0.379	0.273	–0.57	0.57
Printed material	0.373	–0.581 to 1.328	0.487	0.77	0.44
Music relaxation CD	–0.562	–1.492 to 0.369	0.475	–1.18	0.24
Family therapy	0.379	–0.507 to 1.265	0.452	0.84	0.4

CD, compact disc; SE, standard error.
Notes
'b' is the SMD using TAU as the control group. The formulas for Hedges' *g* in White and Thomas[87] are used.
Supported by the non-significant test for inconsistency ($\chi^2 = 0.79$, $p = 0.67$, $I^2 = 0$) and non-significant differences between direct and indirect treatment effects.

treatment (SUCRA = 0.9), followed by CBT (SUCRA = 0.8), counselling and computerised material (SUCRA = 0.7 for both), psychotherapy and usual care (SUCRA = 0.5 for both) and printed material and family therapy (both SUCRA = 0.3 for both). Creative therapy and attention control (SUCRA = 0.1 for both) are most likely to be the two worst therapies (see *Appendix 13*, *Table 34*).

Music therapy (music relaxation CD) was assessed in only one study, with a sample size of 58 participants. To reduce overestimation of effects and test the robustness of the findings, we conducted further analyses restricted to treatments with more than two studies.

Results of reduced number of treatments (more than two studies per treatment)

A total of 37 studies with 48 treatment and 49 control arms were included in the meta-analyses, with a total sample size of 11,467 participants (*Table 14*) in the reduced data set.

Given that we had five conditions, 10 contrasts were possible. *Figure 22* shows the network plots of evidence for all studies. The plot shows that five contrasts were investigated. Psychotherapy was connected only with usual care. Rerunning a sensitivity analyses without psychotherapy did not alter conclusions regarding the four main arms (this is not shown).

TABLE 14 Number of studies and arms included in the NMAs of studies of adults with T2DM

Arm	Studies (*n*)	Studies (%)	Arm	Cases (*n*)
CBT	16	16.5	T	717
Counselling	29	29.9	T	4636
Psychotherapy	3	3.1	T	268
Usual care	37	38.1	C	5050
Attention control	12	12.4	C	796
Total	97	100	100	11,467

C, arm was defined as control group in original study; T, arm was defined as treatment arm.

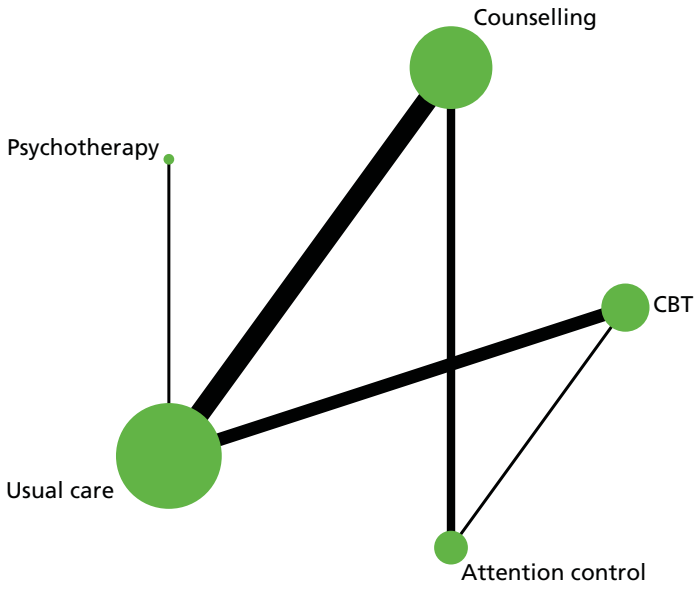


FIGURE 22 Network plots for reduced number of studies. Network plots of direct comparisons for the NMA of studies of adults with T2DM. The width of the lines is proportional to the number of trials comparing each pair of treatments and the size of each node is proportional to the number of studies testing the specific treatment. It shows, roughly, how much information is available for each treatment and for each treatment comparison.

Table 15 shows that the estimated direct and indirect effects between interventions did not differ significantly. The non-significant chi-squared test for inconsistency [$\chi^2(1) = 2.45$; $p = 0.12$, $I^2 = 18.4\%$] supports the conclusion of model consistency. *Table 16* shows the results of the consistency NMAs comparing treatments with usual care. Similar to the analyses using all studies, it should be noted that some direct and indirect effects again show opposite treatment effects, that is CBT shows a significant positive treatment effect in direct comparison with usual care (–0.292, 95% CI –0.564 to –0.02), but a (non-significant) worsening effect when looking at the indirect evidence (0.278, 95% CI –0.804 to 1.48).

Assuming inconsistency, no treatment demonstrates statistically significant reduction of treatment outcome compared with usual care. Observed effect sizes ranged between negligible and small. *Appendix 13*, *Table 36*, reports pairwise comparisons of treatment effect.

The rankogram graph (*Figure 23*) shows that CBT has a 48.4% probability of being the best treatment, followed by counselling (30.5%) and psychotherapy (21%). The probabilities of attention control (< 0.1%) and usual care (0.1%) are negligible. An assessment of the rescaled mean rank (SUCRA) shows that CBT and counselling are estimated to be the best treatments (SUCRA = 0.8), followed by psychotherapy (SUCRA = 0.5); usual care (SUCRA = 0.3) and attention control (SUCRA = 0.1) are most likely to be the worst therapies.

TABLE 15 Direct and indirect treatment effects (where indirect treatment effects were available) and the difference between them for studies of adults with T2DM, including significance test for difference

Comparison		Direct		Indirect		Difference		
Treatment	Control	SMD	SE	SMD	SE	SMD	SE	*p*-value
CBT	Usual care	0.292	0.136	–0.278	0.338	0.571	0.364	0.117
CBT	Attention control	0.153	0.277	0.723	0.236	–0.571	0.364	0.117
Counselling	Usual care	0.120	0.103	0.690	0.350	–0.570	0.364	0.118
Counselling	Attention control	0.551	0.164	–0.020	0.326	0.571	0.364	0.117

SE, standard error.

TABLE 16 Summary of treatment effects compared with TAU (usual care), assuming a common heterogeneity estimate for all treatment comparisons, for studies of adults with T2DM

Treatment	b	95% CI	SE	*z*-value	*p*-value
Usual care	0				
CBT	–0.213	–0.464 to 0.038	0.128	–1.66	0.10
Counselling	–0.166	–0.362 to 0.03	0.1	–1.66	0.10
Psychotherapy	0.009	–0.543 to 0.56	0.281	0.03	0.98
Attention control	0.27	–0.056 to 0.596	0.166	1.63	0.10

Note
Supported by the non-significant test for inconsistency [$\chi^2(1) = 2.45$; $p = 0.12$, $I^2 = 18.4\%$] and non-significant differences between direct and indirect treatment effects (see *Table 5*).
'b' is the SMD using TAU as the control group. The formulas for Hedges' *g* in White and Thomas[87] are used.

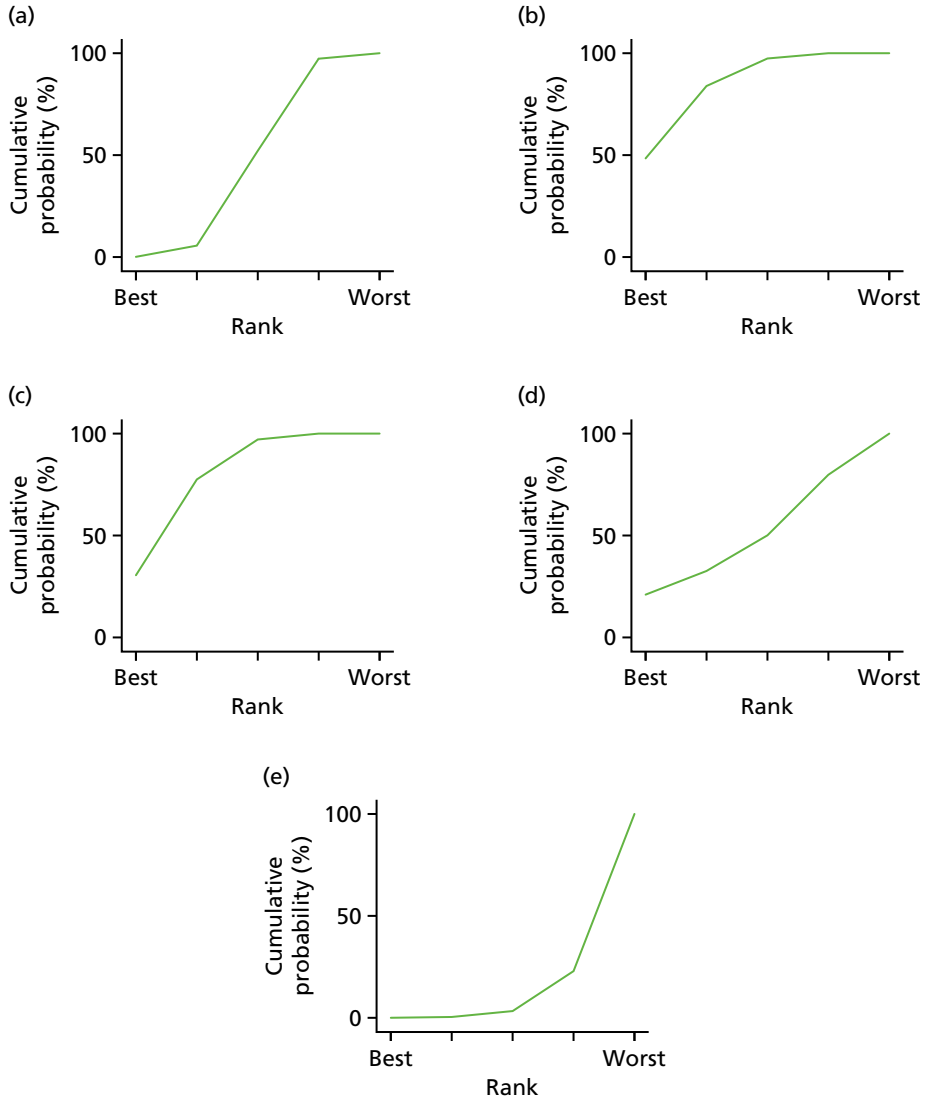


FIGURE 23 Rankogram for all treatments in studies of adults with T2DM. (a) Usual care; (b) CBT; (c) counselling; (d) psychotherapy; and (e) attention control. The plot shows the SUCRA curves for all treatments. For example, usual care has a very low probability of being the best or second-best treatment.

Chapter 6 Individual patient data meta-analysis results

The IPD meta-analyses consisted of 29 studies published between 2007 and 2016, with a total sample size of 5823 participants. The type of diabetes was not known for two people. Fifteen studies[104–106,129,163,164,168–171,176,179,181,183,184] included a total of 2182 people with T1DM (range 8–390) and 19 studies[104–106,113,118,123,129,132,135–137,140,142,143,145,147,150,151,169] included a total number of 3639 (range 15–521) patients with a diagnosis of T2DM. Of the 29 studies (study IDs listed in *Appendix 14, Table 37*), five studies[104–106,129,169] included a mixed population of T1DM and T2DM cases.[104–106,129,169] There were no issues with IPD integrity. There were no statistically significant differences between studies that provided data and those that did not with regard to sample size, country, year of publication, type of psychological intervention or risk of bias (see *Appendix 14*, *Table 38*).

Studies of T1DM were divided into adolescents and children (i.e. those aged < 18 years at recruitment; there were nine such studies, including one with a mixed T1DM and T2DM population) and adult participants (i.e. those aged ≥ 18 years; there were six such studies, including four with a mixed T1DM and T2DM population). People with T1DM were, therefore, typically younger [1392 were adolescents or children (< 18 years); 751 were adults (aged ≥ 18 years)] and typically had higher HbA_{1c} levels at baseline and lower BMI values (*Table 17*). Adults with T1DM had higher HbA_{1c} level baseline values [9.26% (SD 1.47%); $n = 726$] and lower BMI values [25.92 kg/m^2 (SD 4.62 kg/m^2); $n = 374$) than participants with T2DM. Diabetes duration was, on average, similar in both groups. Only one study[145] provided the gender of the participants. Baseline recordings for HbA_{1c} levels were above 95% for both types of diabetes groups, and follow-up rates were 85% and 81% for T1DM and T2DM populations, respectively. Participants with T1DM received mainly insulin treatment whereas only one-quarter of people with T2DM were treated with insulin.

TABLE 17 Clinical and demographic variables for participants with T1DM or T2DM

	T2DM ($N = 3639$)			T1DM ($N = 2182$)		
Variable	*n* (%)	Mean (SD) or *n* [%]	Range	*n* (%)	Mean (SD)	Range
Age (years)	3117 (85.6)	58.9 (10.16)	11.47–90	2143 (98.2)	21.9 (13.95)	8–78
HbA_{1c} at baseline	3471 (95.4)	7.9 (1.69)	2.7–19	2100 (96.2)	9.1 (1.76)	4.6–19.5
HbA_{1c} at follow-up	2797 (80.6)	7.5 (1.5)	2–20.8	1846 (84.6)	9.2 (1.81)	5.4–18.3
Gender (Male = 1)	57 (1.6)	25 [43.9]	N/A	0 (0)	N/A	N/A
Duration (years)	2060 (59.3)	7.1 (6.73)	0.08–44	1695 (77.7)	7.9 (7.56)	0.08–52.7
BMI (kg/m^2)	2909 (83.8)	32.1 (6.26)	13.9–63.2	1098 (50.3)	22.9 (5.65)	0.08–119.1
Treatment	1988 (91.1)	–	–	481 (13.2)	–	–
Insulin	535 (26.9)	–	–	480 (99.8)	–	–
Diabetic medication	154 (7.8)	–	–	0 (0)	–	–
Diet/exercise	1299 (65.3)	–	–	1 (0.2)	–	–

N/A, not available.

We conducted linear regression models with HbA_{1c} level as outcome and treatment type and baseline values of HbA_{1c} level as fixed independent variables, with a random intercept for study, random treatment effect and a random effect for baseline measures of HbA_{1c} levels. To identify moderators of improvement in HbA_{1c} levels, we ran several analyses, initially using only one predictor variable and its interaction with treatment arm at a time to avoid reducing sample size. For adolescents/children with T1DM, only a random effect for treatment arm was included.

Individual patient data meta-analysis for studies of adults with type 1 diabetes mellitus

Two studies[168,169] had one and two participants, respectively, aged 18 years with T1DM; therefore, they were not included in the analyses.

Step 1

In step 1, we investigated the effect of treatment and baseline values for HbA_{1c} levels only.

Glycated haemoglobin levels at baseline did not moderate the treatment outcome [interaction HbA_{1c} level and arm: b = –0.053 (95% CI –0.20 to 0.094; $p = 0.480$), $n = 455$ participants, $n_{studies} = 6$]. After removing the interaction, there was a small but non-significant decrease in HbA_{1c} level at follow-up, after controlling for baseline values in the treatment compared with the control group [mean difference –0.084 (95% CI –0.412 to 0.244; $p = 0.615$)]. There was no within-study correlation [intracluster correlation coefficient (ICC) = 0]. The forest plot of the meta-analyses is shown in *Appendix 14*, *Figure 51*. Between-study heterogeneity was small ($I^2 = 0.05$).

Step 2

In step 2, we explored age and duration of illness as potential moderators of treatment effect, in addition to treatment arm and baseline HbA_{1c} level.

There were only two studies with diabetes duration information; therefore, we included 'study' as a fixed effect in the model. No combined analyses with age were performed.

Including age and the interaction between age and treatment arm did not reveal a significant moderating effect of age [arm × age = –0.002 (95% CI –0.018 to 0.021; $p = 0.844$, $n = 455$ participants, $n_{studies} = 6$)]. After removing the interactions from the model, age did not predict HbA_{1c} level at follow-up: [age: = –0.008 (95%. CI –0.018 to 0.002; $p = 0.112$)] and there was a non-significant treatment effect (b = –0.095, 95% CI –0.414 to 0.224; $p = 0.561$). The ICC for 'study' site remained 0. *Appendix 14*, *Figure 52*, shows the forest plot of estimated treatment effects after controlling for age and duration of study. There was little between-group variance ($I^2 = 0.047$).

Step 3

The year of publication was not significant ($p = 0.520$) and did not alter the conclusion of the results.

The analyses of duration of illness with two studies did not reveal a significant moderating treatment effect (arm × duration: 0.002, 95% CI –0.023 to 0.027; $p = 0.878$, $n = 261$ participants, $n_{studies} = 2$). There was no main effect for duration of treatment after removing the interaction with treatment arm (b = –0.009, 95% CI –0.026 to 0.007; $p = 0.262$). However, after controlling for duration of outcome, a significant treatment effect was observed. Participants receiving treatment improved, on average, more after treatment (b = –0.38, 95% CI –0.661 to 0.099; $p = 0.008$, $n = 261$ participants, $n_{studies} = 2$).

Individual patient data meta-analysis for studies of adolescents/children with type 1 diabetes mellitus

Step 1

In step 1, we investigated the effect of treatment and baseline values for HbA_{1c} levels only.

Glycated haemoglobin levels at baseline did not moderate the treatment outcome (interaction HbA_{1c} level and arm: b = –0.022, 95% CI –0.101 to 0.0581; $p = 0.595$, $n = 1257$, $n_{studies} = 9$). After removing the interaction, there was a small but non-significant decrease in HbA_{1c} levels at follow-up, after controlling for baseline values in the treatment group compared with the control group (mean difference –0.127, 95% CI –0.282 to 0.030; $p = 0.112$). Within-study correlation was small (ICC 0.039, 95% CI 0.012 to 0.12). The forest plot of the meta-analyses is shown in *Appendix 14*, *Figure 53*. Between-study heterogeneity was moderate ($I^2 = 0.28$).

Models included a random study intercept and random treatment HbA_{1c} at baseline effects.

Step 2

In step 2, we explored age and duration of illness as potential moderators of treatment effect, in addition to treatment arm and baseline values for HbA_{1c} levels.

Including age and the interaction between age and treatment arm did not reveal a significant moderating effect of age (arm × age = –0.048, 95% CI –0.115 to 0.019; $p = 0.160$, $n = 1234$ participants, $n_{studies} = 9$). Similarly, there was no moderating effect of duration of diabetes in years with treatment arm (arm × duration: –0.028, 95% CI –0.017 to 0.073; $p = 0.224$, $n = 1125$ participants, $n_{studies} = 8$).

Including age and duration together as moderators in the model resulted in similar non-significant moderating effects (arm × age: – 0.068, 95% CI – 0.14 to 0.009; $p = 0.07$) (arm × duration: 0.039, 95% CI –0.008 to 0.085; $p = 0.10$, $n = 1122$ participants, $n_{studies} = 8$).

After removing the interactions from the model, age and duration of treatment were significant as main effects: independent of treatment arm, younger patients improved more (age: 0.046, 95% CI 0.005 to 0.086; $p = 0.03$) and patients with longer duration of diabetes improved more (b = –0.038, 95% CI –0.062 to –0.014; $p = 0.002$). The treatment effect remained non-significant after including age and duration (–0.149, 95% CI –0.306 to 0.016; $p = 0.08$). The ICC for 'study' site remained small (0.035). *Appendix 14*, *Figure 54*, shows the forest plot of estimated treatment effects after controlling for age and duration of study. There was a small amount of between-group variance ($I^2 = 0.24$).

Step 3

The year of publication was not significant ($p = 0.273$) and did not alter the conclusion of the results.

Individual patient data meta-analysis for studies of adults with type 2 diabetes mellitus

Step 1

In step 1, we investigated the effect of treatment and baseline values for HbA_{1c} levels only.

The models included a random study intercept and random treatment HbA_{1c} level baseline effects.

Glycated haemoglobin level at baseline significantly moderates treatment outcome (interaction HbA_{1c} level and arm: b = –0.077, 95% CI –0.127 to –0.027; $p = 0.003$, $n = 2541$ participants, $n_{studies} = 19$) (*Figure 24*). *Appendix 14*, *Figures 24* and *55*, show the predicted mean differences in HbA_{1c} levels at follow-up at varying HbA_{1c} baseline levels. At about 6.5% HbA_{1c} (48 mmol/mol) at baseline, there were no treatment differences between the intervention and control groups predicted. There was an increasing advantage of intervention

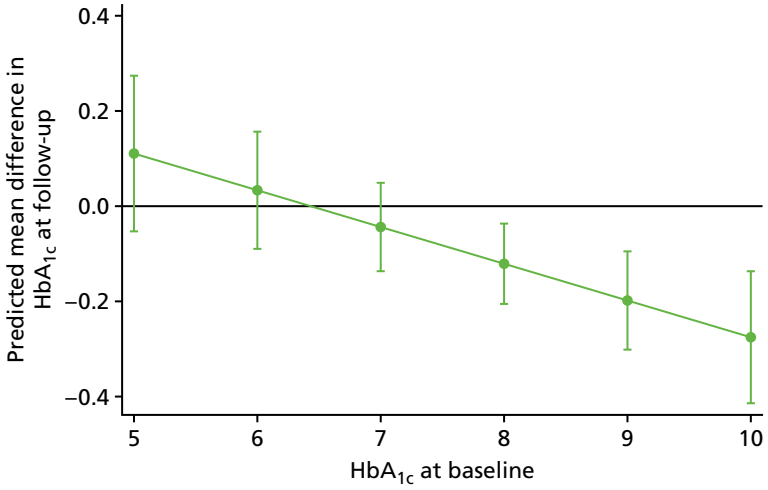


FIGURE 24 The IPD meta-analysis comparing treatment with control in terms of HbA_{1c} levels at follow-up for studies of adults with T2DM. The plot shows the differences in predicted mean treatment outcome together with 95% CIs follow-up between intervention and control groups in dependency of the moderator HbA_{1c} level at baseline. Effect sizes are unstandardized differences in % HbA_{1c}.

with increasing HbA_{1c} baseline levels. At the mean baseline level of HbA_{1c} of 7.8% (62 mmol/mol), patients in the intervention group had, on average, 0.107% (1 mmol/mol) (95% CI –0.190% to –0.023%; $p = 0.013$%) lower levels of HbA_{1c} at follow-up than patients in the control group. The random effect of baseline HbA_{1c} level suggests considerable variation between study sites (SD 0.124%, 95% CI –0.081% to 0.190%) and considerable within-study correlation (ICC 0.329, 95% CI 0.147 to 0.582). The forest plot of the meta-analyses with centred baseline HbA_{1c} levels [equivalent to holding baseline values constant at 7.8% (62 mmol/mol)] is shown in *Appendix 14*, *Figure 56*. No between-study heterogeneity was estimated ($I^2 = 0$).

Step 2

In step 2, we explored age and duration of illness as potential moderators of treatment effect, in addition to treatment arm and baseline values of HbA_{1c}, and the interaction between arm and HbA_{1c} baseline values.

Including age and the interaction between age and treatment arm did not reveal a significant moderating effect of age (arm × age = –0.003, 95% CI –0.012 to 0.006; $p = 0.580$, $n = 2336$, $n_{studies} = 13$). After removing the interactions from the model, age predicted HbA_{1c} level at follow-up (b = –0.009 (95% CI –0.014 to –0.004; $p < 0.001$). The interaction between baseline HbA_{1c} levels and treatment arm and treatment difference at mean baseline values remained significant. The ICC for study site remained large (0.187).

Including duration of diabetes and the interaction between duration and treatment arm did not reveal a significant moderating effect of duration (arm × duration = 0.012, 95% CI –0.027 to 0.003; $p = 0.11$, $n = 1457$ participants, $n_{studies} = 11$). After removing the interaction from the model, duration of diabetes predicted HbA_{1c} level at follow-up: participants with a longer duration of illness had lower HbA_{1c} values at follow-up (b = –0.011, 95% CI –0.002 to –0.019; $p = 0.011$). The interaction between baseline HbA_{1c} level and treatment arm and treatment difference at mean baseline values remained significant. The ICC for study site remained large (0.265).

Including type of treatment and the interaction between type of treatment and treatment arm did not reveal a significant moderating effect of type of treatment ($p = 0.211$, $n = 1415$ participants, $n_{studies} = 11$). After removing the interaction from the model, type of treatment predicted HbA_{1c} level at follow-up ($\chi^2(2) = 14.83$; $p < 0.0001$): participants treated with diet and exercise improved by 0.47% (5 mmol/mol) HbA_{1c} at follow-up compared with participants treated with insulin (b = –0.471, 95% CI –0.728 to –0.214; $p < 0.001$). Participants treated with medication also improved compared with those treated with insulin (b = –0.223, 95% CI –0.373 to –0.074; $p = 0.003$), but significantly less so than those treated with diet and exercise (b = 0.247 95% CI 0.02 to 0.475; $p = 0.033$).

The interaction between baseline HbA_{1c} level and treatment arm (b = –0.042, 95% CI –0.113 to 0.030; $p = 0.251$) and treatment difference at mean baseline values (b = –0.042, 95% CI > –0.187 to 0.048; $p = 0.245$) were not significant. The ICC for study site remained large (0.265).

Including age and duration of illness in the model resulted in a similar conclusion. Independent of treatment type, older people improved more than younger people (b = –0.008, 95% CI –0.013 to –0.002; $p = 0.011$) and the longer the duration of diabetes, the less the improvement at follow-up (b = 0.013, 95% CI 0042 to 0.021; $p = 0.003$). The interaction between treatment and HbA_{1c} level remained significant (b = –0.09, 95% CI –0.013 to –0.002; $p = 0.008$): participants in the intervention group improved more with increasing HbA_{1c} baseline values than participants in the control group. At average HbA_{1c} baseline levels, participants in the intervention group had 0.0134% lower HbA_{1c} levels at follow-up than participants in the control arm (b = –0.0134, 95% CI = –0.232 to –0.035; $p = 0.008$). The large ICC of 0.236 shows that study site was a factor in the degree to which participants' HbA_{1c} levels changed.

The forest plot of the meta-analyses with centred baseline HbA_{1c} levels [equivalent to holding baseline values constant at 7.8% (62 mmol/mol)] and controlling for age and duration of illness is shown in *Appendix 14*, *Figure 57*. No between-study heterogeneity was estimated ($I^2 = 0$).

Removing the study[169] with the small sample size ($n = 15$) did not alter the results or conclusion in any of the analyses. *Appendix 14*, *Figure 58*, shows the forest plot of the previous meta-analyses repeated but excluding this study.[169]

Including all three potentials in the model reduced the sample size to six study sites with 873 participants. There were no significant interactions of age, duration of illness or treatment type with treatment. Main effects of age, duration and type of treatment were also not significant. There was no significant treatment effect.

Step 3

The year of publication did not have any significant influence on treatment outcome (p-values of > 0.19) and did not alter conclusions of the meta-analyses.

Chapter 7 Non-randomised controlled trial results

Study selection

A total of 16,900 citations were identified; 1794 duplicates were removed and 15,054 citations were excluded following title/abstract screening. The full texts of 52 citations were screened; 38 were excluded for the following reasons: unable to access published paper ($n = 2$), not nRCTs ($n = 11$), did not include a psychological intervention ($n = 16$), interventionists not trained in psychological therapy ($n = 4$), HbA_{1c} level was not an outcome ($n = 3$) and was not limited to a T1DM/T2DM population (and did not report separate analysis for diabetes; $n = 2$). The remaining 14 studies met the inclusion criteria for review (T1DM, 6 studies; T2DM, 7 studies; and T1DM and T2DM, 1 study). Inter-reliability for full-text inclusion was calculated; 58.8% (Cohen's kappa 0.588) agreement was found between the two raters (AK and RU). Higher agreement (Cohen's kappa 0.910) was found after initial discussion. All the included studies were nRCTs (comprising prospective/retrospective cohort studies, quasi-experimental studies, pre-/post-test control designs and observational controlled pre/post studies) published in English.

Characteristics of studies of people with type 1 diabetes mellitus

Six studies[226–231] had a T1DM population. People with T1DM and people with T2DM were included in the Harris *et al.*[232] study, in which 55 patients had T1DM. These 55 patients were included in the T1DM qualitative synthesis. Study characteristics are summarised in *Table 18*.

Study location

The studies originated from the following places: the USA ($n = 3$),[229,231,232] Asia [Japan ($n = 1$)[226] and Iran ($n = 1$)[227]] and Europe [Germany ($n = 1$)[228] and Spain ($n = 1$)[230]].

Participant characteristics

The seven studies investigating people with T1DM included a total of 419 participants (ranging from 4 to 117 people with T1DM per study). Studies included adult ($n = 3$)[226–228] or adolescent populations ($n = 4$).[229–232]

Studies of T1DM stipulated various inclusion criteria for participants, for example a HbA_{1c} level of $\geq 9\%$;[232] or $\geq 14\%$.[229] Age criteria were also outlined: 12–16 years,[229] 16–30 years[227] and 11–18 years.[230] Other inclusion criteria included being at a high risk of developing hypoglycaemia;[228] no impaired vison, cognitive impairment or psychiatric comorbidity;[228] binge-eating behaviours;[226] missed more than two clinic appointments;[232] and non-adherence to pharmacological treatment and/or mental state of concern to medical providers.[231]

Intervention characteristics

Psychological interventions were underpinned by various psychological models or principles: family-based interventions,[229,232] inpatient therapy,[226] stress management,[227] a self-management intervention,[228] psychoeducation[230] and psychotherapy.[231] The number of therapy sessions per study ranged from 6 to 56 (2 or 3 times a week over a 7-month period).[229] The following facilitators delivered the psychological interventions: therapists ($n = 2$),[226,229] psychiatrists/psychologist ($n = 4$)[227,228,230,231] and social worker/trainee psychologist ($n = 1$).[232]

Control characteristics

The nRCTs delivered the following control groups: usual care ($n = 5$);[227,229–232] counselling ($n = 1$);[226] and hypoglycaemia education ($n = 1$).[228] Details regarding the components and delivery of usual care were limited.

TABLE 18 Summary of all included studies in the nRCT systematic review

Year, country, first author	Number of participants with T2DM	Mean (SD) age (years) (intervention and control)	Inclusion criteria for individual studies	Mean duration of diabetes (intervention and control)	Type of psychological intervention	Number of sessions	Intervention name; facilitator; format; individual/group	Control category, facilitator, format, individual/group	Follow-up
T2DM nRCT studies									
2004, South Korea, Kim[233]	45	• Intervention: 53.82 (07.42) • Control: 52.78 (12.46)	T2DM for < 20 years; HbA_{1c} level of < 10.0%; no chronic complications; no insulin	• Intervention: 7.45 (7.32) • Control: 7.32 (6.37)	Transtheoretical model	NR	Staged-matched intervention; researcher; face to face and telephone; individual	Usual educational advice; NR	Post intervention
2007, South Korea, Song[234]	59	• Intervention: 51 (11.3) • Control: 49.5 (10.6)	T2DM; HbA_{1c} level of > 7.0%; no mental illness; no diabetic complications	• Intervention: 4.9 (5.3) • Control: 5.0 (5.7)	Counselling and multidisciplinary diabetes education	NR	Counselling and education; psychologist; face to face and telephone; individual and group	Usual care; diabetes education; NR	3 months
2009, Italy, Forlani[235]	822	• Intervention: 56.7 (8.5) • Control: 64.8 (10.3)	T2DM	NR	CBT	12–15	CBT; psychologist; face to face; group	Usual care (prescriptive diet); dietitian; face to face; individual	Up to 48 months
2009, the USA, Harris[232]	3	• Intervention: 16.0 (0.9) • Control: 15.2 (1.5)	T1DM or T2DM; HbA_{1c} level of ≥ 9.0%; missed more than two clinic appointments	• Intervention: 16.0 (0.9) • Control: 15.2 (1.5)	BFST-D	10	Family therapy; Master's level social worker/trainee psychologist; face to face; group	Usual care; NR	Post intervention
2011, South Korea, Lee[236]	83	• Intervention: 61.14 (6.01) • Control: 63.18 (5.11)	T2DM; aged > 50 years; no exercise for > 3 days per week for 1 month; no microvascular complications	NR	Cognitive psychology, educational theory, social problem-solving	12	Chronic disease self-care using heart rate monitor; research assistant; face to face; group	See intervention description; without heart rate monitor	3 and 6 months
2013, Spain, Cervantes Cuesta[237]	72	• Intervention: 66.37 (11.96) • Control: 61.04 (09.54)	T2DM; aged 30–75 years; HbA_{1c} level of ≥ 6.5%	NR	Psychoeducation	11	Psychoeducative group; NR; face to face; group	Usual diabetes education; NR	3 months

Year, country, first author	Number of participants with T2DM	Mean (SD) age (years) (intervention and control)	Inclusion criteria for individual studies	Mean duration of diabetes (intervention and control)	Type of psychological intervention	Number of sessions	Intervention name; facilitator; format; individual/group	Control category, facilitator, format, individual/group	Follow-up
2014, Thailand, Ounnapiruk[238]	60	• Intervention: 66.97 (1.54) • Control: 69.20 (1.29)	T2DM for > 6 months; aged 60–79 years; no complications	• Intervention: 9.35 (1.53) • Control: 11.27 (1.74)	Bandura's concept of self-efficacy[239]	4	Behavioural modification programme; researcher; face to face; individual and group	Usual care; NR	3–4 months
2014, Taiwan, Wu[240]	228	60.83 (12.48) for all participants	T2DM; aged > 20 years; language: Mandarin or Taiwanese; home telephone	10.27 (8.34) for all participants	Diabetes self-management programme	4	Self-management; trained nurses; face to face and telephone, individual and group	Usual care, diabetes education consultant; face to face; individual	1 month
T1DM nRCT studies									
2003, the USA, Ellis[229]	4	14–15	T1DM for ≥ 1 year; HbA_{1c} levels of ≥ 14%; aged 12–16 years	5 –10	Multisystemic therapy	2 or 3 times a week	Multisystemic therapy; trained therapist; face to face; group	Usual care; NR	3 months
2003, Japan, Takii[226]	19	• Intervention: 23.8 (5) • Control: 21.3 (4)	T1DM for ≥ 1 year; female; 3 years post treatment or no treatment for ≥ 2 years after first visit; binge-eating > 500 calories in one sitting and compensatory behaviour two or more times a week for 3 months	• Intervention: 7.6 (5.1) • Control: 8.8 (4.9)	Integrated inpatient therapy	NR	Integrated inpatient therapy; therapist; face to face; individual and group	Counselling; physician; face to face; individual	• Intervention: up to 36 months from discharge • Control: up to 24 months from discharge
2006, Iran, Attari[227]	60	• Intervention: 19.7 (3.29) • Control: 20.8 (9.52)	T1DM for ≥ 1 year; aged 16–30 years	• Intervention: 2.10 (0.6) • Control: 2.14 (2.3)	Stress management	8	Stress management training; experienced psychiatrist; face to face; group	Usual care; NR	Post intervention

continued

TABLE 18 Summary of all included studies in the nRCT systematic review (*continued*)

Year, country, first author	Number of participants with T2DM	Mean (SD) age (years) (intervention and control)	Inclusion criteria for individual studies	Mean duration of diabetes (intervention and control)	Type of psychological intervention	Number of sessions	Intervention name; facilitator; format; individual/group	Control category, facilitator, format, individual/group	Follow-up
2006, Germany, Kubiak[228]	107	• Intervention: 37 (14.1) • Control: 34.3 (12.9)	T1DM; at a high risk of developing hypoglycaemia; no impaired vision, cognitive impairment or psychiatric comorbidity	• Intervention: 16.4 (10.6) • Control: 16.2 (9.3)	Self-management intervention	6	Self-management treatment; psychologist; face to face; group	Education on hypoglycaemia; psychologist; face to face; group	6 months
2009, the USA, Harris[232]	55	• Intervention: 16.0 (0.9) • Control: 15.2 (1.5)	T1DM or T2DM; HbA_{1c} level of $\geq$ 9.0%; missed more than two clinic appointments	• Intervention: 16.0 (0.9) • Control: 15.2 (1.5)	BFST-D	10	Family therapy; Master's level social worker/trainee psychologist; face to face; group	Usual care; NR	Post intervention
2010, Spain, García-Pérez[230]	57	• Intervention: 13.79 (2.16) • Control:13.61 (1.44)	T1DM; aged 11–18 years	• Intervention: 5.74 (3.39) • Control: 6.20 (4.1)	Psychoeducation	NR	Summer camp for T1DM; psychologist; face to face; group and individual	Usual care; NR	3 and 12 months
2013, the USA, Bitsko[231]	117	• Intervention: 15.24 (0.49) • Control: 15.19 (0.43)	T1DM; non-adherence to pharmacological treatment/mental state of concern by medical providers	• Intervention: 4.59 (0.52) • Control: 6.23 (0.57)	Psychotherapy	9	Talk therapy; licensed doctoral-level psychologist; face to face; individual and group	Usual care; NR	12 months

NR, not reported.

The control counselling intervention[226] was delivered on a one-to-one basis by a physician. The education on hypoglycaemia control intervention[228] was delivered in a group environment by a psychologist.

Primary outcome

In all studies, HbA_{1c} level (in % or mmol/mol) was assessed at baseline and follow-up. Follow-up periods ranged from immediately post intervention to 12 months post intervention.

Secondary outcomes

The types of measures for secondary outcomes are outlined in *Appendix 15*. The following outcomes were assessed for T1DM studies: presence of eating disorders,[226] depression,[228] control beliefs,[228] fear of hypoglycaemia,[228] fear of diabetes complications,[228] stress management[227] and anxiety.[228,230]

Risk of bias in studies of type 1 diabetes mellitus

The quality assessment for each study is reported in *Appendix 15*, *Table 39*. Four studies[226–228,230] had information missing for more than one domain, which made the assessment of quality difficult; therefore, no decision was made regarding the RoB for these studies. The domains that had missing information included bias arising from deviations from intended interventions and missing data. The remaining three studies[229,231,232] also had no information for the bias arising from missing data, but an assessment could be made based on other domains. One study[231] was considered to be at a 'serious' RoB because of confounding issues with inclusion of participants, non-adjustment of baseline characteristics and possible selection bias. Two studies were rated as being at a critical RoB[169,232] because of problems with participant recruitment for the control group and absence of separate information for each group regarding demographic characteristics.

Results of individual studies of type 1 diabetes mellitus

Five studies with a T1DM population reported mean HbA_{1c} levels at baseline and follow-up for intervention groups; two studies[226,229] did not report these values (see *Appendix 15*, *Table 40*). Of the five studies, only one demonstrated a significant difference between the intervention and control groups, with a greater reduction in HbA_{1c} levels in the intervention group.[227] Three studies did not provide a test for significance for the difference in HbA_{1c} levels between baseline and follow-up, or between groups.[226,229,232]

For other outcomes, Takii *et al.*[226] reported that, in the intervention group, 78% participants no longer met the clinical criteria for eating disorders at follow-up. Attari *et al.*[227] demonstrated statistically significant between-group differences in positive coping for stress management in favour of the psychological intervention group (stress management) compared with the control (usual care). García-Pérez *et al.*[230] reported that there were no statistically significant between-group differences in anxiety outcomes.

Harris *et al.*[232] observed a statistically significant group difference at follow-up and improvement in diabetes responsibility and conflict for adolescents and their mothers, but not their fathers. However, for conflict behaviour, Harris *et al.*[232] did find statistically significant group difference and improvement at follow-up for adolescents and both parents (mothers and fathers). Note that this was not limited to a T1DM population (three people with T2DM were included in this analysis).

Kubaik *et al.*'s[228] study did not demonstrate any statistically significant between-group differences for depression, anxiety, control beliefs, fear of hypoglycaemia or fear of diabetic complications.

Characteristics of studies of people with type 2 diabetes mellitus

Seven studies included a T2DM population. In addition, one study (Harris *et al.*[232]) included a mixed T1DM and T2DM population, of which three participants had T2DM; these three participants were included in the T2DM qualitative synthesis when possible. Study characteristics are summarised in *Table 18*.

Study location

The studies originated from Asia (South Korea, *n* = 3; Thailand *n* = 1; and Taiwan *n* = 1), Europe (Italy, *n* = 1; and Spain *n* = 1) and the USA (*n* = 1).

Participant characteristics

The eight studies investigating people with T2DM represented a total of 1372 participants (ranging from 3 to 822 people with T2DM per study). Studies included adult (*n* = 7)[233–238,240] or adolescent populations (*n* = 1).[97]

Studies stipulated various inclusion criteria for people with T2DM to participate, for example a HbA_{1c} level of < 10%,[233] ≥ 6.5%,[237] > 7%,[234] or ≥ 9%.[232] Some studies specified no complication status,[233,234,236,238] no mental health illness,[234] treatment type (no insulin[233]) and duration of diabetes (< 20 years[233]). Age criteria were also outlined: > 20 years,[240] 30–75 years,[237] > 50 years[236] and 60–79 years.[238]

Intervention characteristics

Psychological interventions were underpinned by various psychological models or principles: trans-theoretical model,[233] counselling,[234,240] cognitive–behavioural approach,[235,236] BFST-D,[232] psychoeducation[237] and Bandura's concept of self-efficacy.[238] Two studies reported the use of manuals.[232,235] The number of therapy sessions per study ranged from 4 to 15.

Psychological interventions were delivered by the following facilitators: researcher or research assistant (*n* = 3),[233,236,238] psychologist (*n* = 2),[234,235] trainee psychologist (*n* = 1)[232] and nurses (*n* = 1);[240] one study did not report the type of facilitator.[237] The level of training received by the facilitators was reported in two studies: one provided intensive training[232] and the other reported that the facilitator was provided with reading material regarding the intervention.[240]

Control characteristics

Control groups consisted of usual care (*n* = 7)[232–235,237,238,240] and chronic disease self-care (*n* = 1).[236] In some cases, usual care included diabetes education or dietary advice. Details regarding delivery and components of control groups was limited.

Primary outcome

In all studies, HbA_{1c} level (% or mmol/mol) was assessed at baseline and follow-up. The follow-up period ranged from post intervention to 48 months.

Secondary outcomes

The type of measures used are outlined in *Appendix 15*, *Table 41*. The following outcomes were assessed: readiness to exercise;[233] diabetes responsibility and conflict;[232] coping;[236] diabetes self-management self-efficacy;[238] depression, anxiety and stress;[240] perceived treatment efficacy;[240] and well-being.[240]

Risk of bias in studies of people with type 2 diabetes mellitus

The quality assessment for each study is reported in *Appendix 15*, *Table 39*. Four studies had information missing for more than one domain, which made the assessment of quality difficult; no decision was made regarding the RoB for this study. The domains that had missing information included bias owing to deviations from intended interventions and missing data. The remaining four studies also had no information for the bias arising from missing data, but an assessment could be made based on other domains. One study was considered to be at a 'serious' RoB,[235] mainly because of confounding issues with inclusion of participants, non-adjustment of baseline characteristics and possible selection bias. Two studies were rated as being at a 'critical' RoB[232,240] and one as was rated as being at a 'moderate' RoB[236] because of major problems with participant recruitment for the control group and absence of information regarding demographic characteristics for both groups separately.

Results of individual studies of people with type 2 diabetes mellitus

The following paragraphs present a summary of individual studies. *Appendix 15*, *Table 40*, reports HbA_{1c} values (primary outcome) and *Appendix 15*, *Table 41*, presents secondary outcomes for all individual studies.

Only two of the eight studies demonstrated a significant difference between the psychological intervention group and the control group, with a greater improvement in HbA_{1c} level in the intervention group.[234,240] Harris *et al.*[232] and Lee *et al.*[236] did not provide a significance test for the difference in HbA_{1c} levels between baseline and follow-up, or between groups.

For secondary outcomes, Kim *et al.*[233] reported a statistically significant increase in the participants' readiness to change and participate in physical activities in the psychological intervention group, but not the control group. Lee *et al.*[236] demonstrated no between-group differences in coping strategies post intervention. In one study,[238] self-efficacy regarding diabetes management did significantly improve in the intervention group compared with control group at 3 months.

In the study by Wu *et al.*,[240] statistically significant group differences and improved perceived self-efficacy and self-care, and levels of depression, anxiety and stress were demonstrated in favour of the psychological intervention.

Limitations of the type 1 and type 2 diabetes mellitus studies

Most studies reported the method of non-randomisation as a potential limitation that hindered the validity and reliability of the test results. Other limitations that were reported included small sample size;[229,231,233,238] possible selection bias in recruiting participants;[144,229,230,235] study design, such as retrospective or lack of participant blinding;[231,240] duration of the follow-up;[231,234,238,240] difference between the recruiting sites;[228,230,238] psychological assessments lacking validity and reliability;[234,236] absence of standardisation of measures to gauge clinical significance;[232] effect of media or self-study;[234,236] and non-adjustment of baseline data for psychological characteristics.[230,235]

Chapter 8 Health economic analyses

Overview

In this chapter, we cover the methods and results of two cost-effectiveness modelling exercises:

1. the cost-effectiveness of CBT versus counselling versus usual care in adults with T1DM using an adapted health economic individual-level simulation model – the Sheffield Type 1 Diabetes Policy Model
2. the cost-effectiveness of CBT versus counselling versus usual care in adults with T2DM using an adapted health economic individual-level simulation model – the SPHR Type 2 Diabetes Prevention Model.

Detailed methods on the Sheffield Type 1 Diabetes Policy Model

Sheffield Type 1 Diabetes Policy Model framework

The Sheffield Type 1 Diabetes Policy Model, version 1.4, henceforth 'the model', is an individual-level simulation model used to estimate the lifetime costs and QALYs for adults with T1DM. An individual's HbA_{1c} level determines their risk of progression for all diabetic complications in the model, which include nephropathy, neuropathy, retinopathy, macular oedema, myocardial infarction, stroke, heart failure, angina, severe hypoglycaemia and DKA (see *Appendix 16*, *Tables 48* and *50*). A higher HbA_{1c} level increases the risk of progression for all complications in the model, except severe hypoglycaemia, for which a lower HbA_{1c} level increases the risk of experiencing an event. Individuals in the model are at risk of death from the incidence of nephropathy, myocardial infarction, stroke, heart failure, angina and all-cause mortality. HbA_{1c} level indirectly affects mortality in the model, as the probability of death does not differ by HbA_{1c} level; however, the risk of experiencing these events is higher for someone with a higher HbA_{1c} level.

The model has previously been used to assess the cost-effectiveness of various versions of the Dose Adjustment For Normal Eating (DAFNE) course[241,242] (see *Appendix 16*, *Table 49*), stratification of DAFNE by psychological factors,[243] structured education for children with T1DM and extending the use of insulin pumps[244,245] to all adults with T1DM who are eligible to receive a structured education course.

Complete details of how the model calculates the incidents of diabetes complications is provided in Heller *et al.*[245] and Thokala *et al.*[246]

The model attaches costs to clinical events and health states allowing the calculation of costs over a lifetime. Full details are given in *Appendix 16*, *Tables 42–45*.

The model attaches utilities to health states, allowing the calculation of QALYs over a lifetime.[247–250] Utility decrements are applied additively; if an individual experiences decrements in two different submodels (e.g. end-stage renal disease in the nephropathy submodel and myocardial infarction), then both decrements are applied. If an individual progresses in a submodel (e.g. in the retinopathy submodel, an individual can progress from proliferative retinopathy to blindness), then only the decrement associated with the more severe health state is applied. Full details are given in *Appendix 16*, *Table 48*.

Baseline characteristics for the people with type 1 diabetes mellitus modelled in this study

Individual baseline characteristics were sourced from the NICE T1DM guidelines[27] (see table 69 in the appendices of the NICE guideline NG17[27]) and our previous work on the cost-effectiveness of DAFNE-structured education. Most characteristics and their SDs were sourced from the NICE T1DM guidelines. If SDs were not available from the NICE guidelines[27] (because of transformation of variables),

the correlation between the variables was sourced from the DAFNE research database. Two variables (the baseline cost of insulin used and the baseline cost of diabetes-related contacts with health-care professionals) were sourced from the Relative Effectiveness of Pumps over Structured Education (REPOSE) trial data set.[245] The samples of these variables were conditional on the other samples. Full details are given in *Appendix 16*, *Table 47*.

Incorporating short-term (1 year) clinical effectiveness evidence for people with type 1 diabetes mellitus modelled in this study

In the main economic analysis, the effectiveness of the different psychological interventions was sourced from the NMA shown *Table 6*. The main estimates are presented in *Appendix 16*, *Table 46*. The estimate for the effect of CBT versus usual care was –0.312 (95% CI –0.499 to –0.126). The estimate for the effect of counselling versus usual care was –0.121 (95% CI –0.307 to 0.066). The full variance–covariance matrices used for the PSA on mean effects are presented in *Appendix 16*, *Tables 43–45*.

For each individual, the psychological intervention effect and the individual's baseline HbA_{1c} level were used to generate the HbA_{1c} level at 1 year. In the model, we capture heterogeneity of response to the psychological intervention by allowing individuals' HbA_{1c} levels at year 1 to vary, but ensuring that, when aggregated, they would have the mean effect from the NMA. The statistical method to incorporate this heterogeneity uses evidence on the dispersion of HbA_{1c} from the REPOSE trial of T1DM[244] (see *Appendix 16*, *Tables 47–50*, and table 22 of supplementary B material in Pollard *et al.*[244]). The impact of including heterogeneity in HbA_{1c} response is that the modelled HbA_{1c} profile for an individual is more likely to reflect clinical practice, in which some people's HbA_{1c} level is likely to rise after 1 year and others' levels are likely to fall, with the average across all the individuals being that from the meta-analysis. Another consequence of using this technique is that the use of the dispersion parameter involves using a beta regression framework, which means that people with a low baseline HbA_{1c} level cannot receive an implausibly low HbA_{1c} value (< 4.8%, based on clinical expert opinion) in the simulation.

Incorporating longer-term clinical effectiveness evidence for type 1 diabetes mellitus

The key study found was Ridge *et al.*[251] This study used a RCT of adults with T1DM and suboptimal glycaemic control who received motivational enhancement therapy (i.e. counselling) alone or motivational enhancement therapy CBT. The participants in the group that received motivational enhancement therapy CBT showed a greater reduction in their 12-month HbA_{1c} levels than those who received usual care. Whether or not improvements in glycaemic control persisted up to 4 years after randomisation was tested. Statistical analysis was undertaken on 260 (75.6%) people who consented to take part in this post-trial study.

We used the information from this study[251] and its supplementary material to examine the duration of treatment effects over 2, 3 and 4 years. We calculated the implied trajectory using the sample size weighted average of the 2-, 3- and 4-year follow-ups. This was calculated as:

$$[(\text{weighted average of the year 2-, 3- and 4-year follow-ups}) - (\text{average } HbA_{1c} \text{ level at year 1})] / (\text{mean follow-up time} - 1). \quad (1)$$

This calculation was done separately for the CBT and counselling arms.

We developed to a method to analyse the uncertainty in this trajectory. This was based on the CI for the HbA_{1c} fall at year 1 and the CI for the weighted average HbA_{1c} level in the follow-up years, assuming normal distribution for each. The implied trajectory was calculated for each sample from these distributions. We then calculated the correlation between the trajectory and the fall in HbA_{1c} level at 1 year. We used this to estimate a normal conditional probability distribution for the trajectory, conditional on the 1-year fall in HbA_{1c} level from the NMA. Again, the uncertainty in the trajectory was analysed separately for the CBT and counselling arms.

Appendix 16 (see *Tables 70–72*) shows the resulting parameters for the conditional distributions for CBT and for counselling.

When a PSA run samples a negative trajectory versus usual care (i.e. a persistently widening gap over the long term), we have modelled maintenance of the initial treatment gap, rather than assuming that a psychological intervention can generate a wider gap at year 10 or 20 than it has at year 4. This was partially because the psychological intervention in the Ridge *et al.*[251] study was just a 1-year intervention (i.e. no further active psychological intervention was provided after year 1).

Costing psychological interventions for adults with type 1 diabetes

The cost of psychological interventions was calculated, based on the information from the trials and studies from the systematic reviews. The references[104,105,162–166] were examined in detail to extract information on the main elements of cost, which are as follows:

- costs of staff time to deliver the intervention
- session-related non-contact staff time
- cost of consumables per session
- costs associated with training the staff who will deliver the psychological interventions
- costs associated with supervision of staff
- proportion of sessions that are individual based versus group based
- number of course participants in group sessions.

These are broadly split into two categories: those types of resource use/cost that are assumed to be the same across interventions and those that are different (*Table 19*). The following categories are assumed to be the same across interventions: the interventionists, the session-related non-contact time (either as a ratio of contact time or an absolute value), the cost of consumables and the training costs. In addition, the following categories are assumed to be different: the split between individual and group sessions, the average number of people in a group session, the number of sessions and the duration of each session.

TABLE 19 Key model parameters for Sheffield type 1 Diabetes Policy Model applied to psychological interventions for adults with T1DM

Parameter	Value(s) (95% CI)	Source/calculation
Cost of CBT per participant	£657.22	This study (see *Appendix 16*, *Table 75*)
Cost of counselling per participant	£580.42	This study (see *Appendix 16*, *Table 75*)
Mean reduction in HbA_{1c} level in first year, CBT versus usual care (%)	–0.312 (–0.499 to –0.126)	*Chapter 5* of this study. See *Appendix 16*, *Table 66*, for variance–covariance matrix
Mean reduction in HbA_{1c} level in first year, counselling versus usual care (%)	–0.121 (–0.307 to 0.066)	*Chapter 5* of this study
Long-term trajectory of HbA_{1c} levels 12 months after CBT: annual change in % HbA_{1c} level versus usual care (%)	–0.009 (–0.176 to 0.158)[a]	Ridge *et al.*[251] and further analysis in *Appendix 16*, *Table 66*
Long-term trajectory of HbA_{1c} levels 12 months after counselling: annual change in % HbA_{1c} level versus usual care (%)	–0.062 (–0.341 to 0.216)[a]	Ridge *et al.*[251] and further analysis in *Appendix 16*, *Table 66*

a When a PSA run samples a negative trajectory versus usual care (i.e. a persistently widening gap over the long term), we have modelled maintenance of the initial treatment gap, rather than assuming that a psychological intervention can generate a wider gap at year 10 or 20 than it has at year 4. This was partially because the psychological intervention in the Ridge *et al.*[251] study was just a 1-year intervention (i.e. no further active psychological intervention was provided after year 1).

For T1DM, the estimated cost per participant of delivering the interventions is as follows:

- cost of CBT intervention – £657.22 per participant
- cost of counselling intervention – £580.42 per participant.

When examined in terms of cost per participant per session, these costs are £82.34 for CBT and £72.72 for counselling, which are of a similar order of magnitude to the costs (£81.12 for CBT and £49.14 at 2005/6 prices) reported in the 2010 Health Technology Assessment study by Ismail *et al.*[252]

All costs were adjusted to 2015/6 GBP prices using the hospital and community health services pay and prices index.[253] A summary of the costs is given in *Table 19* and details of the methods and costs can be seen in *Appendix 16*.

Usual care costs presented in the studies included in the systematic review were either in the context of the intervention being an enhancement to usual care or the usual care contacts when related to protocol requirements (e.g. collection blood samples at baseline). Therefore, it was assumed that there were no additional costs associated with usual care.

Main analysis of cost-effectiveness

The analysis conducted 500 model runs, with each PSA iteration sampling every uncertain parameter from its associated probability distribution, and each PSA run modelling 5000 individuals in each arm of the comparison.

The average of these 500 PSA runs is used to estimate expected discounted lifetime costs and expected discounted QALYs associated with each strategy being compared.

Methods to analyse decision uncertainty in type 1 diabetes model using expected value of perfect parameter information

Uncertainty is analysed using expected value of information statistics. The first is the overall EVPI, which calculates how valuable it would be to a decision-maker (e.g. NICE) to eliminate all uncertainty on all the model parameters (i.e. CIs do not exist, as every parameter is certainly known). The second is the EVPPI, which is the same idea but focused only on particular model parameters (i.e. only a defined subset of model parameters are certainly known, the rest are still uncertain).

The expected value of information calculations were estimated efficiently using a recently developed online tool called SAVI[254] at a maximum acceptable ICER of £20,000 per QALY gained, in line with NICE decision-making thresholds.

Two subsets of parameters were explored in the EVPPI calculations: the parameters that would be generated directly by trial information (i.e. 1-year change in HbA_{1c} level for psychological intervention vs. usual care) and the parameters that would be generated directly by the trial and a long-term follow-up study (1-year HbA_{1c} level effects, the long-term trends in HbA_{1c} level post usual care, and the long-term trends in HbA_{1c} level post psychological intervention).

To quantify the overall scale of this uncertainty for the country, we need to consider the number of people affected. We assumed that every adult currently living with T1DM in the UK could potentially be affected by the decision as to whether or not they might benefit from a psychological intervention over a 10-year decision relevance time horizon. This means that ≈370,000 people[255] could be affected by the decision to have or not have a psychological intervention over the next 10 years in the UK.

Detailed methods on the School for Public Health Research Type 2 Diabetes Prevention Model

School for Public Health Research Type 2 Diabetes Prevention Model framework

The SPHR Diabetes Prevention Model was developed to forecast long-term health and health-care costs under alternative scenarios for diabetes prevention. A wide range of stakeholders were involved in its development, including clinicians, public health commissioners, diabetes and health economic researchers and members of the public with diabetes. A detailed description of the methodology and assumptions used in the model can be found elsewhere.[99,256] Here we present a summary of the model.

The model is an individual patient simulation model based on the evolution of personalised trajectories for metabolic factors including BMI, SBP, cholesterol and measures of blood glucose (including HbA_{1c}).

The usual baseline population consists of a representative sample of the English population obtained from the Health Survey for England, an annual survey that is designed to provide a snapshot of the nation's health.[257] Note that we discuss in a later section of this report how the population has been adapted to focus on a population of people already diagnosed with T2DM and treated (see *Baseline characteristics for people with type 2 diabetes mellitus modelled in this study*).

The model runs in annual cycles over a lifetime horizon. Individuals' BMI, cholesterol levels, SBP and HbA_{1c} level fluctuate from year to year, representing natural changes as they age and depending on personal characteristics such as gender, ethnicity and smoking status.

The evolution of these individual-level trajectories, apart from HbA_{1c} level, is based on a statistical analysis of the Whitehall II cohort[258,259] (see *Appendix 16*, *Tables 51–53*), a longitudinal data set of civil servants. Every year in the model, an individual may visit their general practitioner or undergo an opportunistic health check, and be diagnosed with and treated for hypertension, high cardiovascular risk or diabetes, depending on their personal characteristics.

The model simulates a three-stage treatment regimen for people with T2DM:

1. First-line treatment assumes the use of low-cost treatments such as metformin (Glucophage®; Bristol-Myers Squibb, Uxbridge, UK).
2. A second treatment [assumed to be sitagliptin (Januvia®; Merck, Sharp & Dohme Inc., Kenilworth, NJ, USA) for the costings] is added if HbA_{1c} levels rise above 8.48%, based on a recent study by Bennet *et al.*[260]
3. Initiation of insulin or triple therapy (third-stage treatment) occurs if HbA_{1c} level rises above 9.5%, which is the weighted average of the mean HbA_{1c} level when people switched to insulin (9.78%) and triple oral therapy (8.71%), from the same Bennett *et al.*[260] study.

Individuals with HbA_{1c} levels of $\geq$ 6.5% are at a risk of microvascular complications of diabetes, whether or not they are diagnosed with diabetes (see *Appendix 16*, *Tables 54* and *55*). The UK Prospective Diabetes Study (UKPDS)[261,262] outcomes model risk equations are used to model the annual risk of kidney disease, ulcer, amputation and blindness (see *Appendix 16*, *Table 56*).

For this diabetes treatment version of the model, we have updated the risk of cardiovascular events for people with diabetes to be based on UKPDS CVD risk equations.

All-cause mortality is based on life tables for England and Wales.[263]

Appendix 16 contains a detailed list of parameters and sources used in the model. These include cancer (see *Appendix 16*, *Tables 57* and *58*), osteoarthritis (see *Appendix 16*, *Table 59*), depression (see *Appendix 16*, *Table 60*) and associated utilities (see *Appendix 16*, *Table 61*) and unit health-care costs (see *Appendix 16*, *Table 62*).

Each condition is associated with a utility decrement and a cost.

The utility of each individual in each year of the model is dependent on their age, gender and medical conditions.

Costs are derived from published literature and inflated to 2015/16 GBP values using the hospital and community health services pay and prices index.[264] Costs for medications were obtained from the *British National Formulary*[265] and costs for health-care resource use were obtained from the Personal Social Services Research Unit (PSSRU) unit costs.[266]

The model perspective is that of the NHS and PSS.

Baseline characteristics for people with type 2 diabetes mellitus modelled in this study

The baseline characteristics are taken from recently published NICE guidelines (NG28)[267] for T2DM, in which the full health economics report (see appendix F of the guidelines[267]) undertook simulation modelling for groups of people who are at the first line, second line and third line of diabetes therapy. In appendix F of the NICE guideline,[267] section 3.3.3 (tables 20–28) sets out the methods for generating sampled patients in each of the three groups, which we have simply replicated for this study.

Some of the variables needed for the UKPDS outcomes model 2 risk equations were not present in these tables, such as triglycerides,[7] haemoglobin[262] and sets of other variables[268] (low-density lipoprotein, estimated glomerular filtration rate, heart rate, presence of micro- and macro-albuminuria and white blood cell count); therefore, we generated procedures to sample or impute these, based on NICE guidance.[267]

Incorporating short-term (1-year) clinical effectiveness evidence for patients with type 2 diabetes mellitus modelled in this study

In the main economic analysis, the effectiveness of the different psychological interventions was sourced from the NMA shown *Table 15*. The main estimates are presented in *Appendix 16*, *Table 64*.

The estimate for the effect of CBT versus usual care is –0.234 (95% CI –0.372 to –0.096). The estimate for the effect of counselling versus usual care is –0.132 (95% CI –0.23 to –0.033). These effects are somewhat smaller than the equivalents for T1DM. The full variance–covariance matrices used for the PSA on mean effects are presented in *Appendix 16*, *Table 63*.

For each individual, the mean psychological intervention effect and their baseline HbA_{1c} level were used to generate the HbA_{1c} levels at 1 year (see *Appendix 16*, *Table 65*). In the T2DM model, we do not capture heterogeneity of response to the psychological intervention because there was an absence of evidence available from the NMA or other sources regarding this.

Incorporating longer-term clinical effectiveness evidence for type 2 diabetes mellitus

There is an absence of any T2DM long-term psychological intervention follow-up studies analogous to the Ridge *et al.*[251] study we used for T1DM. Therefore, we used the same conditional distribution for the trajectory, conditional on the initial fall that we obtained from Ridge *et al.*[251] (see *Appendix 16*, *Tables 66* and *67*).

This enabled us to sample trajectories for CBT and for counselling in T2DM. The resulting mean trajectories are shown in *Appendix 16*, *Tables 66* and *67*.

Costing psychological interventions for adults with type 2 diabetes mellitus

The cost of psychological interventions was calculated, based on the information from the trials and studies from the systematic reviews (see *Chapter 4* for included studies). The references were examined in detail to extract information on the main elements of cost, which are:

- costs of staff time to deliver the intervention
- session-related non-contact staff time
- cost of consumables per session
- costs associated with training the staff who will deliver psychological interventions
- costs associated with supervision of staff
- proportion of sessions that are individual based versus group based
- number of course participants in group sessions.

These are broadly split into two categories: those types of resource use/cost that are assumed to be the same across interventions and those that are different. The following categories are assumed to be the same across interventions: the interventionists, the session-related non-contact time (either as a ratio of contact time or as an absolute value), the cost of consumables and the training costs (see *Appendix 16*, *Tables 73* and *74*). The following categories are assumed to be different: the split between individual and group sessions, the average number of people in a group session, the number of sessions and the duration of each session.

For T2DM, the estimated cost per participant of delivering the interventions is estimated to be as follows:

- The cost of the CBT intervention is £633.20 per participant.
- The cost of counselling intervention is £940.02 per participant.

Note that the cost of counselling for T2DM is somewhat higher than the equivalent cost of counselling for T1DM (see *Appendix 16*, *Tables 71* and *72*); the main reason for that is a larger number of sessions per participant (≈11 for T2DM compared with ≈7 for T1DM, in the studies from the systematic review) (*Table 20*).

TABLE 20 Key model parameters for SPHR Type 2 Diabetes Prevention Model applied to psychological interventions for adults with T2DM

Parameter	Value(s) (95% CI)	Source/calculation
Cost of CBT per participant	£633.20	This study (see *Appendix 16*, *Table 75*)
Cost of counselling per participant	£940.02	This study (see *Appendix 16*, *Table 75*)
Mean reduction in HbA_{1c} level in first year, CBT versus usual care (%)	–0.234 (–0.372 to –0.096)	*Chapter 5* of this study. See *Appendix 16*, *Figure 28*, for variance–covariance matrix
Mean reduction in HbA_{1c} level in first year, counselling versus usual care (%)	–0.132 (–0.23 to –0.033)	*Chapter 5* of this study
Long-term trajectory of HbA_{1c} levels post 12 months after CBT: annual change in % HbA_{1c} level versus usual care (%)	–0.063 (–0.257 to 0.130)[a]	Ridge *et al.*[251] and further analysis based on distribution for trajectory, conditional on initial fall
Long-term trajectory of HbA_{1c} levels post 12 months after counselling: annual change in % HbA_{1c} level versus usual care (%)	–0.043 (–0.299 to 0.213)[a]	Ridge *et al.*[251] and further analysis based on distribution for trajectory, conditional on initial fall

a When a PSA run samples a negative trajectory versus usual care (i.e. a persistently widening gap over the long term), we have modelled maintenance of the initial treatment gap, rather than assuming that a psychological intervention can generate a wider gap at year 10 or 20 than it has at year 4. This was partially because the psychological intervention in Ridge *et al.*[251] was just a 1-year intervention (i.e. no further active psychological intervention was provided after year 1).

All costs were adjusted to 2015/6 prices using the hospital and community health services pay and prices index.[264] A summary of the costs is given in *Appendix 16*, *Tables 68–70*, and details of the methods and costs can be found in *Appendix 16*, *Tables 76* and *77*.

Usual care costs presented in the studies included in the systematic review were in the context of either the intervention being an enhancement to usual care or the usual care contacts being related to protocol requirements (e.g. collection of blood samples at baseline). Therefore, it was assumed that there were no additional costs associated with usual care.

Methods to analyse decision uncertainty in the type 2 diabetes mellitus model using expected value of perfect parameter information

The methods for this are broadly the same as those described for T1DM in *Methods to analyse decision uncertainty in type 1 diabetes model using expected value of perfect parameter information*.

Uncertainty is analysed using expected value of information statistics. The first is the overall EVPI, which calculates how valuable it would be to a decision-maker (e.g. NICE) to eliminate all uncertainty on all the model parameters (i.e. CIs do not exist, as every parameter is certainly known). The second is the EVPPI, which is the same idea but focused on particular model parameters only (i.e. only a defined subset of model parameters are certainly known; the rest are still uncertain).

The expected value of information calculations were estimated efficiently using a recently developed online tool called SAVI[254] at a maximum acceptable ICER of £20,000 per QALY gained, in line with NICE decision-making thresholds.

Two subsets of parameters were explored in the EVPPI calculations: the parameters that would be generated directly by trial information (i.e. 1-year change in HbA_{1c} levels for psychological intervention vs. usual care) and the parameters that would be generated directly by the trial and a long-term follow-up study (1-year HbA_{1c} level effects, the long-term trends in HbA_{1c} levels post usual care and the long-term trends in HbA_{1c} levels post psychological intervention).

To quantify the overall scale of this uncertainty for the country, we need to consider the number of people affected. In the NICE guidelines,[267] appendix F reported the number of people at first intensification as 17,871, those at second intensification as 14,069 and those at third intensification as 4462, from the The Health Improvement Network (THIN) database. In 2016, Public Health England reported[269] that 3.8 million people in England have diabetes, of whom 90% are estimated to have T2DM, that is 3,420,000 people. It is estimated that 1 in 4 people are unaware of their condition. This means that approximately 2,565,000 people are aware and undergoing treatment.

We used the above information to estimate that:

- The number of adults with T2DM who are currently at the first-line therapy stage (i.e. people treated with diet and lifestyle advice plus metformin) is 1,259,000.
- The number of adults with T2DM who are currently at the second-line therapy stage (i.e. people treated with metformin plus another oral agent) is 991,000.
- The number of adults with T2DM who are currently at the third-line therapy stage (i.e. people on combination triple oral therapy or insulin) is 314,000.

We have assumed that all of these adults could potentially be affected by the decision as to whether or not they might benefit from a psychological intervention over a 10-year decision relevance time horizon.

Main health economic analysis results for adults with type 1 diabetes mellitus

Table 21 shows the mean cost-effectiveness of psychological interventions for adults with T1DM. The main findings are as follows:

- The CBT strategy is marginally less costly over a lifetime than both the counselling strategy and the usual care strategy. Counselling is marginally more costly than the usual care strategy.
- The CBT strategy is estimated to provide more QALYs over a lifetime than the counselling strategy, which in turn is estimated to provide more QALYs than the usual care strategy.
- The CBT strategy is, therefore, the most cost-effective of the three strategies.
- The counselling strategy is estimated to be more cost-effective than usual care, with an ICER of £3800 per QALY gained, below the typical thresholds of £20,000 per QALY used by NICE.

Analysis of uncertainty for adults with T1DM

All of these results are subject to substantial uncertainty (shown in the next section) because there is uncertainty about both the 1-year HbA_{1c} level reduction effectiveness of each of the strategies, and because there is uncertainty about the long-term maintenance of the effects.

Figure 25 shows the results of the PSA. The results in *Figure 25a* show that, although the average of the PSA runs shows that we expect CBT to be more cost-effective than usual care (because the central dark blue dot is below the diagonal line that indicates the cost-effectiveness threshold of £20,000 per QALY gained), there is substantial uncertainty and CBT could be less cost-effective. Similar pictures are shown for *Figure 25b* and *c*. The cost-effectiveness acceptability curve (CEAC) shown in *Figure 25d* demonstrates that the probability that CBT is the most cost-effective of the three strategies is 64.6%.

TABLE 21 The mean health economic results for adults with T1DM based on 500 PSA runs: per person lifetime discounted

Outcomes	Usual care	Counselling	CBT
Lifetime discounted cost of strategy (£)	70,258	70,365	68,505
Incremental cost versus usual care (£)		106	–1754
Lifetime discounted QALYs	12.268	12.2959	12.3735
Incremental QALY versus usual care	–	0.0279	0.1055
Net monetary benefit of strategy (QALYs × £20,000 – cost) (£)	175,102	175,553	178,307
Incremental net monetary benefit versus usual care (£)	–	452	3205
Net benefit on QALY scale (QALYs – cost/£20,000)	8.7551	8.7777	8.9154
Incremental net benefit on QALY scale versus usual care	–	0.022591	0.1602725
ICER	Dominated by CBT	Dominated by CBT	Dominant
Stability of model results	Average	Standard error	Probability negative[a]
Incremental net monetary benefit of CBT versus the most cost-effective option out of counselling or usual care in each PSA run at			
£20,000 per QALY gained	£911	£269	0.0004
£30,000 per QALY gained	£1249	£342	0.0001

a A negative value implies that a different strategy would be the most cost-effective strategy, on average.

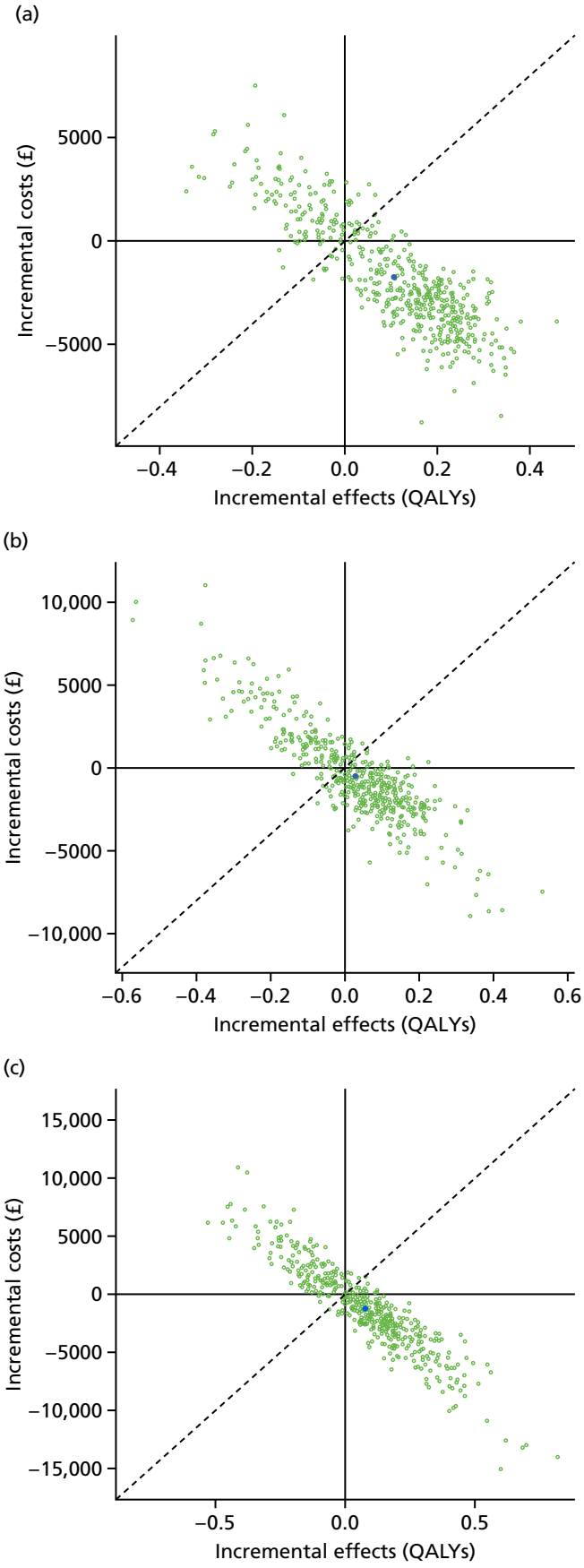


FIGURE 25 Analysis of the uncertainty in cost-effectiveness for adults with T1DM. (a) CBT vs. usual care; (b) counselling vs. usual care; (c) CBT vs. counselling; and (d) the cost-effectiveness acceptability curve for CBT vs. usual care. (*continued*)

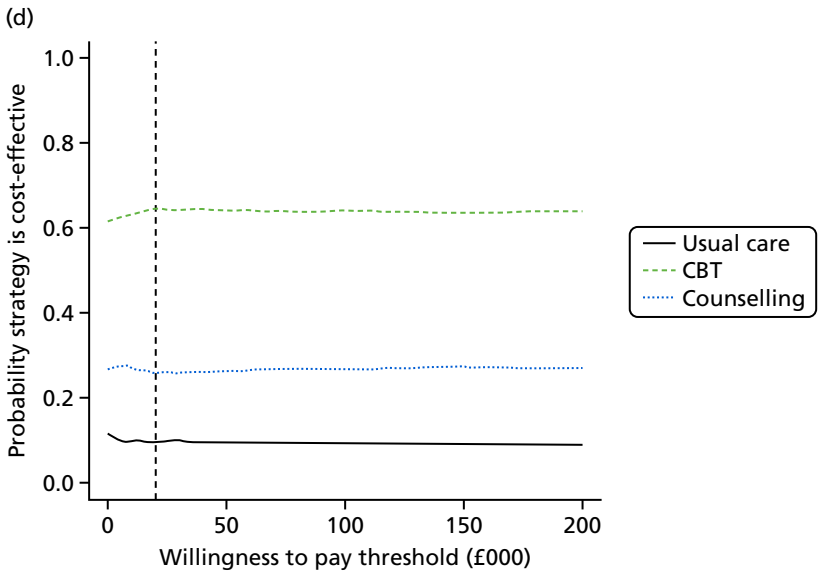
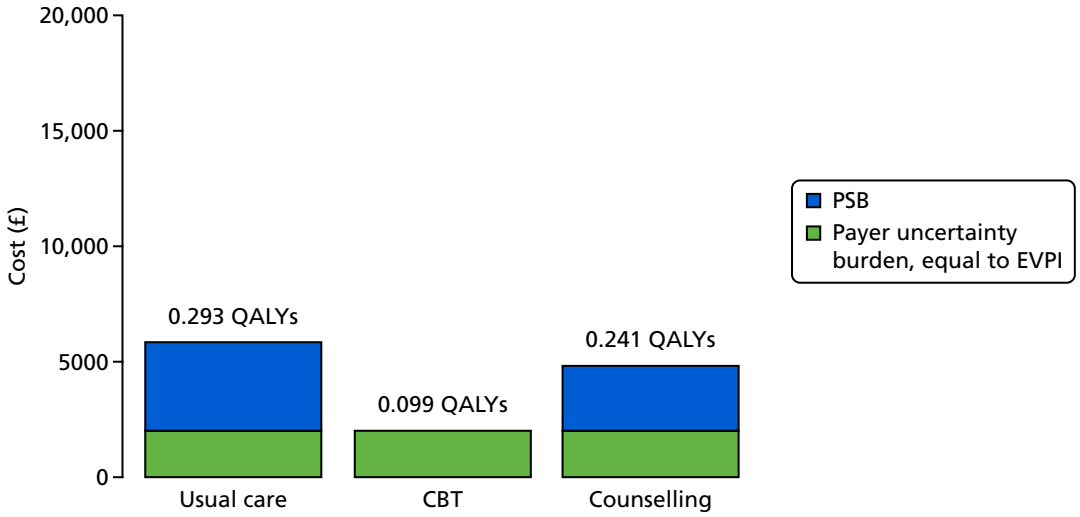


FIGURE 25 Analysis of the uncertainty in cost-effectiveness for adults with T1DM. (a) CBT vs. usual care; (b) counselling vs. usual care; (c) CBT vs. counselling; and (d) the cost-effectiveness acceptability curve for CBT vs. usual care.

The overall EVPI is estimated at £1989 per person, which is equivalent to 0.0995-worth of uncertainty per person affected by the decision between CBT, counselling and usual care. We can multiply this up by the estimated 370,000 people with T1DM in the UK, and assuming that, say, 10% of these people might be affected by the decision per year over a decision relevance horizon of 10 years, the decision uncertainty is estimated to be valued at £73.6M per annum or £735.9M over the 10 years. This would be equivalent to 36,790 QALYs-worth of uncertainty.

Figure 26 shows a new way of visualising the decision uncertainty called the HTA risk analysis chart,[270] which is generated automatically from the PSA results by the online SAVI tool. The HTA risk analysis chart is a method for conveying the uncertainty associated with the decision problem (the green element) as well as the differences in cost-effectiveness measured using the net monetary benefit between the strategies (the blue element) in a single, simple plot. The green bars represent the overall EVPI (also known as the payer uncertainty burden in the risk analysis chart method). They are the same height for each intervention because the payer uncertainty burden is the risk relating to uncertainty associated with the whole decision problem rather than any specific decision strategy. The overall EVPI is £1989 per person affected by the decision, which, at a maximum acceptable ICER of £20,000, is equivalent to 0.0995 QALYs-worth of decision uncertainty per person (*Table 22*). The payer strategy-specific burden (PSB) is represented by the blue bars stacked on top of the payer uncertainty burden. The PSB is the difference in cost-effectiveness measured using the net monetary benefit between each strategy and the most cost-effective strategy. The most cost-effective intervention, CBT, has a PSB of zero (a blue element of zero).

Given current costs and evidence, both usual care and counselling are less cost-effective than CBT, which is indicated by their respective PSBs of £3862 and £2831 per person (equivalent to 0.1931 QALYs for usual care and 0.1416 QALYs for counselling). The sum of the uncertainty burden and the payer strategy-specific risk burden is shown on the cost scale on the *y*-axis (£5851 and £4820 respectively) and on the QALY scale above each bar (0.293 and 0.241 QALYs, respectively). Shown below the graph, for the affected patient population per annum, are the overall EVPI (£73.6M) and the PSBs for usual care (£142.9M) and for counselling (£104.8M). This enables cross-comparison between decision problems in terms of the national scale of risk involved. Interpretation of the implications of the HTA risk analysis chart is straightforward. If there is a substantial PSB (a large blue component for an intervention), this suggests that the intervention would need to be cheaper, more cost-saving or more effective for it to be considered cost-effective. If there is a large payer uncertainty burden (a large green component to each bar), this means that there is substantial uncertainty in model parameters based on current evidence, and suggests further evidence collection could help reduce decision uncertainty.



Population-level burdens: 37,000 people affected by decision per annum in jurisdiction

Population payer uncertainty burden per annum (EVPI) = £73.59M (3679.46 QALYs-worth of uncertainty per annum)

Population PSBs for each strategy:
Population PSB = £142.90M (7144.85 QALYs) for usual care
Population PSB = £0.00M (0.00 QALYs) for CBT
Population PSB = £104.76M (5237.94 QALYs) for counselling

FIGURE 26 The HTA risk analysis chart for the health technology assessment of CBT, counselling and usual care for adults with T1DM in the UK.

TABLE 22 For adults with T1DM, which parameters most affect the decision uncertainty and are, therefore, the highest priorities for further evidence collection?

Parameter(s)	EVPPI per person (£)	SE of EVPPI estimate	EVPPI indexed to EVPI (EVPI = 1.00)
All parameters	1989	–	1.00
110. CBT 1-year HbA_{1c} effect (HbA_{1c}_drop_CBT)	53	29	0.03
111. Counselling 1-year HbA_{1c} effect (HbA_{1c}_drop_Cou)	184	63	0.09
112. CBT longer-term HbA_{1c} effect (Traj_CBT)	1143	114	0.57
113. Counselling longer-term HbA_{1c} effect (Traj_COU)	145	101	0.07
110 and 112	1149	99	0.58
111 and 113	566	93	0.28
110, 111, 112 and 113	1752	56	0.88

SE, standard error.

The EVPPI analysis allows us to understand which are the most uncertain parameters driving decision uncertainty and, therefore, which might be the highest priorities for further evidence collection. The results show that four main parameters are the key drivers of uncertainty. It is partly the 1-year effectiveness that is a key driver – for both CBT and counselling. The single most uncertain and important parameter is the long-term effectiveness of CBT. The long-term effectiveness of counselling is also important to decision uncertainty. Together, these four parameters represent 88% of the overall decision uncertainty (EVPPI = 0.88 when overall EVPI is indexed to 1.00).

Conclusions on the cost-effectiveness of cognitive–behavioural therapy versus counselling versus usual care in adults with type 1 diabetes mellitus

The results of these analyses suggest the following conclusions:

- CBT could be considered a cost-effective psychological intervention compared with usual care and compared with counselling.
- Counselling appears to be more cost-effective than usual care but less cost-effective than CBT.
- There is substantial decision uncertainty around these conclusions and priorities for further evidence collection would, in particular, focus on the longer-term (i.e. beyond 12 months) maintenance of effectiveness compared with usual care. In other words, is the HbA_{1c} level gap between CBT and usual care maintained beyond year 1, and, if not, how quickly does the effect wane and the HbA_{1c} level return to what it would have been without the psychological intervention?
- We have not been able to analyse subgroups of patients, either by baseline HbA_{1c} level or by those who might respond more or less well than average to psychological interventions, because the NMA could not provide effectiveness evidence on such subgroups.

Results for the cost-effectiveness of cognitive–behavioural therapy versus counselling versus psychotherapy versus usual care in adults with type 2 diabetes mellitus

Main health economic analysis results for adults with type 2 diabetes mellitus

Table 23 shows the mean cost-effectiveness results for adults with T2DM. It is split into three parts: (1) patients receiving first-line treatment (i.e. people treated with diet and lifestyle advice plus metformin), (2) patients receiving second-line treatment (i.e. people treated with metformin plus another oral agent) and (3) patients receiving third-line treatment (i.e. people treated with combination triple oral therapy or on insulin).

The main findings for patients receiving first-line treatment are as follows:

- The CBT strategy is marginally less costly over a lifetime than the counselling strategy, which in turn is marginally more costly than the usual care strategy.
- The CBT strategy is estimated to provide more QALYs over a lifetime than the counselling strategy, which in turn is estimated to provide more QALYs than the usual care strategy.
- The CBT strategy is the most cost-effective of the three strategies as it has an ICER of £11,135 per QALY gained, compared with usual care.
- The counselling strategy is estimated to be more cost-effective than usual care.

The main findings for patients receiving second-line treatment are as follows:

- The CBT strategy is marginally less costly over a lifetime than the counselling strategy, which in turn is marginally more costly than the usual care strategy.
- The CBT strategy is estimated to provide more QALYs over a lifetime than the counselling strategy, which in turn is estimated to provide more QALYs than the usual care strategy.
- The CBT strategy is the most cost-effective of the three strategies.
- The counselling strategy is estimated to be more cost-effective than usual care.

The main findings for patients receiving third-line treatment are as follows:

- The CBT strategy is marginally less costly over a lifetime than the counselling strategy, which in turn is marginally more costly than the usual care strategy.
- The CBT strategy is estimated to provide more QALYs over a lifetime than the counselling strategy, which in turn is estimated to provide more QALYs than the usual care strategy.
- The CBT strategy is, therefore, the most cost-effective of the three strategies using a maximum acceptable ICER of £30,000 per QALY gained, but not at £20,000 per QALY gained.
- The counselling strategy is estimated to be less cost-effective than usual care at both maximum acceptable ICER values.

TABLE 23 Mean health economic analysis results for adults with T2DM based on 100 PSA runs, per person lifetime discounted

Outcomes	Usual care	Counselling	CBT
(Part 1) Patients receiving first-line treatment (i.e. people treated with diet and lifestyle advice plus metformin)			
Lifetime discounted cost (£)	36,857	37,581	37,013
Lifetime discounted QALYs	8.7002	8.7059	8.7142
Incremental cost (£)	–	–	156
Incremental QALYs	–	–	0.0140
ICER		Dominated by CBT	£11,135
Net monetary benefit (£)	137,147	136,538	137,271
Net benefit on QALY scale	6.8574	6.8269	6.8635
(Part 2) Patients receiving second-line treatment (i.e. people treated with metformin plus another oral agent)			
Lifetime discounted cost (£)	31,582	32,353	31,861
Lifetime discounted QALYs	8.9253	8.9304	8.9398
Incremental cost (£)	–	–	279
Incremental QALYs	–	–	0.0145
ICER	–	Dominated by CBT	£19,246
Net monetary benefit (£)	146,923	146,255	146,935
Net benefit on QALY scale	7.3462	7.3127	7.3468
(Part 3) Patients receiving third-line treatment (i.e. people on combination triple oral therapy or insulin)			
Lifetime discounted cost (£)	43,526	44,479	44,195
Lifetime discounted QALYs	7.6199	7.6344	7.6531
Incremental cost (£)	–	–	£669
Incremental QALYs	–	–	0.0332
ICER	–	Dominated by CBT	£20,163
Net monetary benefit (£)	108,873	108,210	108,868
Net benefit on QALY scale	5.4437	5.4105	5.4434

All of these results are subject to substantial uncertainty (shown in the next section) because there is uncertainty about both the 1-year HbA_{1c} reduction effectiveness of each of the strategies, and because there is uncertainty about the long-term maintenance of the effects.

Analysis of uncertainty of the results for adults with type 2 diabetes mellitus

Figure 27 shows the results of the PSA.

The results for people on first-line therapies (see *Figure 27a–d*) show that, although the average of the PSA runs shows in *Figure 27a* that we expect CBT to be more cost-effective than usual care (because the central dark blue dot is below the diagonal line that indicates the cost-effectiveness threshold of £20,000 per QALY gained), there is substantial uncertainty, and CBT could be less cost-effective. Similar pictures are shown for *Figure 27b* and *c*. The CEAC shown in *Figure 27d* demonstrates that the probability that CBT is the most cost-effective of the three strategies is 43%.

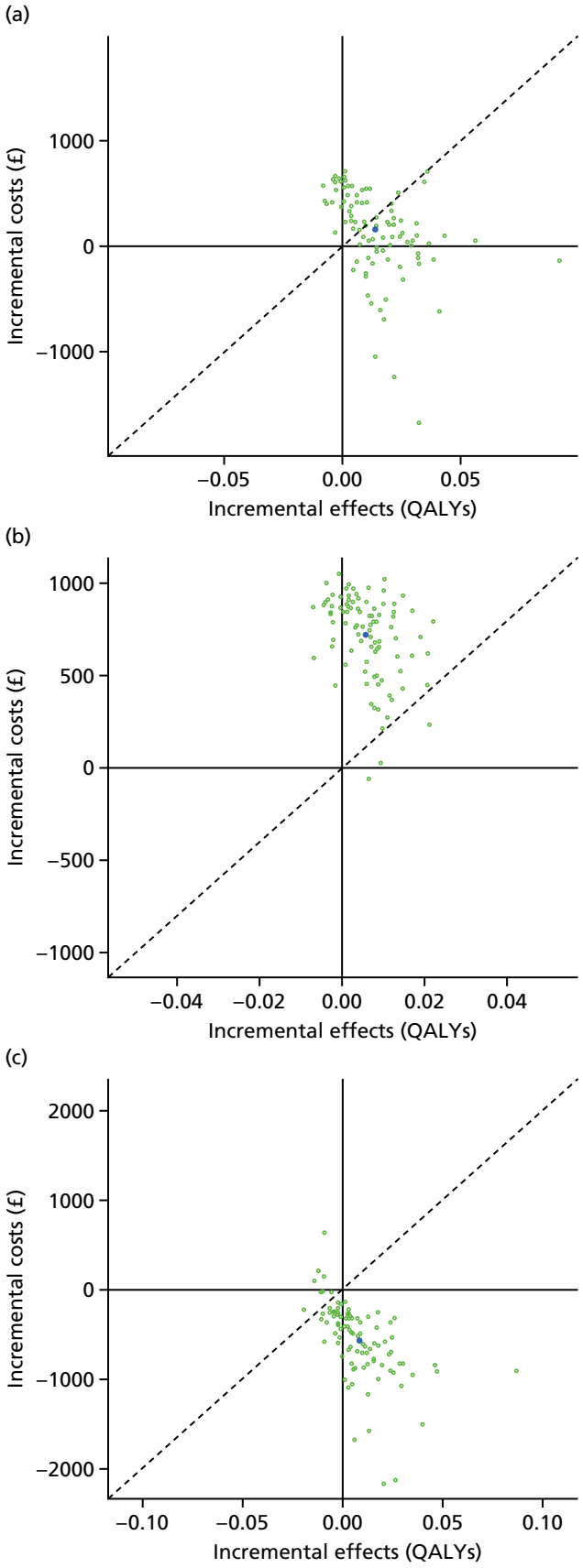


FIGURE 27 Analysis of uncertainty in cost-effectiveness results for adults with T2DM. (a) CBT vs. usual care (first line); (b) counselling vs. usual care (first line); (c) CBT vs. counselling (first line); (d) CEAC (first line); (e) CBT vs. usual care (second line); (f) counselling vs. usual care (second line); (g) CBT vs. counselling (second line); (h) CEAC (second line); (i) CBT vs. usual care (third line); (j) counselling vs. usual care (third line); (k) CBT vs. counselling (third line); and (l) CEAC (third line). (*continued*)

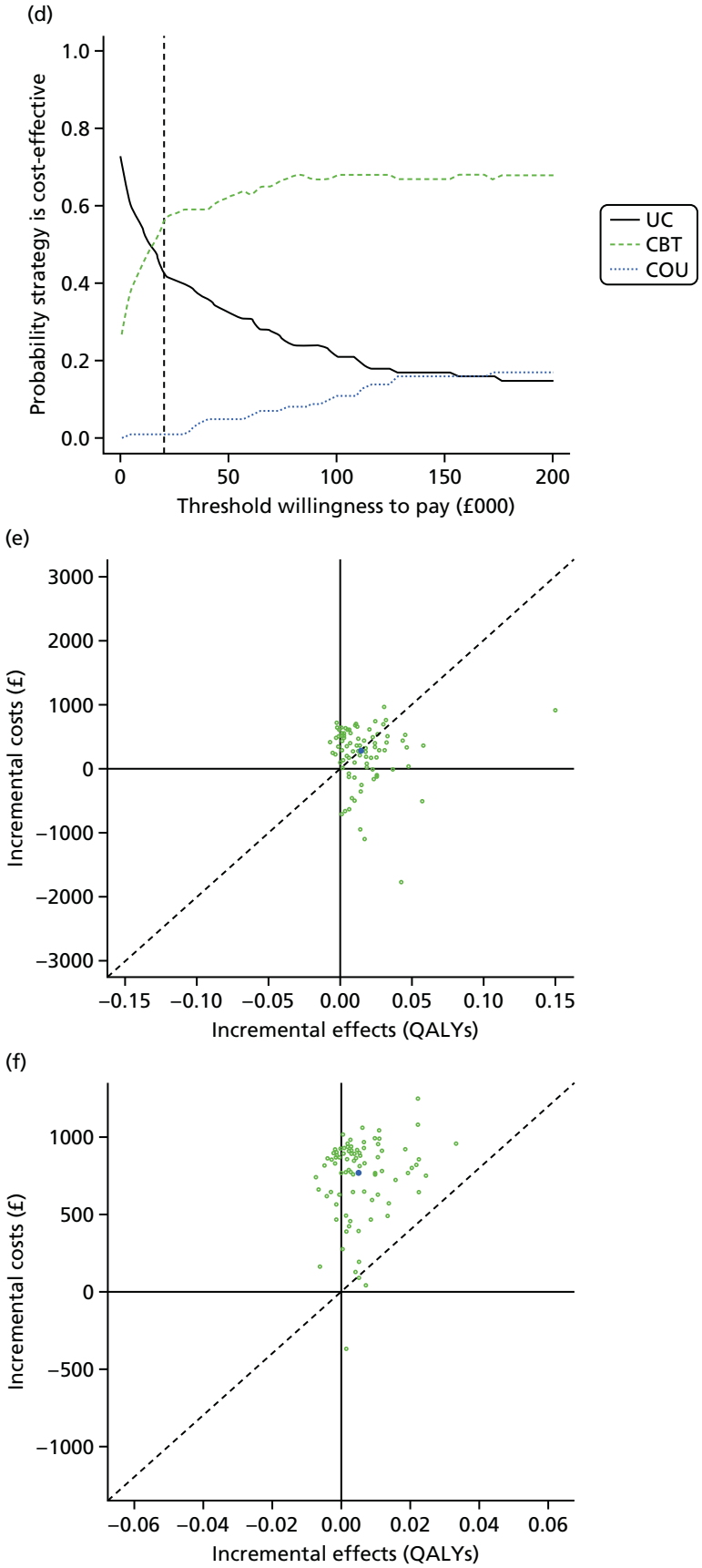


FIGURE 27 Analysis of uncertainty in cost-effectiveness results for adults with T2DM. (a) CBT vs. usual care (first line); (b) counselling vs. usual care (first line); (c) CBT vs. counselling (first line); (d) CEAC (first line); (e) CBT vs. usual care (second line); (f) counselling vs. usual care (second line); (g) CBT vs. counselling (second line); (h) CEAC (second line); (i) CBT vs. usual care (third line); (j) counselling vs. usual care (third line); (k) CBT vs. counselling (third line); and (l) CEAC (third line). (*continued*)

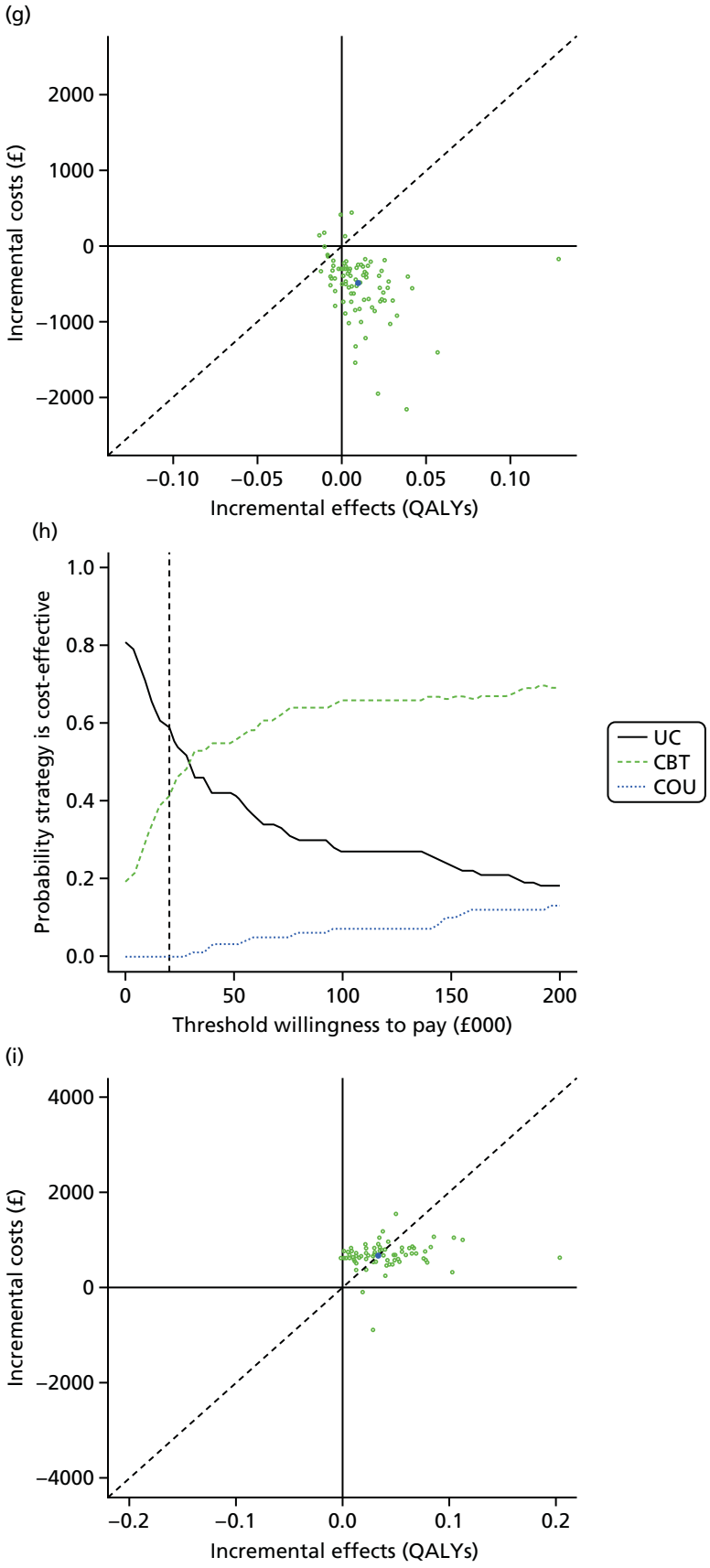


FIGURE 27 Analysis of uncertainty in cost-effectiveness results for adults with T2DM. (a) CBT vs. usual care (first line); (b) counselling vs. usual care (first line); (c) CBT vs. counselling (first line); (d) CEAC (first line); (e) CBT vs. usual care (second line); (f) counselling vs. usual care (second line); (g) CBT vs. counselling (second line); (h) CEAC (second line); (i) CBT vs. usual care (third line); (j) counselling vs. usual care (third line); (k) CBT vs. counselling (third line); and (l) CEAC (third line). (*continued*)

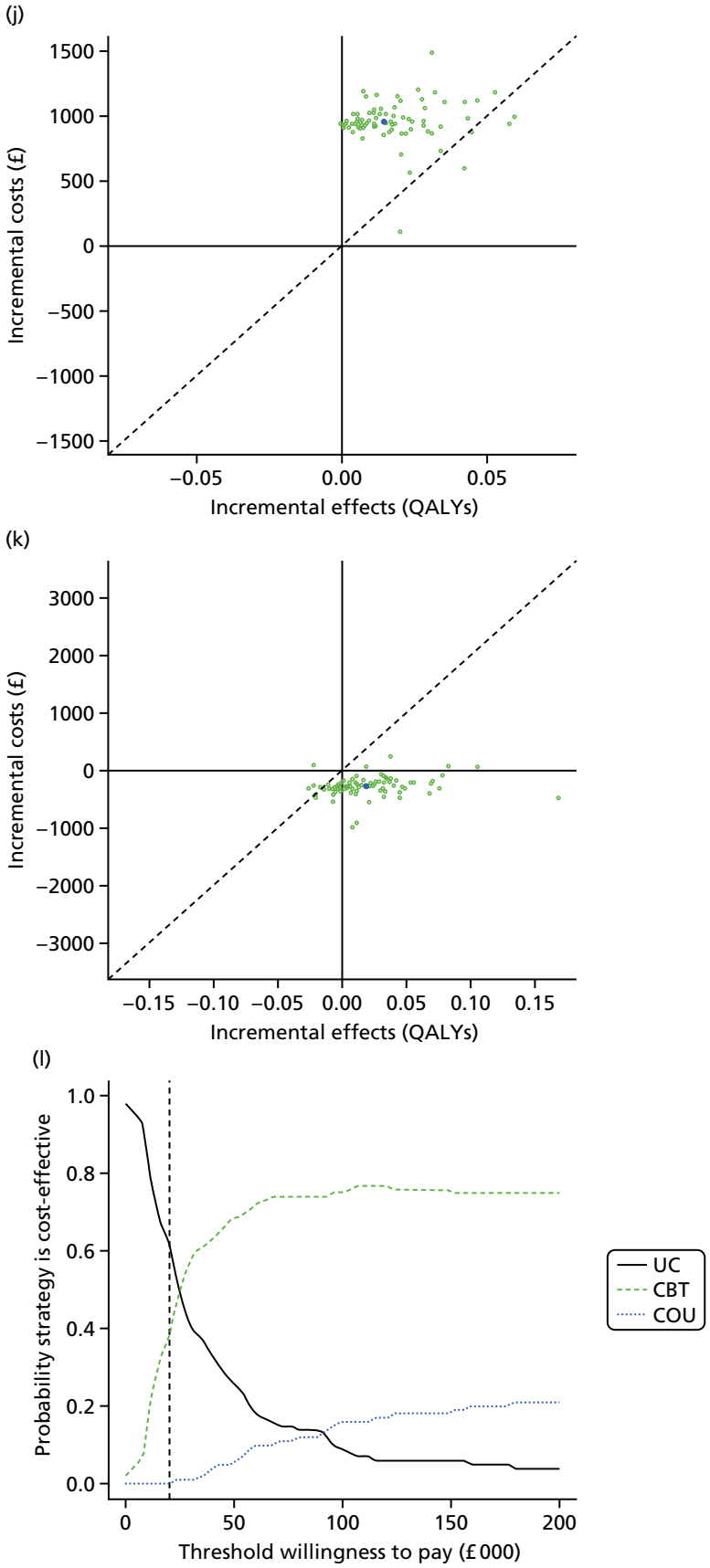


FIGURE 27 Analysis of uncertainty in cost-effectiveness results for adults with T2DM. (a) CBT vs. usual care (first line); (b) counselling vs. usual care (first line); (c) CBT vs. counselling (first line); (d) CEAC (first line); (e) CBT vs. usual care (second line); (f) counselling vs. usual care (second line); (g) CBT vs. counselling (second line); (h) CEAC (second line); (i) CBT vs. usual care (third line); (j) counselling vs. usual care (third line); (k) CBT vs. counselling (third line); and (l) CEAC (third line).

The results for people on second-line therapies show (see *Figure 27e–h*) that, although the average of the PSA runs shows in *Figure 27e* that we expect CBT to be more cost-effective than usual care (because the central dark blue dot is just below the diagonal line that indicates the cost-effectiveness threshold of £20,000 per QALY gained), there is substantial uncertainty, and CBT could be less cost-effective. Similar pictures are shown for *Figure 27f* and *g*. The CEAC shown in *Figure 27h* demonstrates that the probability that CBT is the most cost-effective of the three strategies is 41%.

The results for people on third-line therapies show (see *Figure 27i–l*) that, although the average of the PSA runs shows in *Figure 27i* that we expect CBT to be just less cost-effective than usual care (because the central dark blue dot is just above the diagonal line that indicates the cost-effectiveness threshold of £20,000 per QALY gained), there is substantial uncertainty, and CBT could be more cost-effective. Similar pictures are shown for *Figure 27j* and *k*. The CEAC shown in *Figure 27l* demonstrates that the probability that CBT is the most cost-effective of the three strategies is 37%.

Figure 28 shows the HTA risk analysis charts[270] for patients on first-, second- and third-line therapies, separately. The green bars represent the overall EVPI (also known as the payer uncertainty burden in the risk analysis chart method). The PSB is represented by the blue bars stacked on top of the payer uncertainty burden. The PSB is the difference in cost-effectiveness measured using net monetary benefit between each strategy and the most cost-effective strategy. Interpretation of the implications of the HTA risk analysis chart are straightforward. If there is a substantial PSB (a large red component for an intervention), this suggests that the intervention would need to be cheaper or more cost saving or more effective for it to be considered cost-effective. If there is a large payer uncertainty burden (a large blue component to each bar), then this means that there is substantial uncertainty in model parameters based on current evidence, and suggests further evidence collection could help reduce decision uncertainty.

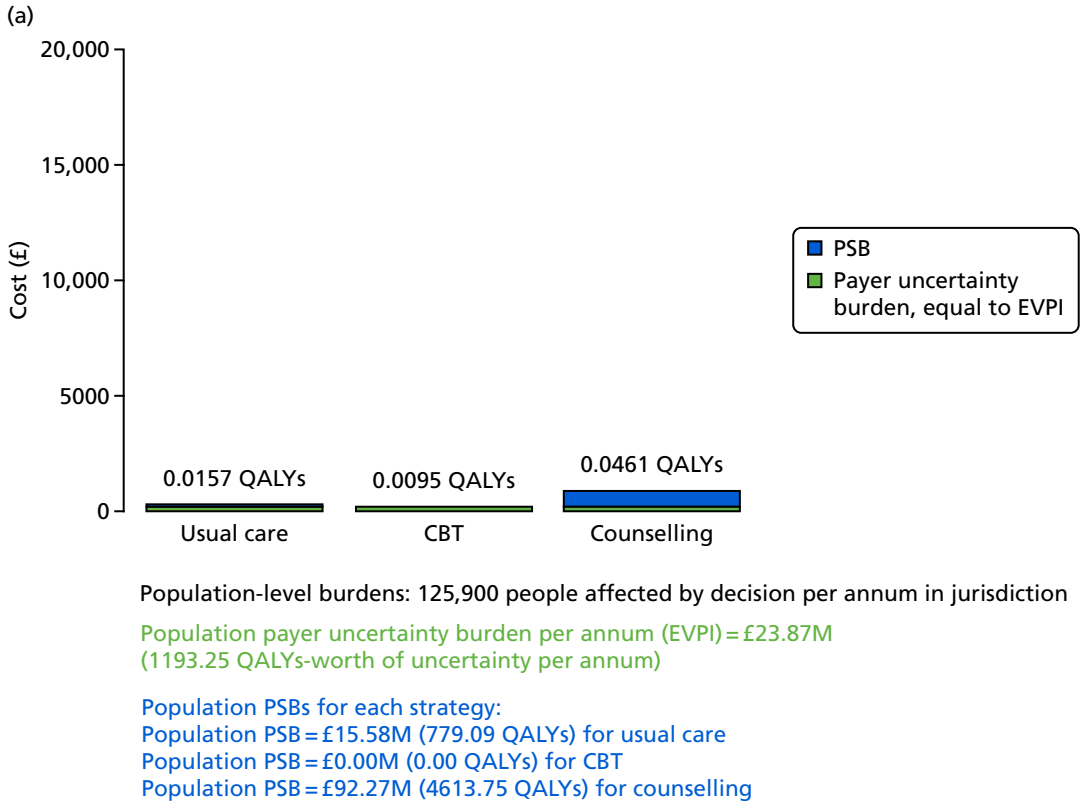
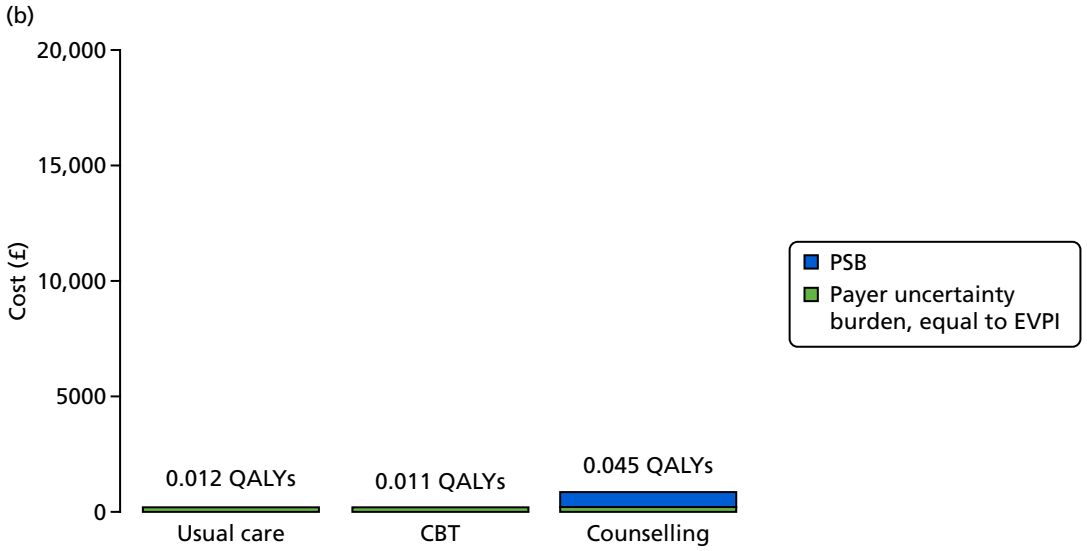


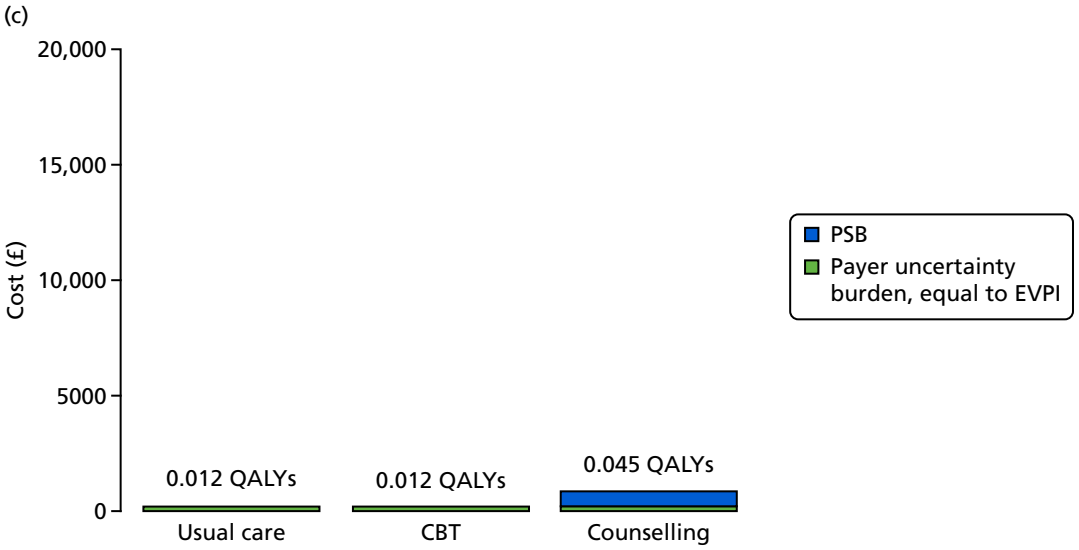
FIGURE 28 The HTA risk analysis charts for health technology assessment of CBT, counselling and usual care for adults with T2DM in the UK. (a) First line; (b) second line; and (c) third line. (*continued*)



Population-level burdens: 99,100 people affected by decision per annum in jurisdiction

Population payer uncertainty burden per annum (EVPI) = £22.40M (1120.06 QALYs-worth of uncertainty per annum)

Population PSBs for each strategy:
Population PSB = £1.21M (60.36 QALYs) for usual care
Population PSB = £0.00M (0.00 QALYs) for CBT
Population PSB = £67.47M (3373.60 QALYs) for counselling



Population-level burdens: 31,400 people affected by decision per annum in jurisdiction

Population payer uncertainty burden per annum (EVPI) = £7.37M (368.27 QALYs-worth of uncertainty per annum)

Population PSBs for each strategy:
Population PSB = £0.00M (0.00 QALYs) for usual care
Population PSB = £0.17M (8.62 QALYs) for CBT
Population PSB = £20.82M (1041.06 QALYs) for counselling

FIGURE 28 The HTA risk analysis charts for health technology assessment of CBT, counselling and usual care for adults with T2DM in the UK. (a) First line; (b) second line; and (c) third line.

In *Figure 28a*, results for people on first-line therapies show that the overall EVPI is estimated to be £189.60 per person, which is equivalent to 0.01 QALYs-worth of uncertainty per person affected by the decision between CBT, counselling and usual care. When multiplied by the estimated 1,259,000 people with T2DM in the UK who are receiving first-line therapy, decision uncertainty is estimated to be valued at £23.9M per annum or £238.7M over 10 years (equivalent to 11,930 QALYs-worth of uncertainty). Given current costs and evidence, both usual care and counselling are less cost-effective than CBT, which is indicated by their respective PSBs of £124 and £733 per person (equivalent to 0.0062 QALYs for usual care and 0.0366 QALYs for counselling). Shown at the bottom of *Figure 28*, for the affected patient population per annum, are the PSBs for usual care (£15.6M) and for counselling (£92.3M).

In *Figure 28b*, results for people on second-line therapies show that the overall EVPI is estimated to be £226 per person, which is equivalent to 0.01 QALYs-worth of uncertainty per person affected by the decision between CBT, counselling and usual care. When multiplied by the estimated 991,000 people with T2DM in the UK who are receiving second-line therapy, decision uncertainty is estimated to be valued at £22.4M per annum or £224M over 10 years (equivalent to 11,200 QALYs-worth of uncertainty). Given current costs and evidence, both usual care and counselling are less cost-effective than CBT, which is indicated by their respective PSBs of £12 and £681 per person (equivalent to 0.0006 QALYs for usual care and 0.0340 QALYs for counselling). Shown at the bottom of *Figure 28*, for the affected patient population per annum, are the PSBs for usual care (£1.2M) and for counselling (£67.5M).

In *Figure 28c*, results for people on third-line therapies show that the overall EVPI is estimated to be £234.60 per person, which is equivalent to 0.01 QALYs-worth of uncertainty per person affected by the decision between CBT, counselling and usual care. When multiplied by the estimated 314,000 people with T2DM in the UK who are receiving third-line therapy, decision uncertainty is estimated to be valued at £7.4M per annum or £74M over 10 years (equivalent to 3683 QALYs-worth of uncertainty). Given current costs and evidence, usual care is just slightly more cost-effective than CBT, and both are much more cost-effective than counselling, which is indicated by the PSBs of £5 and £663 per person for CBT and counselling, respectively (equivalent to 0.0003 QALYs for CBT and 0.0332 QALYs for counselling). Shown at the bottom of *Figure 28*, for the affected patient population per annum, are the PSBs for CBT (£0.2M) and for counselling (£20.8M).

The EVPPI analysis allows us to understand which are the most uncertain parameters driving decision uncertainty and, therefore, which might be the highest priorities for further evidence collection. The results for each of the first-, second- and third-line therapy analyses show that four main parameters are the key drivers of uncertainty (*Table 24*). It is partly the 1-year effectiveness that is a key driver, for both CBT and counselling. The single most uncertain and important parameter is the long-term effectiveness of CBT. The long-term effectiveness of counselling is also important to decision uncertainty.

The results for people on first-line therapies show that it is the 1-year effectiveness that is a key driver, for both CBT (indexed EVPPI = 0.75) and counselling, with counselling much less important to decision uncertainty (indexed EVPPI = 0). The long-term effectiveness of CBT has an indexed EVPPI of 0.25. The long-term effectiveness of counselling is also important (indexed EVPPI = 0).

The results for people on second-line therapies show that it is the 1-year effectiveness that is a key driver – for both CBT (indexed EVPPI = 0.64) and counselling, with counselling much less important to decision uncertainty (indexed EVPPI = 0). The long-term effectiveness of CBT has an indexed EVPPI of 0.25. The long-term effectiveness of counselling is also important (indexed EVPPI = 0.06).

The results for people on third-line therapies show that it is the 1-year effectiveness that is a key driver, for both CBT (indexed EVPPI = 0.64) and counselling, with counselling somewhat important to decision uncertainty (indexed EVPPI = 0.11). The long-term effectiveness of CBT has an indexed EVPPI of 0.26. The long-term effectiveness of counselling is also important (indexed EVPPI = 0.06).

TABLE 24 Which parameters most affect the decision uncertainty and are, therefore, the highest priorities for further evidence collection?

Parameter	EVPPI per person (£)	SE of EVPPI estimate	Indexed to overall EVPI = 1.00
(Part 1) Patients receiving first-line treatment (i.e. people treated with diet and lifestyle advice plus metformin)			
All parameters	189.60	–	1.00
743. CBT, 1-year HbA_{1c} effect (HbA_{1c}_drop_CBT)	141.97	22.87	0.75
745. Counselling, 1-year HbA_{1c} effect (HbA_{1c}_drop_Cou)	0.16	11.02	0.00
744. CBT, longer-term HbA_{1c} effect (Traj_CBT)	47.04	20.40	0.25
746. Counselling, longer-term HbA_{1c} effect (Traj_COU)	0.26	11.26	0.00
743 and 744	147.63	18.41	0.78
745 and 746	3.00	15.62	0.02
(Part 2) Patients receiving second-line treatment (i.e. people treated with metformin plus another oral agent)			
All parameters	226.00	–	1.00
743. CBT, 1-year HbA_{1c} effect (HbA_{1c}_drop_CBT)	145.28	23.66	0.64
745. Counselling, 1-year HbA_{1c} effect (HbA_{1c}_drop_Cou)	0.00	11.56	0.00
744. CBT, longer-term HbA_{1c} effect (Traj_CBT)	58.47	23.50	0.26
746. Counselling, longer-term HbA_{1c} effect (Traj_COU)	14.12	15.51	0.06
743 and 744	150.13	20.27	0.66
745 and 746	27.43	18.90	0.12
(Part 3) Patients receiving third-line treatment (i.e. people on combination triple oral therapy or insulin)			
All parameters	234.60	–	1.00
743. CBT, 1-year HbA_{1c} effect (HbA_{1c}_drop_CBT)	150.29	18.76	0.64
745. Counselling, 1-year HbA_{1c} effect (HbA_{1c}_drop_Cou)	25.77	17.32	0.11
744. CBT, longer-term HbA_{1c} effect (Traj_CBT)	61.01	25.81	0.26
746. Counselling, longer-term HbA_{1c} effect (Traj_COU)	3.42	13.81	0.01
743 and 744	164.43	17.00	0.70
745 and 746	28.80	19.79	0.12

SE, standard error.
Note
Adults with T2DM (first-, second- and third-line therapies shown separately).

Conclusions on the cost-effectiveness of cognitive–behavioural therapy versus counselling versus usual care in adults with type 2 diabetes mellitus

The results of these analyses suggest the following conclusions for patients receiving:

- first-line therapy –
  - CBT could be considered a cost-effective psychological intervention compared with usual care (ICER ≈£11,000 per QALY gained) and compared with counselling (CBT dominates counselling).
  - Counselling would appear not to be cost-effective compared with usual care (ICER ≈£127,000 per QALY gained).
  - There is considerable decision uncertainty around these conclusions (although less so than for T1DM). Priorities for further evidence collection would focus on the CBT versus usual care short-term effectiveness, and longer-term (i.e. beyond 12 months) maintenance of effectiveness compared with usual care.
- second-line therapy –
  - CBT could be considered a borderline cost-effective psychological intervention compared with usual care (ICER ≈£19,000 per QALY gained) and very cost-effective compared with counselling.
  - Counselling would appear not to be cost-effective compared with usual care (ICER ≈£151,000 per QALY gained).
  - There is considerable decision uncertainty around these conclusions (although less so than for T1DM). Priorities for further evidence collection would focus on the CBT versus usual care short-term effectiveness, and longer-term (i.e. beyond 12 months) maintenance of effectiveness compared with usual care.
- third-line therapy –
  - CBT could be considered a borderline cost-effective psychological intervention compared with usual care (ICER ≈£20,000 per QALY gained) and very cost-effective compared with counselling.
  - Counselling would appear not to be cost-effective compared with usual care (ICER ≈£65,000 per QALY gained).
  - Once again, there is considerable decision uncertainty around these conclusions (although less so than for T1DM). Priorities for further evidence collection would, again, focus on the CBT versus usual care short-term effectiveness, and longer-term (i.e. beyond 12 months) maintenance of effectiveness compared with usual care.

For all therapy lines, a confirmatory trial with a long-term follow-up is necessary to establish the long-term treatment effect of psychological interventions for people with T2DM, as the only available long-term evidence is from a population with T1DM.

Chapter 9 Patient and public involvement focus groups

Participants

Ten people with diabetes participated in the focus groups (five from Sheffield and five from London) (*Table 25*). Four participants had T1DM and six had T2DM. Three males and seven females participated.

Results of focus groups

Five main themes of discussion were prevalent in both focus groups: (1) the need for psychological support in practice, (2) views on psychological intervention delivery, (3) views on diabetes research outcomes, (4) the importance of diabetes and psychology research and (5) dissemination of diabetes research.

Need for psychological support in practice

Several participants in both locations identified psychological interventions as a missing aspect of their care, and that it should, at least, be offered. The Sheffield group seemed in agreement that if clinicians were more psychologically aware, then some of their diabetes-related issues might be more likely to be addressed:

> *. . . that psychology behind it and that's never, that kind of stuff isn't brought up in those consultant meetings . . .*
>
> *Male Participant (MP), London*

> *. . . quite a lot of it is emotional, managing your emotions with it, you know, when you have a bad day . . .*
>
> *Female participant (FP), London*

> *. . . they have something in place for that person, and that is a choice, you're not saying you have to do it, but give the person the choice . . .*
>
> *FP, Sheffield*

Views on psychological intervention delivery

Participants identified that interventions could be particularly important for children and adolescents, but it can depend on how they are delivered. Their views were in line with the studies, as most studies looked at

TABLE 25 Patient characteristics of peoples with diabetes participating in focus groups

Characteristic	London focus group (*n*)	Sheffield focus group (*n*)	Total (*n*)
Type of diabetes			
T1DM	3	1	4
T2DM	2	4	6
Gender			
Male	1	2	3
Female	4	3	7
Total	10	10	

family interventions, and this was highlighted as important. They also identified peer support groups as being potentially effective for them.

In relation to who should facilitate psychological therapy, psychologists with diabetes knowledge or psychologically trained diabetes nurses were identified as suitable interventionists:

> *I think that the dream would be a psychologist who had some, even just background knowledge of diabetes . . . if the diabetes nurse had been psychology trained then that should really be the ideal scenario . . .*
>
> *MP, London*

Others expressed a need for a differentiation between a clinician who takes care of medical health, and a clinician addressing mental health:

> *. . . I think the psychologist is good because you've kind of got your consultant and your nurse looking after your medical side of it and I think if you've got a psychologist looking after your, you know, perhaps I think I would probably prefer that and not necessarily to mix the two as much.*
>
> *FP, London*

One participant explained that, no matter what illness or condition you have, you need the nurse and psychological input.

> *. . . you need both for any patient, I don't care what illness you got, you need that . . .*
>
> *FP, Sheffield*

Views on diabetes research outcomes

In regards to views on components of psychological interventions and how they are explored in research, the London group appeared surprised that follow-up points were not longer and they emphasised that psychological problems are not easily resolved:

> *Because I would think, you know, if you're having, like, psychological intervention, that might take longer . . .*
>
> *FP, London*

> *I would think, if you were having psychological support, that's going to take a couple of months to get ingrained in you and then to change and then for you to start to change your behaviour, so I wouldn't imagine that a year is quite a short time . . .*
>
> *FP, London*

There appeared to be a consensus that psychological outcomes were more important to group members than HbA_{1c} level. It was suggested that HbA_{1c} level is of more importance to clinicians and researchers than the patients. Several participants reiterated the fact that only HbA_{1c} level was commented on in clinical appointments:

> *. . . they are looking only at the HbA_{1c} and not at the whole approach.*
>
> *FP, London*

In the Sheffield group, there was some disagreement about who psychological interventions for people with diabetes should target. For example, some believed interventions should be focused only on people with suboptimal glycaemic control:

> *It's a waste of resources going after someone who is already in control of it.*
>
> *MP, Sheffield*

In contrast, a couple of other participants felt psychological interventions should be 'part of the preventative programme' (FP, Sheffield) and that patients should be offered this support before glycaemic control worsens.

Both groups emphasised the importance of spending money and investing in psychological support to save money in the long term from complications caused by poor self-management and psychological issues:

> *. . . what we're saying is, it's going to cost a lot of money to put these things into place, but if it means people stay healthier both physically and mentally, in the long run it will save them.*
>
> *FP, London*

Importance of diabetes and psychology research

The participants also emphasised the importance of research being undertaken, in terms of linking diabetes and psychology. The participants identified frequently that there is a psychological impact of living with diabetes:

> *. . . there is no health without mental health.*
>
> *MP, London*

> *It's diabetes forever . . . is that we don't have a holidays, we have diabetes, even when you go on holiday you still have it to control, we still have it to care, so it's life without a holiday . . .*
>
> *FP, London*

> *I think that's one of the things that's so difficult is that you don't get a weekend off or a day off or a minute off, it's relentless in that way . . .*
>
> *MP, London*

The focus group itself seemed to have a positive impact on participants:

> *Yeah it's really marvellous that we can come here and give our own view, I think that that's so important, as it's psychological, you needed to talk to diabetics themselves, don't you?*
>
> *FP, London*

Dissemination of diabetes research

There were a number of points raised that addressed how the research should be disseminated. Some participants belonged to a variety of different research groups and charities, such as Diabetes UK. They expressed interest in seeing updates of the research in Diabetes UK newsletters and magazines:

> *I always look at the Diabetes UK! In the Diabetes UK website, there is quite a lot.*
>
> *FP, London*

In addition, the knowledge of this research project itself was positively commented on. The participants wanted to be informed about the research and to have copies of the outcomes:

> *. . . is so important and it's nice to see that this is actually . . . I'd never heard about any research being done into this side of it until now . . .*
>
> *MP, London*

Some participants expressed concern about whether or not the outcomes of the research could positively and directly influence practice and provide access to psychological support. The group expressed a desire to have this support available and accessible. One member explained that there was no point in being informed about psychological interventions if there was no chance of having access to this support:

> *. . . if we can't access it, it's not much use us knowing about it.*
>
> *FP, Sheffield*

Chapter 10 Discussion

Summary of main results

This systematic review and meta-analysis of psychological interventions to improve self-management in people with T1DM and people with T2DM demonstrates that this is an active area of research; using our original protocol, we identified 96 new RCTs from the literature that were reported between 2003 and 2016. This included five RCTs of adults with T1DM, 20 RCTs of adolescents/children with T1DM, 56 RCTs of adults with T2DM and 13 RCTs with a mixed adult T1DM and T2DM population; there were also two studies that used a mixed adolescent T1DM and T2DM population.[189,194] Only adult studies were included in the meta-analysis of T2DM. Most of the increased level of activity in this field has been in the development and testing of psychological interventions for adults with T2DM.

The main results of the aggregate meta-analysis indicate that, for adults and adolescents/children with T1DM in receipt of a psychological treatment, there is no significant improvement in glycaemic control. Overall, psychological interventions have a statistically significant improvement in glycaemic control for adults with T2DM, but the effect size is small and of borderline clinical significance. Results are discussed in more depth for T1DM and T2DM and refer to the outcome of additional NMAs and IPD meta-analyses.

Adults with type 1 diabetes mellitus

In the aggregate meta-analysis, there was no statistically significant improvement in glycaemic control for adults with T1DM in receipt of psychological treatment compared with those in the control group (i.e. receiving usual care or attention control). These findings are consistent with our previous review of adults with T1DM, which demonstrated a non-significant improvement in glycaemic control compared with controls.[57] However, when one of the outlier adult studies (a study aiming to improve depressive symptoms in which glycaemic control was a secondary outcome)[105] was removed from the meta-analysis in the current review, there was a statistically significant improvement in glycaemic control, although it is likely to be a clinically non-significant effect size (SMD –0.20, 95% CI –0.37 to –0.02, equivalent to a –0.25 change in % HbA_{1c} level or a reduction of ≈3 mmol/mol). It is important to consider the problems of ignoring outliers in meta-analysis, especially when removal results in a change to the overall conclusion.[271] Therefore, considering that this remains a small effect size and of limited clinical benefit for adults with T1DM, a reduction of 0.4% in HbA_{1c} level (≈4 mmol/mol) is considered beneficial.[58] Our overall conclusion remains the same: that, based on the available evidence, psychological interventions do not improve glycaemic control in adults with T1DM. To underscore this, when data from the previous review and the current review were combined, there was no change to this conclusion, although the evidence from the current review is of high quality according to GRADE.

Which psychological treatment is the most effective for adults with type 1 diabetes mellitus?

According to the results of the aggregate meta-regression, it was not possible to determine which psychological treatment was more effective, as CBT and counselling studies were not significantly different. However, we also conducted a NMA and, as this uses the same aggregate data, although drawing on direct and indirect comparisons, this does suggest that some treatments may be more effective than others and that treatments can be ranked based on the probability of effectiveness. Therefore, the treatment arm suggested by the NMA to be most effective was not a psychological intervention but 'attention control'; this was used in two out of seven studies in which 'BGAT' and 'diabetes education' were compared with a psychological intervention. The fact that the 'attention control' groups here are probably most effective is not surprising as, essentially, both are diabetes education interventions predicated on supporting individuals to develop their knowledge and skills to improve self-management and achieve optimal glycaemic control, and they parallel the success of the DAFNE-structured education programme[272] and BGAT, which is a

treatment to improve blood glucose awareness and glycaemic control.[273] The next most successful treatment identified by the NMA was CBT. Other meta-analyses[60,274,275] focusing specifically on CBT interventions have established these as effective in improving depressive symptoms for people with T1DM and T2DM, and one study[274] has established short-term improvement in glycaemic control (3–6 months) but not longer-term, namely 12 months, which was the follow-up we used. Longer-term evaluation from the ADaPT study[163] suggests that, even when CBT based treatment is effective in improving HbA_{1c} levels for adults with T1DM at 12 months, without ongoing treatment the benefits completely disappear by 24 months.[251]

Who should deliver psychological treatments to adults with type 1 diabetes mellitus?

According to the results of the aggregate meta-regression, there was no statistically significant difference in outcome according to who delivered the psychological treatment, for example psychology professionals compared with diabetes specialists. This contrasts with a pilot study of MI for adolescents with T1DM delivered by a psychologist, which was effective,[276] but not when diabetes specialists were trained in the intervention for a RCT.[174]

Who benefits the most from psychological treatments for adults with type 1 diabetes mellitus?

For the IPD meta-analysis, we had data for six of the seven studies included in the aggregate meta-analysis but data were limited in terms of potential independent or moderating variables, that is only age of participants was available for all studies, and age was not found to be a moderator of treatment outcome or a main effect. Therefore, more and comparable IPD across trials would be required to improve our understanding of which individuals benefit most from psychological interventions.

Interpretation

Explanations for the lack of effectiveness of psychological interventions for adults may be summarised as follows:

- Improved quality of RCT design and reporting, and, therefore, less potential for biased treatment effect. In our previous review,[57] we established that overall quality of the reporting of the included studies was poor. In the current review, we were able to establish that most included trials were at a low risk of bias, albeit the methods used differed between reviews; therefore, it was not possible to directly compare the quality of the cohorts. However, given that studies included in the current review were more likely to report intention-to-treat analyses, and CONSORT criteria[67] and reporting are prerequisites to publishing in most peer-reviewed journals, there is now less potential for overestimation of treatment effects.
- Use of attention control focused on diabetes education.
  As discussed in *Chapter 5*. The attention control groups used in two of the seven studies were identified by the NMA as having the highest probability of being the best treatment. Therefore, educational interventions that have a direct focus on diabetes self-management are likely to be as effective as, if not more effective than, a psychological treatment that may focus more on improving motivation for diabetes self-management; we did not have data on the secondary outcomes that could be pooled. Furthermore, it may be a consequence that individuals who participated in these trials had not received educational training in self-management prior to participation in the studies.
- Timing of psychological interventions in adults with T1DM.
  Delivering psychological treatments to adults with T1DM at the right time for each individual may influence their effectiveness. It has been suggested by a range of researchers that psychological support should come before, during or after structured education. Poor psychological adaptation to T1DM may occur in childhood-onset[277] or adult-onset T1DM; around half of people with T1DM are diagnosed in adulthood.[278] In a meta-synthesis of qualitative research on adjustment to diagnosis in adults with T1DM, Due-Christensen *et al.*[279] conclude that the physical and social stress of adapting to T1DM causes psychological distress and, without support to minimise the distress, may increase the likelihood of developing beliefs and behaviours that have a detrimental impact on motivation for diabetes self-management and optimisation of glycaemic control. The average duration of diabetes for participants

included in the IPD meta-analysis was ≈8 years; therefore, most of the interventions in the current review were not focused on people with new-onset T1DM. This suggests that we need to determine whether we need to address skills training in diabetes self-management first and psychological distress later or both together. We should also consider what is the best outcome, as measuring change in diabetes distress and depressive symptoms may be more appropriate than glycaemic control. We may also need to consider whether or not existing interventions, such as CBT, are in fact the best approach, as many are derived from mental health models to improve depression and do not necessarily provide the best fit for someone trying to cope with a long-term chronic condition such as diabetes.[280,281]

Health economics

Cognitive–behavioural therapy interventions are potentially cost-effective, because of the potential for a larger improvement in glycaemic control compared with counselling therapies or usual care; this is supported by the NMA. However, there was a substantial uncertainty with the economic modelling; long-term studies are required to determine the maintenance of benefits and to eliminate decision uncertainty.

Adolescents/children with type 1 diabetes mellitus

In the aggregate meta-analysis, there was no statistically significant improvement in glycaemic control for adolescents/children with T1DM in receipt of a psychological treatment compared with those in receipt of a control (i.e. usual care, attention control or a less intensive psychological intervention). The current findings are inconsistent with the previous review for adolescents/children with T1DM, which demonstrated a significant improvement in glycaemic control for people in receipt of a psychological therapy.[57] However, the evidence from the current review is rated as being of high quality according to GRADE and, therefore, is likely to contain more reliable estimates.

Which psychological treatment is the most effective for adolescents/children with type 1 diabetes mellitus?

It was not possible to determine from the meta-regression which type of psychological therapy (i.e. counselling, family therapy or CBT) had the most potential for effectiveness in improving glycaemic control. However, one of the reasons why the results of this review are in contrast to the earlier review could be because of the increased use of attention control groups, used in 27% of included studies. In addition, although the NMA suggests that none of the treatments was effective overall, attention control had the highest probability of being the best treatment in terms of improving glycaemic control for young people, followed by CBT and family therapy. A recent systematic review and meta-analysis[282] of UK-based psychoeducational interventions for adolescents with T1DM achieved a similar non-significant improvement in glycaemic control; the authors did not compare types of psychological therapy,[282] but were able to determine a moderate effect on improving self-efficacy. However, a systematic review[283] of educational interventions that aimed to improve skill development reported improved QoL for young people when interventions incorporated psychological components such as stress reduction and coping skills training.

Who should deliver psychological treatments to adolescents/children with type 1 diabetes mellitus?

We compared interventionist type in the aggregate meta-regression; there were no statistically significant differences in effectiveness for interventions delivered by psychology professionals compared with those delivered by diabetes specialists. Therefore, we can say the challenge now is to make diabetes health professionals more effective in delivering psychological interventions to young people with T1DM; although other recent reviews[282,283] have mainly included studies delivered by nurses, these have not conducted a comparative analysis.

Who benefits the most from psychological treatments for adolescents/children with type 1 diabetes mellitus?

Our IPD meta-analysis was based on 50% of the studies included in the aggregate meta-analysis and suggested that participation in research was beneficial for young people. There were main effects demonstrating that younger participants had improved glycaemic control over the intervention period,

as did participants with a longer duration of diabetes. However, we were not able to determine whether particular subgroups of young people, such as those with behaviour problems or depression,[284] benefited more as these data were not requested from study authors given that it would have been difficult to request comparable information across studies.

Interpretation

Explanations for the lack of effectiveness of psychological interventions for adolescents/children may be summarised as follows:

1. Improved quality of trial reporting, as noted for adults with T1DM.
2. Increased use of attention control groups.
   This highlights the ethical dilemma faced by researchers who may want to ensure 'therapeutic equipoise': the need to establish genuine doubt regarding the superiority of the treatments being compared.[285] This means that offering 'something' rather than nothing, that is standard or usual care alone, is considered important and may encourage participation in a RCT, and that participation can provide benefit. Therefore, on the one hand, this makes it more difficult to derive an overall effect and, on the other hand, attention control is a good comparator if the psychological intervention is more intense and process evaluation is conducted to identify key ingredients that may be common to both groups.
3. Relatively varied psychological interventions tested in combination with varied control groups.
   Under the umbrella of psychological treatments for adolescents/children with T1DM, there are now multiple treatment comparisons, and not only is there heterogeneity in terms of the type of intervention, the mode of intervention delivery and the recipients, be they individual, family, parents or a combination of all three, but also there are numerous control groups to consider. Related to points 2 and 3 is that, for adolescents/children, it was not possible to conduct meta-analysis on secondary outcomes, such as psychological status, DKA admission rates or self-management activities such as blood glucose testing. There were too few studies using secondary outcome measures that could be pooled.

Health economics

It was not possible to determine the cost-effectiveness of psychological interventions for adolescents/children with T1DM as there was no evidence of any improvement in HbA_{1c} levels from the meta-analyses.

Type 2 diabetes mellitus

In an aggregate meta-analysis of 49 trials, there was a statistically significant improvement in glycaemic control for adults with T2DM in receipt of a psychological treatment compared with those in receipt of a control (usual care or attention control). This was a small effect at –0.21 (95% CI –0.31 to –0.10) or –0.33 change in % HbA_{1c} level (a reduction of ≈3.5 mmol/mol) and, therefore, of borderline clinical significance,[58] usually a 0.4% (4–5 mmol/mol) reduction in HbA_{1c} level, as this is associated with a reduction in the development of microvascular disease. Our previous review[40] to determine the effectiveness of psychological interventions for T2DM included in the meta-analysis 12 studies published from 1983 to January 2003, whereas this review compared studies from February 2003 to 2016. The previous review[40] reported a clinically relevant moderate effect size in terms of improved glycaemic control, whereas the current review reported a smaller effect size. When combined ($n = 61$), there remained a small effect, but the combined effect was at the level of clinical significance (SMD –0.22, 95% CI –0.32 to –0.12, equivalent to a –0.35 change in % HbA_{1c} level, or a reduction of ≈4 mmol/mol). However, it is difficult to determine which cohort is most reliable as the moderate GRADE assessment indicates that there was significant heterogeneity across studies for glycaemic control and other outcomes. Other systematic reviews from 2015–17[62,286,287] of psychological interventions for people with T2DM have reported variable improvement in glycaemic control. In other words, the effectiveness of psychological treatments is getting smaller over time.

Which psychological treatment is the most effective for adults with type 2 diabetes mellitus?

The aggregate meta-regression demonstrated that both CBT- and counselling-based interventions were effective in improving glycaemic control, but there was no significant difference between the two. Results of the NMA suggested that, when direct and indirect evidence was combined, there was no psychological treatment that demonstrated an overall effect, although some power is lost to support model consistency and effect sizes were similar to aggregate results (CBT –0.213, $p = 0.09$ and counselling –0.166, $p = 0.09$). The NMA ranking of CBT and counselling suggested that each shared the probability of being the best treatment. A recent systematic review[62] of MI (therefore counselling interventions) reported that three[62,286,287] of the 13 included studies demonstrated a significant reduction in HbA_{1c} levels compared with a control group. In contrast, a systematic review and meta-analysis[287] of CBT for people with depression and T2DM reported moderate to large effect sizes for glycaemic control and improvement in depressive symptoms, respectively.

For secondary outcomes, there was no evidence for psychological therapies improving depression over controls. Previous reviews focusing on distinct populations of people with depression and diabetes find that psychological treatments are effective.[59,60,275] However, the current review included different clinical subgroups, suboptimal glycaemic control, specific age groups and ethnicities and specific diabetes duration, and few were depressed populations. Our earlier reviews[40,288] also demonstrated that psychological interventions significantly reduced psychological distress over controls. QoL and dietary behaviour, a potential moderator of glycaemic control, for participants in receipt of psychological interventions improved significantly compared with controls. However, there was no statistically significant improvement in BMI or blood pressure. Our previous review[40] also found no effect of psychological therapies in improving weight control. However, weight loss, if successful, may take longer than improvement in glycaemic control, and behavioural or lifestyle interventions that specifically target BMI as an outcome are likely to be more effective.[286]

Who should deliver psychological treatments to adults with type 2 diabetes mellitus?

It was not possible to determine whether psychology professionals or diabetes specialists were more effective as interventionists. Both were effective according to aggregate meta-regression; however, there was a high level of heterogeneity for interventions delivered by diabetes specialists. An explanation for these results could be twofold: (1) there may be less variability in psychological interventions delivered by psychologists across studies as the techniques and training is likely to be more in-depth and (2) there is also qualitative evidence that psychological techniques are difficult for non-psychologists to deliver and they may not want to be trained in psychological techniques.[289]

Who benefits the most from psychological treatments for adults with type 2 diabetes mellitus?

Our IPD meta-analysis was based on 50% of the included studies and demonstrated a significant interaction effect between baseline HbA_{1c} level and treatment, suggesting that psychological interventions are most effective when the baseline HbA_{1c} level is $\geq 8\%$ (≥ 64 mmol/mol). This finding has previously been established in a systematic review and NMA of behavioural and lifestyle self-management programmes for people with T2DM.[286] Therefore, it would make sense to target interventions for people who are struggling with glycaemic control rather than for people with relatively good HbA_{1c} levels, who are probably motivated to self-manage their diabetes effectively. This finding may also, in part, explain why there was such heterogeneity of effect across studies in the aggregate meta-analyses. There were main effects for age and diabetes duration, and older participants and people with a shorter duration of diabetes improved over the intervention period. It is concerning that younger people with T2DM are less likely to improve and younger adults with T2DM are less likely to attend for diabetes monitoring such as annual checks (National Diabetes Audit 2016/17). The reasons for this are likely to be multifactorial, reflecting the difficulties faced by people of working age in managing a chronic illness[16] and perhaps also approaches to lifestyle that have led to diagnosis of T2DM when young that may be more resistant to change.

Considering the high level of heterogeneity across trials in terms of their effectiveness in improving glycaemic control, it is helpful to consider whether or not there could be a 'blueprint' for a successful psychological treatment for adults with T2DM. A crude method for doing this is to summarise the main characteristics of trials that demonstrated the largest effect. The five studies with the largest effect size from this meta-analysis suggest that the most effective treatments are counselling, usually MI, and CBT-based interventions. The interventionists were nurses or psychologists/therapists, although most did not adequately describe the training the interventionists received. However, some were pre-trained, such as fully trained therapists, or were in receipt of training delivered by clinical psychologists and psychiatrists. The dose of therapy received by participants was 4 to 12 group or individual face-to-face sessions.

Interpretation

Explanations for the small effect of psychological interventions on improving glycaemic control for adults with T2DM may be summarised as follows:

1. Improved quality of trial reporting, as previously described for T1DM.
2. Improved 'usual' care in control groups and/or availability of attention control groups, both of which may include diabetes education together with a lack of an effect of psychological treatment – the standards of diabetes care for people with T2DM in the UK has improved markedly since the introduction of the primary care targets and Quality and Outcomes Framework.[290]
3. Including diverse populations in the meta-analyses and including interventions for which glycaemic control was a secondary outcome – this includes interventions that recruited participants with optimal glycaemic control, who therefore had little room for improvement and determination of effect of treatment.
4. potential lack of fidelity and quality assurance of psychological treatment – although most studies reported on the training interventionists received, few reported whether or not interventionists actually achieved competency in the techniques prior to the start of the intervention, or quality assurance of ongoing performance was not described. These aspects are inherent to the successful delivery of psychological interventions and, over time, this may become a marker of quality for this type of non-pharmacological intervention.
5. reducing the intensity of the psychological interventions – there is increased pressure on NHS resources and research funders seek the most cost-effective interventions. Researchers are perhaps more likely to get research funding for a low-intensity intervention as it is cheaper to run and, if effective, cheaper to deliver.

Health economics

Cognitive–behavioural therapy was found to be less costly than counselling interventions, mainly because there were fewer sessions involved across studies. CBT was also potentially more cost-effective than counselling interventions or usual care, although this varied according to whether or not participants were in receipt of treatment for T2DM. Therefore, CBT was the most cost-effective when participants were treated with diet and exercise plus or minus metformin, rather than two or more oral antidiabetic agents and/or insulin treatment. However, larger studies are required to reduce decision uncertainty; as for adults with T1DM, more long-term data on effectiveness are required. This is particularly the case for people with T2DM, as no long-term studies were found in a population of people with T2DM that could inform how long the effects of psychological interventions were maintained.

Other evidence

Evidence from the patient and public involvement focus groups

When we presented preliminary findings of our evidence synthesis to people with diabetes, one of the main themes generated from the focus groups was the fact that psychological support and treatment is one aspect of diabetes care that is currently missing. This is interesting, as some of the participants attended King's College Hospital NHS Foundation Trust and others attended Sheffield Teaching Hospitals

NHS Foundation Trust, both of which provide some psychological treatment and much more than smaller hospitals or primary care clinics. All participants spoke about the day-to-day psychological struggle of managing diabetes and they believed that this approach might really help them. Although they understood why we were focusing on glycaemic control for this review, they felt that psychological outcomes were just as important, if not more so, but unfortunately these were not measured in most of the included studies. Despite the fact that psychological treatments, overall, were not effective in improving glycaemic control in adolescents/children and adults with T1DM and of limited effect for adults with T2DM, they believed that these treatments would be cost-effective in the long term.

The importance of psychological support among people with diabetes was recently highlighted by a report generated by Diabetes UK called *The Future of Diabetes*.[291] This report is the result of conversations with 9000 people with diabetes who identified psychological support as the most important area that could make it easier to live with diabetes in the future. Therefore, even though psychological interventions were not, on the whole, effective in terms of glycaemic control, they may have discrete benefits, but we were not able to analyse other outcomes, such as diabetes distress, because of the heterogeneity of outcome measures used across studies.

Evidence from non-randomised controlled trials

We conducted a systematic review of nRCTs comparing the effectiveness of a psychological treatment versus a control group. Fourteen studies were identified (T1DM, $n = 6$;[226–231] T2DM, $n = 7$;[233–238,240] and mixed T1DM and T2DM, $n = 1$[232]); only three demonstrated statistically significant improvement for those receiving psychological treatment versus usual care control[203,234,240] (one study of people with T1DM in receipt of stress management intervention and two studies of people with T2DM in receipt of counselling[240]). Few studies demonstrated significant results for different reasons. The RoB assessment suggested that most studies were of poor quality or did not provide adequate information; sample sizes were small and exhibited selection bias; and the competency of the interventionists was questionable. As studies were generally of poor quality, we did not consider adding them to aggregate meta-analyses or NMAs.

Strengths and limitations of this evidence synthesis

The strengths of this review included our choice of a defined research question and conducting a systematic review according to PRISMA guidance.[292] We did not limit the research to English language publications and we attempted to identify published and unpublished studies, including hand-searching conference abstracts from the main national and international diabetes conferences. We used a detailed protocolised approach to identify studies for inclusion in terms of the definition of the health technology (i.e. psychological intervention) and main and secondary outcomes. We contacted authors when information was missing for inclusion in meta-analyses and also performed network analyses to maximise data from studies comparing multiple interventions. We also conducted an IPD meta-analysis for the main outcome of interest, namely glycaemic control. A further strength is our inclusion of the same protocol we used approximately 10 years ago, to allow us to pool results and so determine cohort effects.

Limitations of the review include that we were unable to determine whether or not psychological interventions worked best among different cultures, as most were conducted in western Europe and North America and few studies adequately described the specific cultural setting. There are also potential difficulties applying psychological interventions developed in one country to another with a different health system, such as the difference between UK and non-UK studies. We did determine that studies conducted in Asian countries were more likely to be effective, but they also had a higher RoB. Although we know that there are periods on a person's journey with diabetes that might be particularly psychologically stressful, such as diagnosis, starting insulin for T2DM or the onset of diabetes complications, we were not able to find studies that had been specifically developed for these subgroups. Other factors that may affect the results of this review include the rising numbers of people diagnosed with T2DM, meaning there may be an increased awareness of diabetes among the general public and an associated awareness of psychological distress,[291] which may make people more aware of the need to seek psychological help. Treatment for depression and anxiety is widespread in the UK since the Improving Access to Psychological

Therapies programme, which provides low-intensity psychological treatments, was introduced in 2008.[293] Prior access to psychological support was not adequately measured in the included studies.

Limitations at the protocol level include our reliance on using title and abstract to screen for relevant studies. In our previous reviews, this was an adequate strategy as the terminology used to describe psychological interventions was explicit. However, in the current work, we identified that this approach was not adequate to detect all studies as the detail of psychological interventions was sometimes described only in the main text rather than the abstract and suggests that there is a dilution and infusion of psychological theory into complex interventions without specifying directly what the components are. We tried to address this by conducting a re-screen of abstracts previously rejected and undertaking sensitivity analyses. Other limitations reflect the concentration of psychological interventions in particular countries; most were from the USA and western Europe. We assume that our search strategy was robust enough to identify trials in other regions as some were identified and included, although these were relatively few. We also restricted our analyses to those reporting follow-up to 12 months from baseline. In terms of the searches, we restricted our grey literature search to conference proceedings for the main diabetes conferences and did not include behavioural medicine or other conferences; this was based on the assumption that diabetes RCTs were more likely to be presented at these. However, we may have missed some eligible studies using this method. For the systematic review of nRCTs, only one researcher screened titles and abstracts although two researchers screened the full-text articles; therefore, there is the potential for some studies to have been missed in error.

Limitations at the study level may relate to publication bias. Our ability to assess this was limited because of the small number of studies in some analyses (e.g. subgroup analyses and secondary outcomes). We tried to address this by using the Egger test, funnel plots and the trim-and-fill method in combination. We found little evidence of publication bias for adolescent/children and adult T1DM studies. We did not limit the systematic review to studies that combined psychological treatment with diabetes self-management strategies. However, we were able to subsequently address this in a meta-regression for the adult T2DM studies.

At the outcome level, our main analyses were limited to glycaemic control; in some studies included in the evidence synthesis, this was not the primary outcome. However, we were unable to conduct meta-analysis for psychological outcomes in studies of people with T1DM. This underlines the need to establish consolidated outcome sets.[294] CONSORT criteria were introduced in 2001[67] and our RoB assessment demonstrated a low to unclear RoB. This is an improvement on the quality of studies included in our previous review, as many of the studies were conducted prior to the introduction of CONSORT criteria. A further limitation at the outcome level is that we used data closest to the 12-month follow-up, but this meant including outcome data at varying time points, such as at the 3- or 6-month follow-ups, and, although we did conduct meta-regression on overall duration of therapy, we did not specifically address this; therefore our analyses may overestimate the effectiveness of psychological treatments.

Our IPD meta-analysis was limited to 40–50% of the included studies from the aggregate meta-analysis. Therefore, the finding from this analysis are subject to response bias. However, there were no significant differences between studies that provided data and those that did not according to date of publication, type of psychological treatment tested and country of origin.

The overall heterogeneity for studies involving adults with T2DM and adults with T1DM was low to moderate for the primary outcome (i.e. glycaemic control) according to GRADE, which may be surprising considering the range of different psychological therapies pooled for analysis. We decided to pool a range of psychological therapies used in diabetes care to address the research question. All psychological therapies met the predefined criteria described in *Chapter 3*, *Types of intervention (health technologies)* which may account for lower heterogeneity than expected. When heterogeneity existed, we conducted meta-regression and sensitivity analyses. Because of the relatively small number of studies, negative results of meta-regressions need to be treated with care because of a lack of power, and estimations of regressions may not be robust.[295]

The key limitation regarding the health economic analysis was the lack of available data on how long any changes in biomarkers would be maintained. Consequently, how long the treatment effects found in the systematic review and meta-analyses would last was highly uncertain and was identified as key driver of decision uncertainty around the cost-effectiveness of psychological interventions for both people with T1DM and people with T2DM. It should be noted that this parameter was more uncertain for people with T2DM, as no evidence on the long-term effects of psychological interventions was available in this population.

The GRADE assessment of certainty of evidence

The evidence for adults with T1DM, and adolescents/children with T1DM was rated as being of high quality, increasing our confidence that the result reflects a true effect for the primary outcome, HbA_{1c} level. The quality of evidence in studies involving adults with T2DM was rated as being of moderate quality, indicating only moderate confidence in the estimate. Further research may improve the quality of evidence in terms of HbA_{1c} level. This moderate rating reflects inconsistency and considerable heterogeneity, which remained moderate to high in most subgroups of psychological interventions (i.e. CBT, counselling) and interventionist subgroups (i.e. diabetes specialists, other).

Secondary outcomes were assessed only for adults with T2DM, when outcomes such as BMI and blood pressure were of high quality. Other outcomes including depression, QoL and general diet behaviour were considered to be of low quality, due to major heterogeneity. The true effect may significantly differ from these estimates. Subgroup analyses were not conducted on these outcomes; therefore, heterogeneity may be less in certain subgroups, for example for different psychological intervention types (i.e. counselling, CBT) or for interventionist type (e.g. diabetes specialists, diabetes professionals).

The NMAs results rely on the assumptions of homogeneity and transitivity. However, the small number of comparisons for most treatments limit the interpretation of the heterogeneity assumptions using inferential statistics. The indirect comparisons are not protected by randomisation and may be confounded by differences between the trials. Unlike homogeneity, transitivity cannot be evaluated quantitatively and is difficult to assess.

Chapter 11 Conclusions

The aim of this evidence synthesis was to determine whether or not psychological interventions are clinically effective and cost-effective in improving self-management for adults and adolescents/children with T1DM and adults with T2DM. The evidence was generally considered to be of good quality according to GRADE[96] and suggests that, overall, psychological interventions to improve motivation for diabetes self-management, specifically glycaemic control, are not clinically effective for adults and adolescents/children with T1DM. For adults with T2DM, there was evidence of a borderline clinically significant effect. Although results for adults with T1DM suggest that there is no effect of psychological interventions on glycaemic control, there was some evidence that CBT is potentially a cost-effective treatment. Likewise, for adults with T2DM, CBT was considered potentially cost-effective for people in receipt of first-line diabetes treatment, namely diet, exercise and metformin (i.e. biguanide). For both adults with T1DM and adults with T2DM, there was substantial uncertainty in the economic modelling, particularly around how long any differences in effectiveness would be maintained.

Implications for clinical practice

Policy-makers and service providers generally recognise the benefits of providing psychological support for people with diabetes, yet there are few services available for adults;[296] however, service provision for children and young people is improving.[297] This review does not support the use of psychological interventions over control interventions (such as diabetes education) to improve glycaemic control for adults and adolescents/children with T1DM;[298] for adults with T2DM there is only weak evidence of borderline clinical significance.[298] However, for adults with T2DM, psychological interventions may be effective in people with suboptimal glycaemic control. There are also additional benefits in terms of healthy eating and improved QoL. Nevertheless, despite the lack of evidence, people with diabetes want access to psychological support;[291] in our focus groups, patients were less concerned regarding the degree of clinical effectiveness in terms of HbA_{1c} levels. A lack of psychological support when indicated may lead to a vicious cycle of maladaptive coping behaviours and poor diabetes self-management.[279]

Implications for future research

In adolescents/children with diabetes, there are challenges in using a RCT to test the effectiveness of psychological interventions, as it may be unethical to withhold potentially effective treatment. In this group, non-randomised designs may be more appropriate.[299] We were unable to determine if psychological treatments improved self-management using outcome variables other than glycaemic control for adolescents/children and adults with T1DM as there were typically fewer available studies; therefore, common outcome sets may be useful.

In the current review, we found it difficult to identify psychological interventions from titles and abstracts and had to re-screen rejected abstracts because of the lack of 'psychological language' used in them.

Although most of the included studies in this review were deemed to be at a low or unclear risk of bias according to the metrics commonly used, it was generally unclear whether or not individuals who were delivering the psychological interventions were competent to do so. Few studies reported this level of detail. A 2018 study[300] highlights this problem: in a pragmatic trial, community practice nurses were trained in psychological techniques to support people with T2DM, but none achieved competency prior to the study starting. In the current review, we were able to demonstrate that psychology professionals and diabetes specialists can deliver psychological treatments, although, perhaps unsurprisingly, there was more heterogeneity between studies when interventions were delivered by diabetes specialists than when they

were delivered by psychology professionals. Further research is required to determine who can be trained to deliver psychological interventions at a competent level.

In summary, based on the findings of this evidence synthesis and the gaps in the literature, we would recommend the following research questions or priorities:

- 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 adolescents/children and adults with T1DM.
- 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 the long-term clinical effectiveness and cost-effectiveness of psychological interventions.
- Develop different models of psychological care depending on where the person is 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 both psychology and education to address psychological distress, such as depressive symptoms, and diabetes self-management.

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Kirsty Winkley (Reader in Diabetes and Primary Care, Chief Investigator) conceived the study design, supervised systematic review methods, screened studies for inclusion, conducted RoB assessments, ran PPI focus groups, interpreted the data, wrote the final report and is accountable for all aspects of the work.

Rebecca Upsher (PhD student, Research Assistant) contributed to the acquisition of data; undertook systematic review methods, screening records, data extraction and RoB assessments; assisted in running PPI focus groups; ran the aggregate meta-analysis; assisted in writing the final report; and is accountable for the work.

Daniel Stahl (Reader of Biostatistics, Co-applicant) substantially contributed to the conception and design of the study, supported the aggregate meta-analysis, conducted network and IPD meta-analyses, wrote the NMA and IPD sections of the report, approved the final report for publication and is accountable for the work.

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Architaa Kasera (MSc student) substantially contributed to the analysis and acquisition of data; undertook systematic review methods, screening records, data extraction and RoB assessments; assisted in writing the final report; approved the final report for publication; and is accountable for the work.

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Publications

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Winkley K, Upsher R, Stahl D, Pollard D, Brennan A, Heller S, Ismail K. Systematic review and meta-analysis of randomized controlled trials of psychological interventions to improve glycaemic control in children and adults with type 1 diabetes. *Diabet Med* 2020;**37**:735–46.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 List of the additions to the original review

List of additions to original review

- Network meta-analysis.
- Individual patient data meta-analysis.
- Cost-effectiveness analysis.
- Non-randomised controlled trials systematic review.
- Patient and public involvement input.

List of changes between current protocol and review

The following amendments were made to version 1.3 of the protocol:

- We were more explicit in the exclusion criteria, by saying that patients who had other medical conditions would be excluded unless the data on patients with diabetes have been summarised and are extractable as a subgroup, or a separate analysis can be provided by the author.
- We updated our definition of a psychological intervention. We defined an intervention as psychological if it: (1) had a reliance on communication, using a therapeutic alliance between patient and the therapist; (2) was facilitated by psychologists, psychotherapists and therapists in training, or facilitated by persons trained/supervised by a clinical psychologist or therapist; (3) was based on a psychological model; and (4) aimed to improve outcome changes in emotional, cognitive or behavioural functioning including adherence. If these criteria were unclear and the intervention could not clearly be described as psychological from the publication, then authors were contacted for more information to determine eligibility.
- We included 'diabetes education' as a comparator.
- We searched international conference abstracts from 2012–current. We also searched clinicaltrials.gov for grey literature.

Appendix 2 Search strategy in MEDLINE for randomised controlled trials

MEDLINE (via OvidSP)

1. exp Diabetes Mellitus/
2. diabet$.ab,ti.
3. (DKA or IDDM).mp. or DMI.ab,ti. [mp=title, original title, abstract, name of substance word, subject heading word]
4. (MODY or DM2 or NIDDM).mp. or IIDM.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
5. insulin$ secret$ dysfunc$.ti,ab.
6. insulin$ resist$.ti,ab.
7. ((impaired glucose tolerance or glucose intoleran$ or insulin$ resist$) and (DM or DM2)).ti,ab.
8. insulin$ depend$.mp. or insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
9. (non insulin$ depend$ or nonisulin$ depend$ or nonisulin?depend).mp. or non insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
10. (("typ$ 1" or typ$ I) adj6 DM).ti,ab.
11. (("typ$ 2" or typ$ II) adj6 DM).ti,ab.
12. ((juvenil$ or child$ or keto$ or labil$ or brittl$ or earl$ onset) adj6 (DM or DM1)).ti,ab.
13. ((keto$ prone or autoimmun$ or auto immun$ or sudden onset) adj6 (DM or DM1)).ti,ab.
14. ((keto$ resist$ or nonketo$ or non keto$ or adult$ onset or matur$ onset or late$ onset or slow onset or stabl$) adj6 (DM or DM2)).ti,ab.
15. exp Insulin Resistance/
16. (insulin$ defic$ adj6 (absolut$ or relativ$)).ti,ab.
17. metabolic$ syndrom$.ti,ab.
18. (syndrom$ X not (fragil$ X or X linked)).ti,ab.
19. (plurimetabolic$ syndrom$ or pluri metabolic$ syndrom$).ti,ab.
20. or/1-19
21. exp Psychotherapy/
22. exp Counseling/
23. exp Mood disorders/
24. exp Depression/
25. psycho$.mp
26. counsel$.mp
27. depression.mp
28. depressive.mp
29. (interpersonal adj5 therap$).mp
30. art therap$.mp
31. aversion therap$.mp
32. balint.mp
33. behavio?r adj5 (intervention or therap* or modific*)
34. cognitive adj5 (therap* or intervention or program* or train* or theory)
35. (family adj3 (intervention or treatment or counsel* or therap*)
36. colo?r therap$.mp.
37. crisis intervention.mp
38. dance therap$.mp
39. gestalt therap$.mp
40. music therap$.mp
41. milieu therap$.mp

42. (assert$ adj5 training).mp
43. Narrative therap$.mp.
44. nondirective therap$.mp
45. (problem solving adj5 therap$).mp
46. (self control adj5 therap$).mp
47. person cent$.mp
48. client cent$.mp
49. psychodrama$.mp
50. paradoxical technique$.mp
51. play therap$.mp
52. rational emotive.mp
53. reality therap$.mp
54. role play$.mp
55. (relax$ adj5 training).mp
56. sociotherap$.mp
57. socioenvironmental.mp
58. supportive therap$.mp
59. transactional.mp
60. acceptance adj2 (commitment therap*)
61. coping skills training.mp.
62. exp Mindfulness/
63. motivation* adj2 (interview* or therap*)
64. multisystemic therapy
65. or/21-64
66. Randomized Controlled Trials as Topic/
67. randomized controlled trial/
68. Random Allocation/
69. Double Blind Method/
70. Single Blind Method/
71. clinical trial/
72. clinical trial, phase i.pt
73. clinical trial, phase ii.pt
74. clinical trial, phase iii.pt
75. clinical trial, phase iv.pt
76. controlled clinical trial.pt
77. randomized controlled trial.pt
78. multicenter study.pt
79. clinical trial.pt
80. exp Clinical Trials as topic/
81. (clinical adj25 trial$).tw
82. ((singl$ or doubl$ or treb$ or tripl$) adj25 (blind$3 or mask$3)).tw
83. PLACEBOS/
84. placebo$.tw
85. randomly allocated.tw
86. (allocated adj2 random$).tw
87. or/66-86
88. case report.tw
89. letter/
90. historical article/
91. or/88-90
92. 87 NOT 91
93. 20 AND 65 AND 92
94. limit 93 to yr="2003-Current"

Appendix 3 Data extraction items for randomised controlled trials

Items for data extraction (conducted in Microsoft Excel):

- reference
- name of first author/trial name
- psychological intervention category
- publication characteristics –
    - Digital Object Identifier (DOI)
    - year of publication
    - country of origin
    - health-care setting
    - language
    - funding source
    - study design
- patient characteristics –
    - type of diabetes
    - number of participants screened/assessed for eligibility
    - number of participants excluded
    - reasons participants were excluded
    - number participants declined before randomisation
    - intervention/control label
    - number of participants randomised to group
    - number of participants lost to follow-up in group
    - reasons for loss to follow-up
    - intervention/control label for age and duration
    - baseline characteristics –
        - age (mean, SD)
        - duration of diabetes in group (years: mean, SD)
        - sex (*n*, %)
        - clinical subgroup information (treatment type, smoking status, weight/BMI)
        - ethnicity group (*n*, %)
        - socioeconomic setting type (e.g. individual's or family's income, education)
        - complication status information
    - receipt of diabetes education
- intervention characteristics –
    - type of therapy
    - number of therapy sessions
    - duration of overall treatment
    - duration of treatment session
    - psychological theoretical framework or model
    - specialty of facilitator

- use of manual
- interventionist training
- format of delivery
- mode of delivery
- use of boost or maintenance sessions

- control characteristics –
  - same as intervention characteristics, if applicable

- primary outcome characteristics –
  - intervention
  - comparison
  - outcome measure
  - time point of follow-up
  - baseline intervention (*n*, mean, SD)
  - baseline control (*n*, mean, SD)
  - intervention follow-up (*n*, mean, SD)
  - control follow-up (*n*, mean, SD)

- secondary outcome characteristics –
  - same as primary outcome characteristics in addition to:
    - type of secondary outcome, for example (1) changes in self-management behaviours or (2) change in psychological functioning or (3) other.

Appendix 4 Data extraction items for randomised controlled trial non-English studies

Items for data extraction (conducted in Microsoft Excel):

- reference
- year
- country of study
- total number of participants
- age (mean, SD) in intervention
- age (mean,SD) in control
- duration of diabetes (mean, SD) in intervention
- duration of diabetes (mean, SD) in control
- type of intervention
- duration of therapy in intervention
- number of sessions in intervention
- interventionist
- interventionist training
- type of control, for example usual care/diabetes education
- follow-up period
- HbA_{1c} level at baseline in intervention (mean, SD)
- HbA_{1c} level at baseline in control (mean, SD)
- HbA_{1c} level at follow-up in intervention (mean, SD)
- HbA_{1c} level at follow-up in control (mean, SD).

Appendix 5 Psychological intervention, control and interventionist categories

T2DM studies	
Psychological intervention category	***Psychological intervention condition***
CBT	• CBT[106,114,116,125–127,131,135,140,155,160] • Self-management group[110] • CBT + DSMT + CST[118] • Cognitive–behavioural pedometer-based group intervention[119] • Minimal psychological intervention • Psychoeducation[147] • CBT-AD • Mindfulness cognitive-based therapy[104,197] • DIAMOS[105] • MET + CBT[148] • TECNOB[156] • Structured behavioural group[192]
Counselling	• MI[97,112,120,128,133,137,145,146,150,154,157,158,191,196] • Telephone support/coaching/counselling[113,115,134,143] • Integrative health coaching[117] • Culturally tailored diabetes self-care intervention[121] • Family-based intervention[123] • Group behavioural intervention[124] • Mindfulness-based intervention[132] • Intensive plus behavioural intervention[142] • Health coaching[149] • Minimal Psychological Intervention[151] • DECIDE[161] • Self-management intervention[152] • Group-based counselling[188]
Collaborative care	• Collaborative care[195,214] • Sociocultural adapted collaborative care[129]
Creative therapy	Music therapy[136]
Family therapy	• Behavioural family systems therapy[189] • Multisystemic therapy[194]
Control condition category	***Control condition***
Usual care	• Usual care[104,106,110,113,115,117,119,121,123,124,126,127,129,131,132,134,135,137,142,143,145–152,154–158,189,191,195,214] • Usual care while on waiting list[114,116,125,188,197] • Enhanced usual care[140,161]
Attention control	• Diabetes education[105,112,118,128,133,136,160,195,196] • Attention control[120,192] • Telephone support[194]
Interventionist category	***Interventionist***
Diabetes specialists	• Diabetes nurses[113,118,126,133,145,150,154,158,188] • CBT-trained nurse[131] • Nurse practitioner[120] • Primary care nurse[127,137] • Diabetes educator[128,192] • Diabetes researcher[110] • Diabetes nurse and dietitian[135] • Diabetes nurse and pharmacist[146] • Clinicians (doctors, nurses and psychologists)[149,191] • Primary care physicians[129,195]

T2DM studies	
Psychology professionals	• Depression clinical specialist[214] • Clinical psychologist[106,112,124,156,197] • Health psychologist[123] • Psychologist[104,105,132,147,189] • Therapist[97,140,194] • Psychotherapist and clinical nurse[148] • Psychology assistant[151] • Psychology researcher[157]
Other	• Undergraduate psychologist[115] • Counsellors[114,125,143] • MSc-level coaches (in physical activity or clinical psychology or social work)[117,119] • Medical assistant[121] • Individuals with degree in physical activity[134] • Music therapist[136] • Lifestyle facilitator[142] • Research assistants[160] • Interventionist with degree in undergraduate or master's health education, psychology or social work[161] • Interventionist trained in MI[152] • Peers[196]
T1DM adult studies	
Psychological intervention category	***Psychological intervention condition***
CBT	• CBT-based intervention (Amsberg *et al.*[162]; Petrak *et al.*[106]) • MET + CBT (Ismail *et al.*[163]) • Cognitive–behavioural group training (Snoek *et al.*[164]) • DIAMOS (Hermanns *et al.*[105]) • Mindfulness cognitive-based therapy (van Son *et al.*[104])
Counselling	• Flexible guided self-determination (Zoffmann *et al.*,[165] Zoffmann *et al.*[166])
Control condition category	***Control condition***
Usual care	• Usual care (Ismail *et al.*,[163] van Son *et al.*[104]) • Usual care and antidepressants (Petrak *et al.*[106]) • Waiting list control (Amsberg *et al.*,[162] Zoffmann *et al.*,[165] Zoffmann *et al.*[166])
Attention control	• BGAT (Snoek *et al.*[164]) • Diabetes education (Hermanns *et al.*[105])
Interventionist category	***Interventionist***
Diabetes specialists	• Diabetes specialist nurse and psychologist (Amsberg *et al.*[162]) • Nurse (Ismail *et al.*,[163] Zoffmann *et al.*,[165] Zoffmann *et al.*[166])
Non-diabetes specialist	• Psychologist (Snoek *et al.*,[164] Hermanns *et al.*,[105] van Son *et al.*,[104] Petrak *et al.*[106])
T1DM adolescent studies	
Psychological intervention category	***Psychological intervention condition***
CBT	• CST (Grey *et al.*,[171] Holmes *et al.*,[185]) • CBT + CST (Najmi *et al.*,[177]) • The Best of Coping (Serlachius *et al.*[184])
Counselling	• MI (Channon *et al.*,[168] Wang *et al.*[172]) • Diabetes personal trainer intervention (Nansel *et al.*[170]) • Positive affect (Jaser *et al.*[179]) • Psychoeducation (Christie *et al.*[181])
Family therapy	• Multisystemic therapy (Ellis *et al.*[169]) • Telehealth behaviour therapy (Lehmkuhl *et al.*[173]) • Family behavioural intervention (Nansel *et al.*[176]) • Care ambassador ultra (Katz *et al.*[180]) • BFST-D (Harris *et al.*,[182] Wysocki *et al.*[186]) • Family intervention (Nansel *et al.*[183]) • CST

T1DM adolescent studies	
Control condition category	***Control condition***
Usual care	• Usual care (Ellis *et al.*,[169] Nansel *et al.*,[176] Najmi *et al.*,[177] Katz *et al.*,[180] Christie *et al.*,[181] Serlachius *et al.*[184] and Wysocki *et al.*[189]) • Waiting list (Lehmkuhl *et al.*[173])
Attention control	Diabetes education (Nansel *et al.*,[170] Grey *et al.*,[171] Wang *et al.*,[172] Jaser *et al.*,[179] Holmes *et al.*[185])
Less intensive psychological intervention	• Non-directive psychological support (Channon *et al.*[168]) • BFST-D via Skype (Harris *et al.*[182])
Interventionist category	***Interventionist***
Diabetes specialists	• Nurse (Channon *et al.*,[168] Christie *et al.*[181]) • Diabetes educators (Wang *et al.*[172])
Psychology professionals	• Therapist (Ellis *et al.*,[169] Harris *et al.*,[182] Wysocki *et al.*[186]) • Mental health professional (Grey *et al.*[171]) • Clinical psychologists (Lehmkuhl *et al.*[173]) • Psychiatrists (Najmi *et al.*[177]) • Health psychologist (Serlachius *et al.*[184])
Other	• Trained non-professional (Nansel *et al.*[170]) • Health advisors (Nansel *et al.*[176]) • Research assistant (Jaser *et al.*,[179] Katz *et al.*,[180] Nansel *et al.*[183]) • Interventionist (Holmes *et al.*[185])
T2DM and T2DM studies	
Psychological intervention category	***Psychological intervention condition***
CBT	• Group-based counselling (Karlsen *et al.*[188]) • Structured behavioural group (Weinger *et al.*[192]) • Mindfulness-based cognitive therapy (Schroevers *et al.*[197])
Counselling	• MI (Rosenbek Minet *et al.*,[191] Safford *et al.*[196])
Family therapy	• Behavioural family systems therapy (Wysocki *et al.*[189]) • Multisystemic therapy (Ellis *et al.*[194])
Collaborative care	• Collaborative care (Lin *et al.*[195])
Control condition category	***Control condition***
Usual care	• Usual care (Wysocki *et al.*[189], Rosenbek Minet *et al.*,[191] Lin *et al.*[195]) • Waiting list (Karlsen *et al.*,[188] Schroevers *et al.*[197])
Attention control	• Group attention control (Weinger *et al.*[192]) • Diabetes education (Safford *et al.*[196])
Less intensive psychological intervention	• Telephone support (Ellis *et al.*[194])
Interventionist category	***Interventionist***
Diabetes specialists	• Nurse (Karlsen *et al.*[188]) • Diabetes educators (Weinger *et al.*[192])
Non-diabetes specialists	• Psychologist (Wysocki *et al.*[189] and Schroevers *et al.*[197]) • Therapist (Ellis *et al.*[194]) • Peers (Safford *et al.*[196]) • Primary care physician (Rosenbek Minet *et al.*,[191] Lin *et al.*[195])

CBT-AD, cognitive–behavioural therapy for adherence and depression; CST, coping skills training; DECIDE, Decision-making Education for Choices In Diabetes Everyday; DIAMOS, Diabetes Motivational Strengthening; DSMT, diabetes self-management training MET, motivational enhancement therapy; TECNOB, TEChnology for Obesity.

Appendix 6 Non-randomised controlled trial search terms for non-randomised studies for MEDLINE

MEDLINE (via OvidSP)

Date range searched: January 2003 to July 2016.

Date searched 8 August 2016.

Search strategy

1. case-control studies/
2. retrospective studies/
3. cohort studies/
4. longitudinal studies/
5. follow-up studies/
6. prospective studies/
7. cohort.ti,ab.
8. longitudinal.ti,ab.
9. follow up.ti,ab.
10. followup.ti,ab.
11. prospective*.ti,ab.
12. retrospective*.ti,ab.
13. comparison group*.ti,ab.
14. control group*.ti,ab.
15. nonrandom*.ti,ab.
16. or/65-79
17. or/21-64
18. 20 and 80 and 81
19. limit 82 to yr="2003 -Current"

Appendix 7 Data extraction items for non-randomised controlled trial studies

Items for data extraction (conducted in Microsoft Excel):

- reference
- name of first author/trial name
- psychological intervention category
- publication characteristics –
    - DOI
    - Year of publication
    - country of origin
    - healthcare setting
    - language
    - funding source
    - study design
- patient characteristics –
    - type of diabetes
    - number of participants screened/assessed for eligibility
    - number of participants excluded
    - reasons for participants excluded
    - number participants declined before randomisation
    - intervention/control label
    - number of participants randomised to group
    - number of participants lost to follow-up in group
    - reasons for loss to follow-up
    - intervention/control label for age and duration
    - baseline characteristics –
        - age (mean, SD)
        - duration of diabetes in group (years: mean, SD)
        - sex (*n*, %)
- intervention characteristics –
    - type of therapy
    - number of therapy sessions
    - duration of overall treatment
    - duration of treatment session
    - psychological theoretical framework or model
    - specialty of facilitator
    - use of manual
    - interventionist training
    - format of delivery
    - mode of delivery
    - use of boost or maintenance sessions

- control characteristics –
  - same as intervention characteristics, if applicable
- outcome characteristics –
  - intervention
  - comparison
  - outcome measure
  - method of assessing outcome
  - type of outcome: (1) HbA_{1c} level, (2) change in psychological functioning, (3) change in self-management behaviours, (4) other
  - time point of follow-up
  - findings
  - limitations.

Appendix 8 Mini posters of preliminary findings of randomised controlled trial aggregate meta-analysis for focus groups

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Type 1 Adolescent Diabetes Research Summary

Preliminary findings from the systematic review of psychological interventions to improve motivation for self-management in people with type 1 and type 2 diabetes

KING'S College LONDON

Introduction

Since 2003, we found 15 studies which explored the effectiveness of psychological interventions in adolescents with type 1 diabetes. We had enough data to conduct analysis on 13 studies.

- Preliminary findings suggest that HbA1c is no better in patients who have received a psychological intervention than those who have received usual care, diabetes education, or less intensive psychological intervention.
  - The number of interventions sessions ranged from 2-36.
    - 9 studies were conducted in the US, 2 UK, 1 Asia and 1 Australia.

The tables below outline some characteristics of the studies. Most interventions were delivered by a clinical psychologist/psychiatrist; delivered face to face; and were in a family setting.

Interventionist	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Clinical psychologist/psychiatrist/ therapist/ mental health professional	5	3 (60%)
Trained non-professional/ research assistant	3	1 (33.3%)
Nurse	2	1 (50%)
Diabetes educator	1	0
Health advisor	1	0
Health psychologist	1	1 (100%)

Mode of delivery	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Face to face	10	4 (40%)
Telephone	2	1 (50%)
Skype	1	1 (100%)

Type of psychological intervention	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Counselling	5	2 (40%)
Family therapy	5	3 (60%)
CBT	3	1 (33.3%)

Group or individual	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Family	7	3 (42.9%)
Group	4	1 (25%)
Individual	1	1 (100%)
Family and individual	1	1 (100%)

Type 1 Adult Diabetes Research Summary

Preliminary findings from the systematic review of psychological interventions to improve motivation for self-management in people with type 1 and type 2 diabetes

Introduction

Since 2003, we found 8 studies which explored the effectiveness of psychological interventions in adults with type 1 diabetes. We had enough data to conduct analysis on 7 studies.

- Preliminary findings suggest that HbA1c is **no better** in patients who have received a psychological intervention than those who have received usual care and/or diabetes education.
  - The number of intervention sessions ranged from 4-14.

The table below outlines some characteristics of the studies. 4 studies were delivered by nurses, the other 4 by psychologists. All studies were delivered face to face, most in a group setting.

Name first author	Country	Type of psychological intervention	Interventionist	Mode of delivery	Group or individual	Did psychological intervention improve in HbA1c more than usual care/diabetes education?
Zoffmann 2006	Denmark	Counselling	Nurses	Face to face	Group	UNKNOWN: requesting data from author
Amsberg 2009	Sweden	CBT	Nurses	Face to face	Group	YES
Ismail/ADaPT 2008	UK	CBT	Nurses	Face to face	Individual	YES
Snoek 2008	Netherlands	CBT	Psychologist	Face to face	Group	NO
Hermanns 2015	Germany	CBT	Psychologist	Face to face	Group	NO
Zoffmann 2015	Denmark	Counselling	Nurses	Face to face	Group	NO
Van Son 2015	Netherlands	CBT	Psychologist	Face to face	Group	YES
Petrak 2015	Germany	CBT	Psychologist	Face to face	Group	NO

Type 2 Diabetes Research Summary

Preliminary findings from the systematic review of psychological interventions to improve motivation for self-management in people with type 1 and type 2 diabetes

Introduction

Since 2003, we found 38 studies which explored the effectiveness of psychological interventions in type 2 diabetes. We had enough data to conduct analysis on 30 studies.

- Preliminary findings suggest that HbA1c is **better (i.e. reduced)** in patients who have received a psychological intervention compared to those who have received usual care and/or diabetes education.
  - These outcomes are for up to 12 months follow-up, i.e. HbA1c measurements were assessed up to 12 months after receiving the intervention.
    - The number of interventions sessions ranged from 1-27.
      - 14 studies were conducted in the US, 9 in Europe (non-UK), 5 Asia, 1 UK and 1 Australia.

The tables below outline some characteristics of the studies. Most interventions were delivered by a clinical psychologist/psychiatrist; delivered face to face; and were one-to-one support.

Interventionist	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Nurse	9	8 (88.8%)
Clinical psychologist/ psychiatrist	8	5 (62.5%)
Psychology assistant/researcher	2	2 (100%)
Coaches	5	3 (60%)
Counsellors	1	1 (100%)
Medical assistant	1	1 (100%)
Health psychologist	1	1 (100%)
Diabetes educator	1	0
GPs	1	0
Music Therapy clinician	1	0

Mode of delivery	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Face to face	21	15 (71.4%)
Telephone	5	3 (60%)
Face to face + telephone	4	3 (75%)

Type of psychological intervention	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Counselling	14	12 (85.7%)
CBT	14	8 (57.1%)
Collaborative care	1	0
Music therapy	1	0

Group or individual	No. of studies	No. (%) of studies where the intervention improved in HbA1c more than usual care/education
Individual	17	12 (70.6%)
Group	12	8 (66.6%)
Family	1	1 (100%)

Appendix 9 Additional tables and figures for the glycated haemoglobin level aggregate meta-analysis for adults with type 1 diabetes mellitus

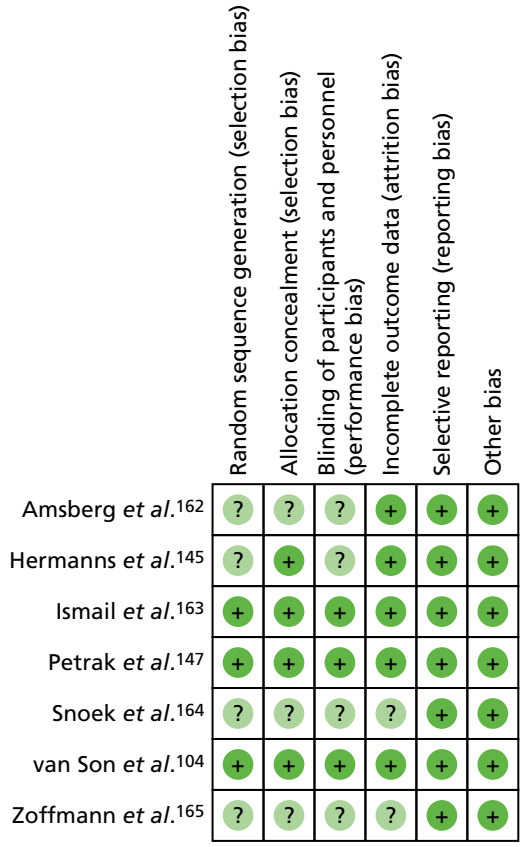

FIGURE 29 The RoB in studies of adults with T1DM.

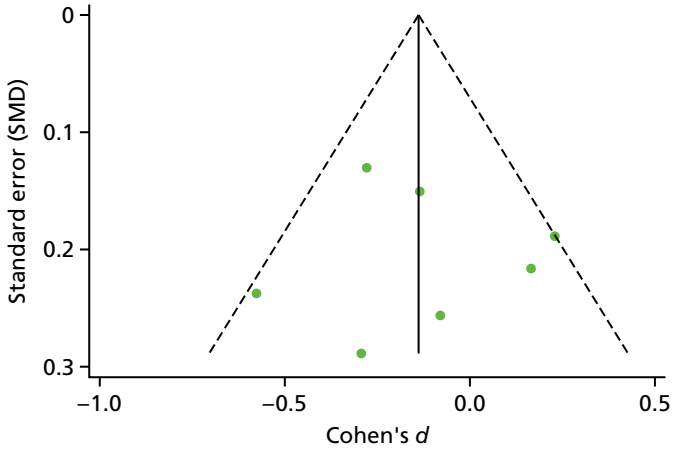

FIGURE 30 Funnel plot of publication bias in HbA_{1c} level outcome for adults with T1DM.

Appendix 10 Additional tables and figures for the glycated haemoglobin level aggregate meta-analysis for adolescents/children with type 1 diabetes mellitus

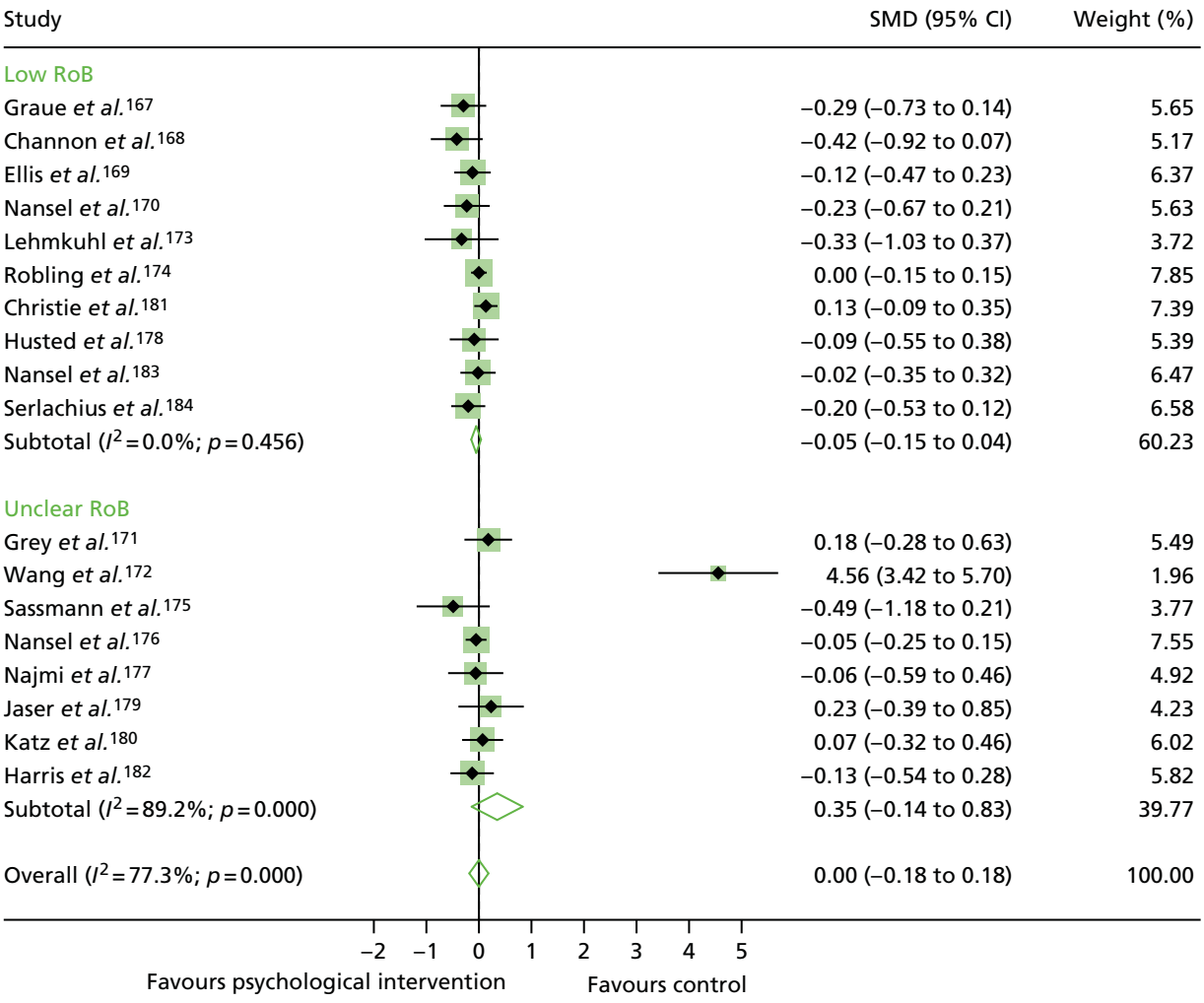

FIGURE 31 Subgroup analysis by RoB for adolescent/children with T1DM. Weights are from random effects analysis.

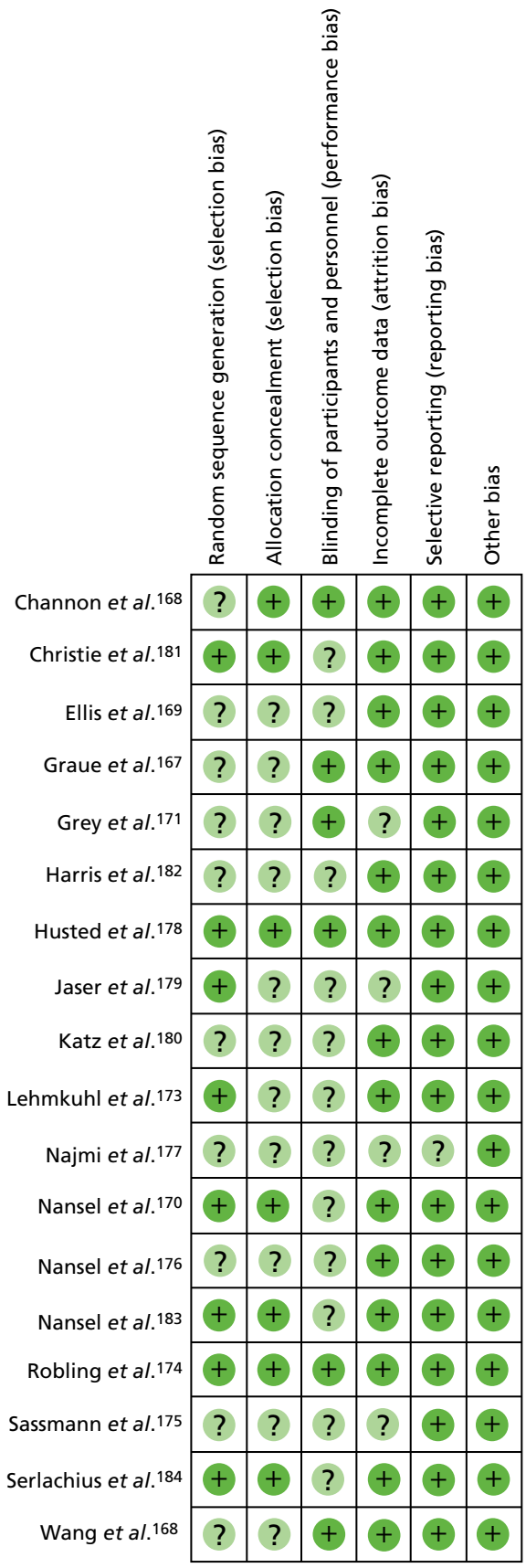

FIGURE 32 The RoB in studies of adolescents/children with T1DM.

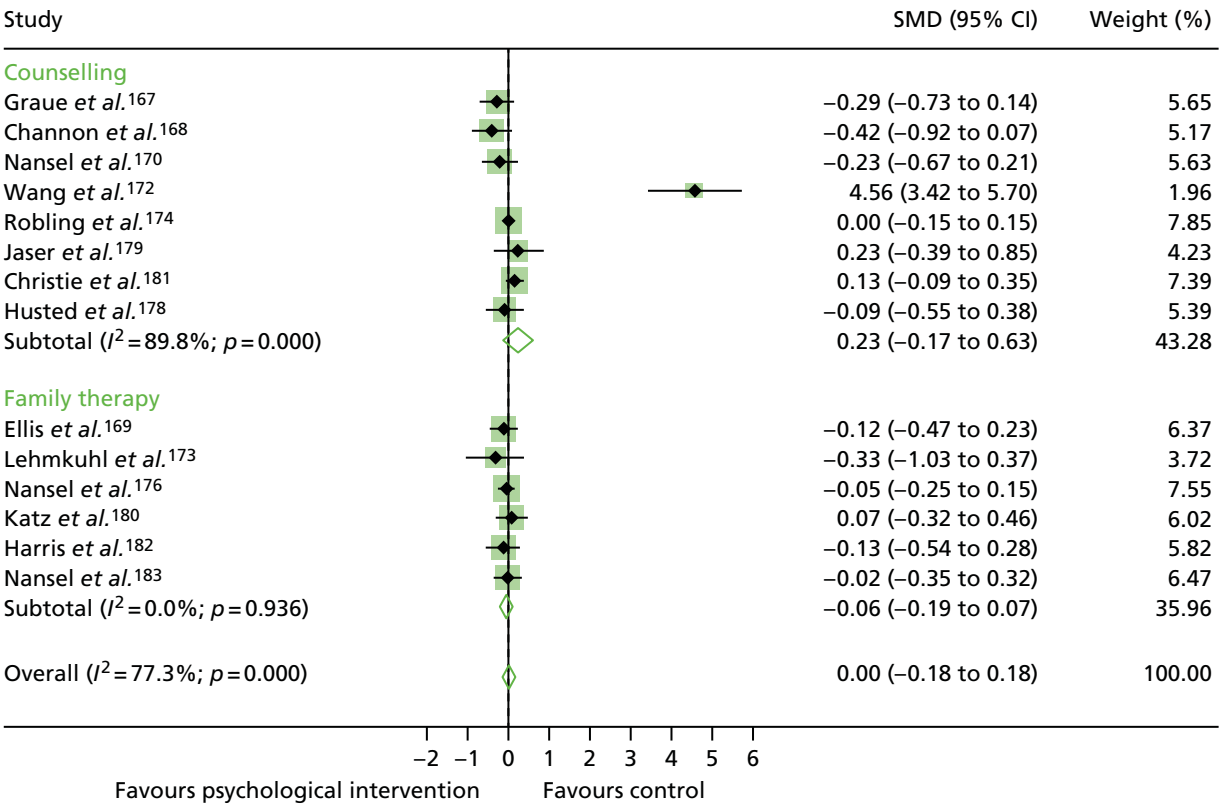

FIGURE 33 A subgroup meta-analysis of the SMD in HbA_{1c} levels by psychological intervention category in the psychological intervention groups compared with control groups in studies of adolescents/children with T1DM. Weights are from random effects analysis.

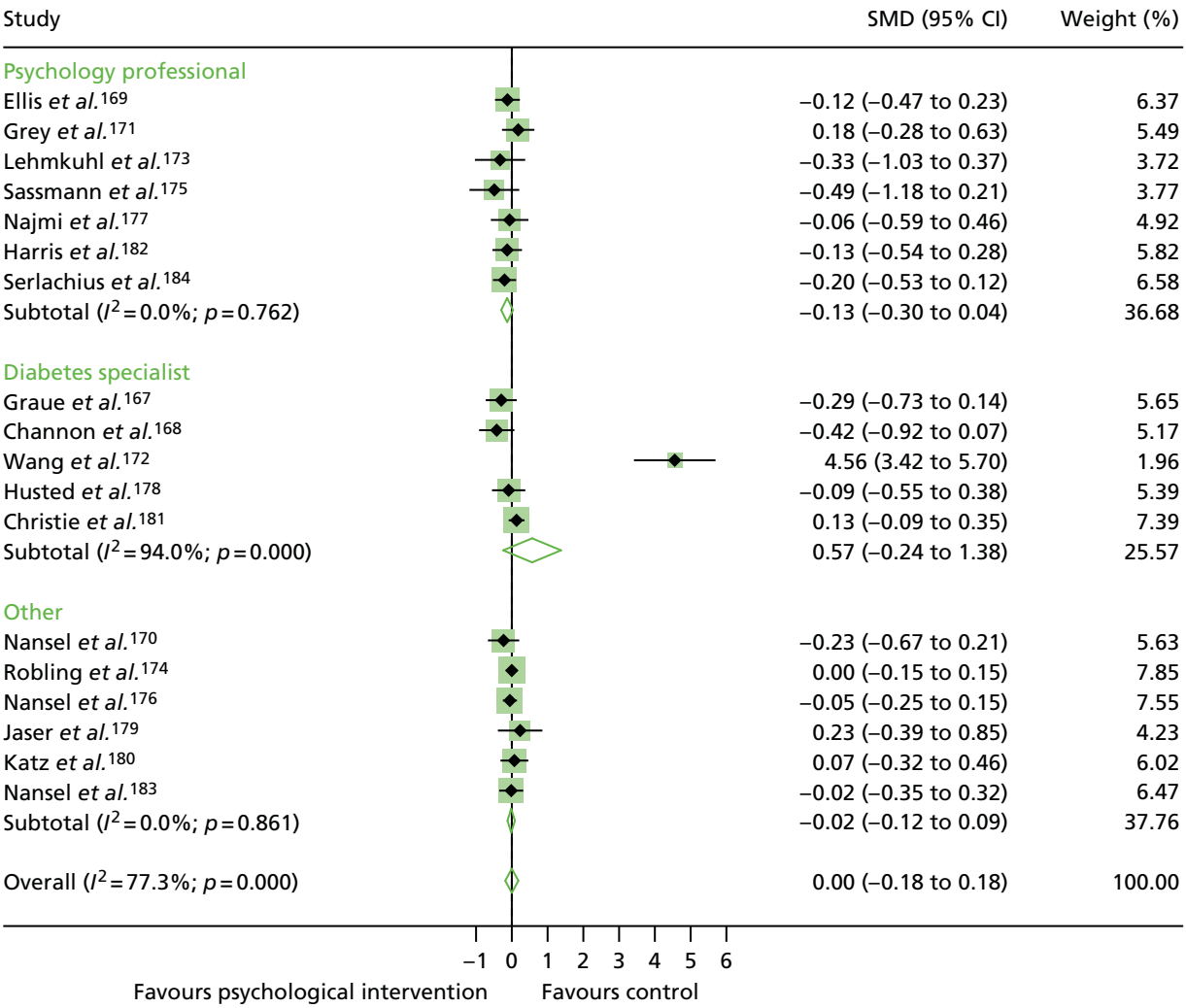

FIGURE 34 A subgroup meta-analysis of the SMD in HbA_{1c} level by interventionist in the psychological intervention groups compared with control groups in studies of adolescents/children with T1DM. Weights are from random effects analysis.

Appendix 11 Additional figures for glycated haemoglobin level aggregate meta-analysis for adults with type 2 diabetes mellitus

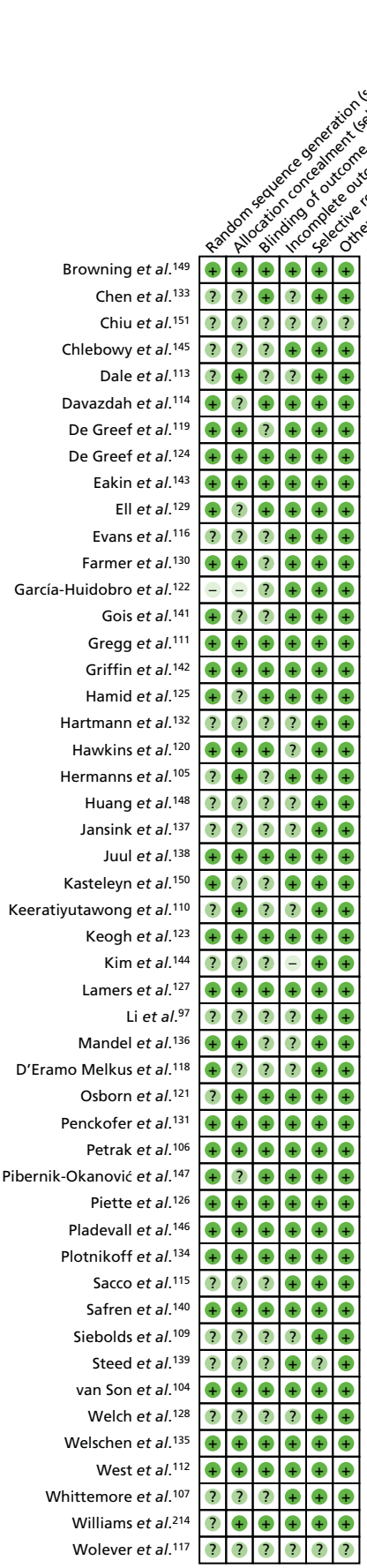

FIGURE 35 The RoB in studies of adults with T2DM.

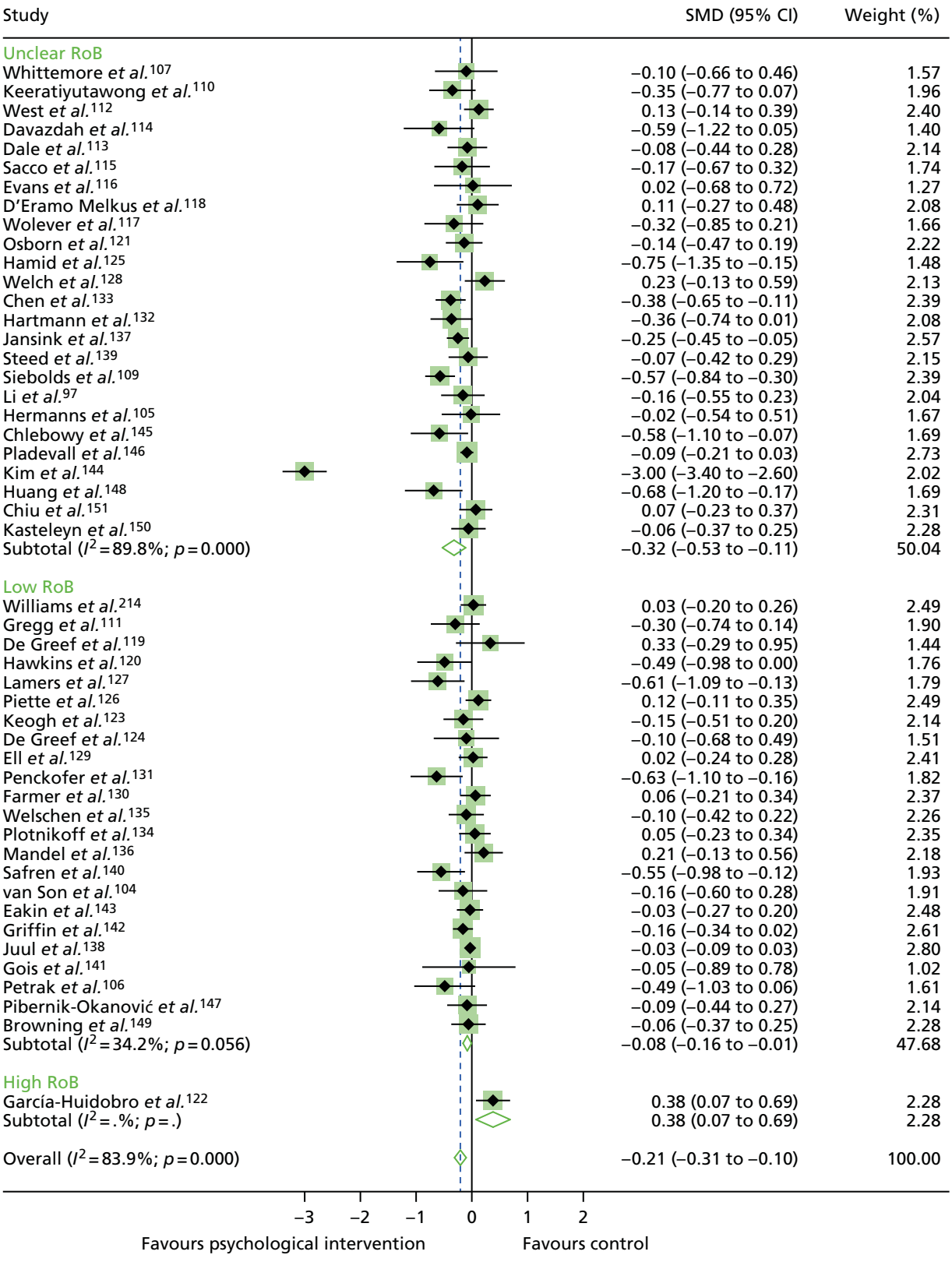

FIGURE 36 Subgroup analysis by RoB for studies of adults with T2DM. Weights are from random-effects analysis.

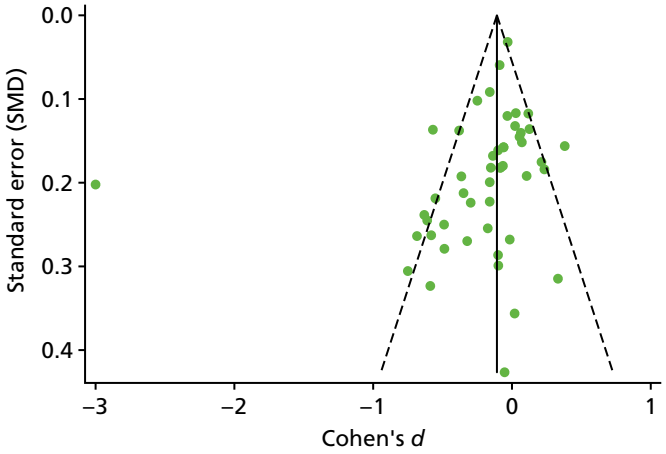

FIGURE 37 Funnel plot of publication bias for the outcome of HbA_{1c} levels in studies of adults with T2DM.

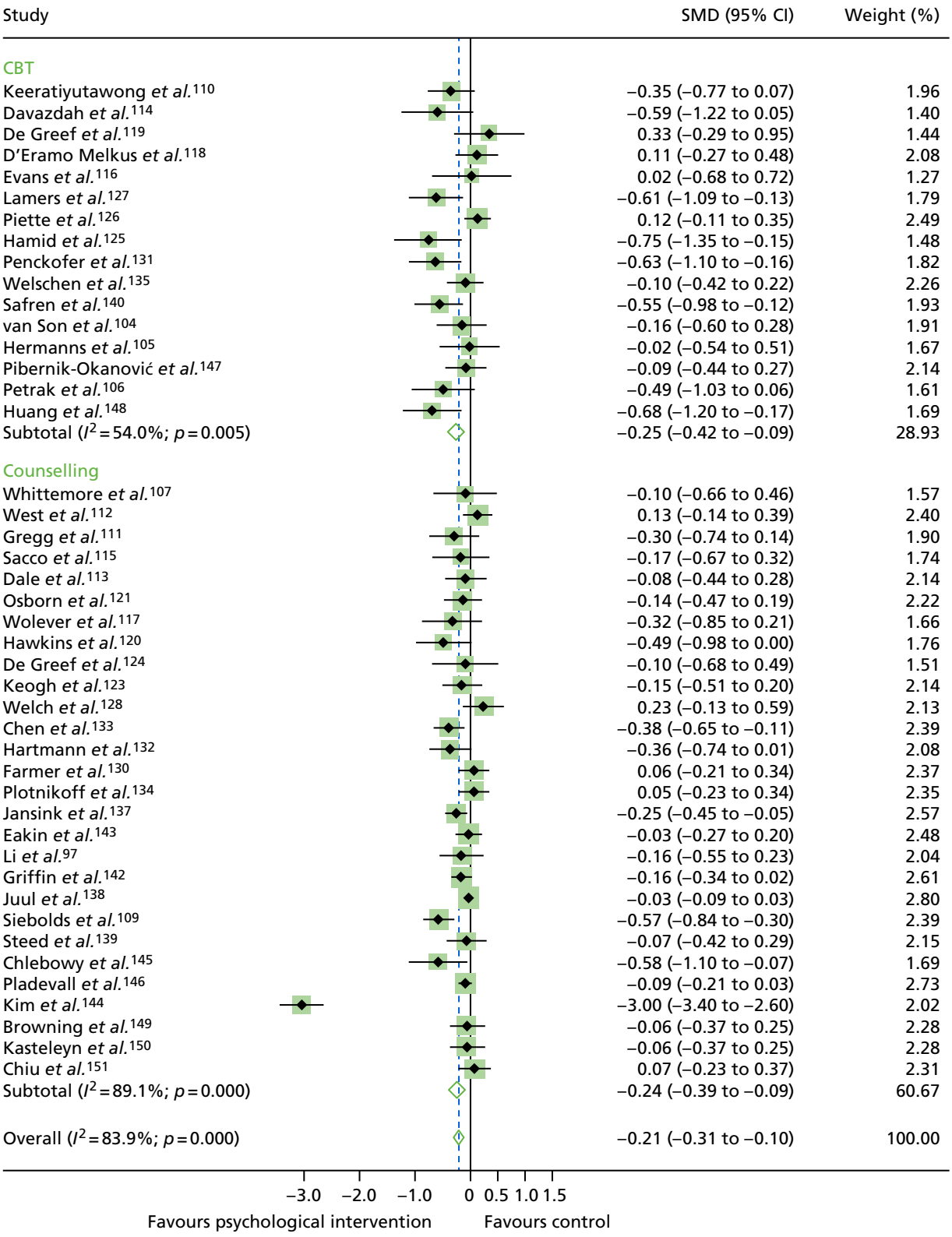

FIGURE 38 Subgroup meta-analysis of the SMD in HbA_{1c} levels by psychological intervention category in psychological intervention groups compared with control groups for studies of adults with T2DM. Weights are from random-effects analysis.

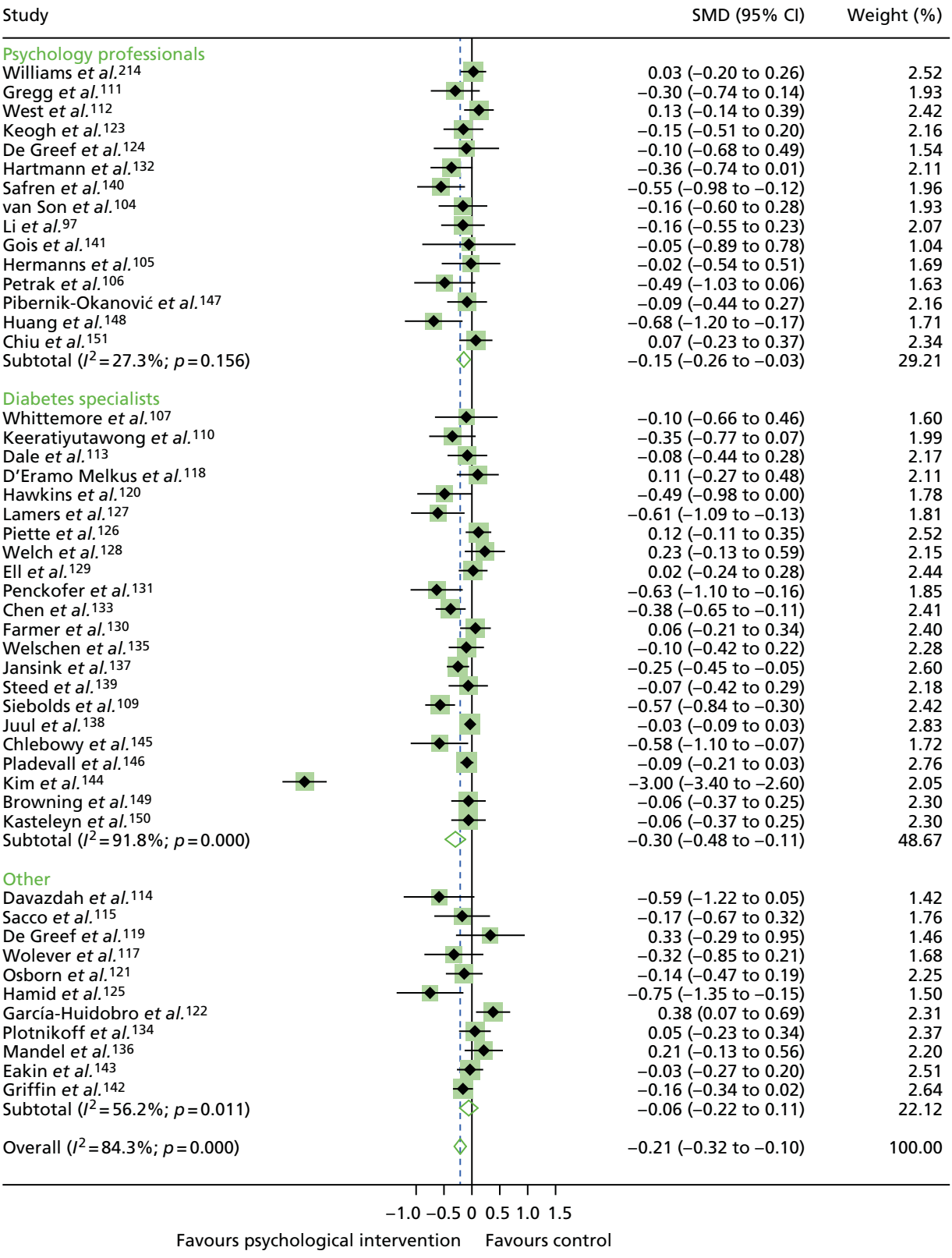

FIGURE 39 Subgroup meta-analysis of the SMD in HbA_{1c} levels by interventionist in psychological intervention groups compared with control groups for studies of adults with T2DM. Weights are from random-effects analysis.

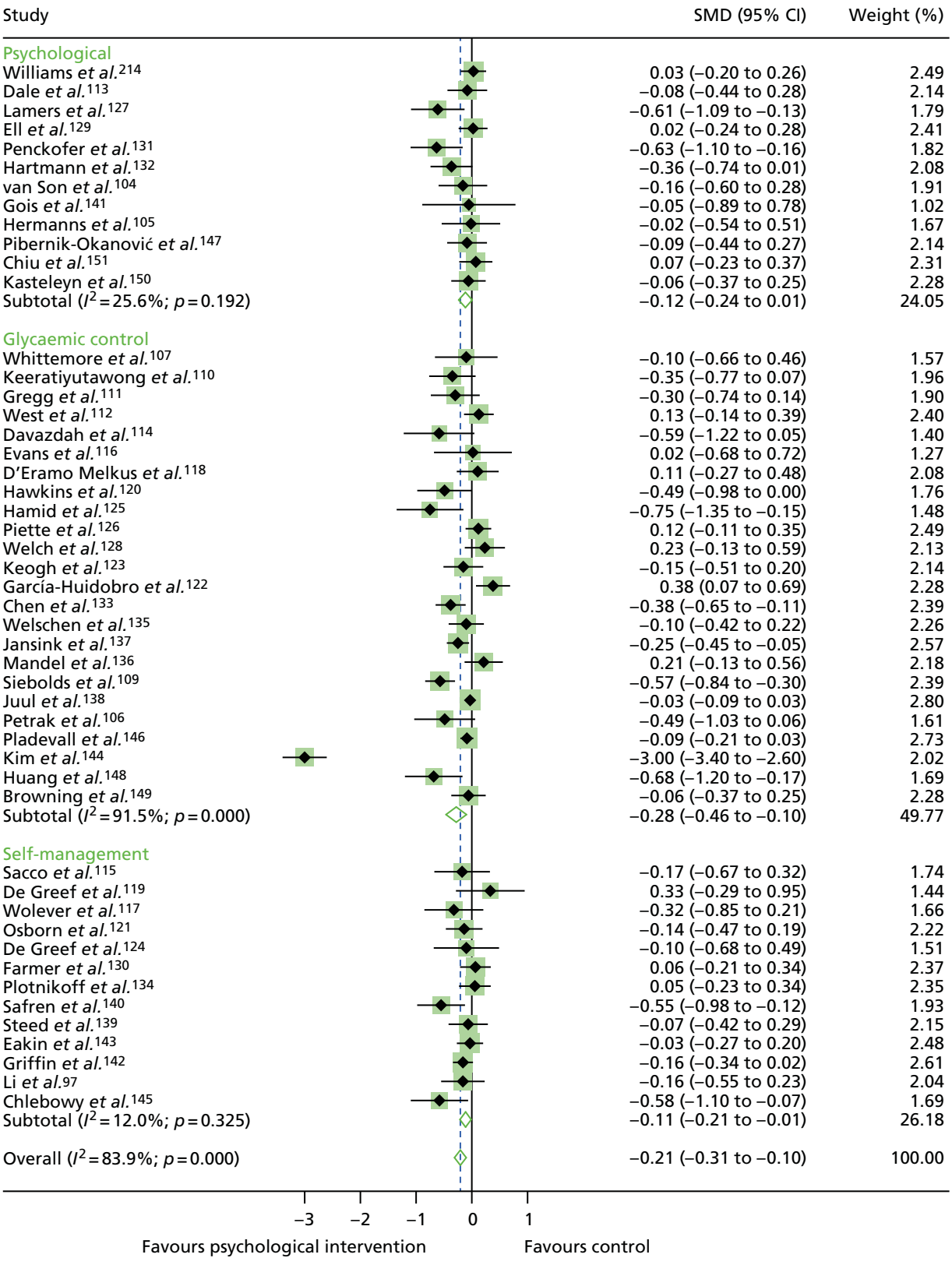

FIGURE 40 Subgroup meta-analysis of the SMD in HbA_{1c} levels by primary outcome in psychological intervention groups compared with control groups for studies of adults with T2DM. Weights are from random-effects analysis.

Appendix 12 Additional figures for secondary outcome aggregate meta-analysis for adults with type 2 diabetes mellitus

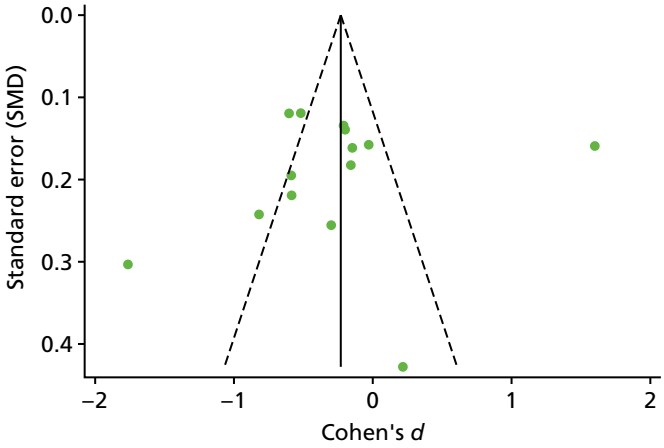

FIGURE 41 Funnel plot of publication bias for depression in studies of T2DM.

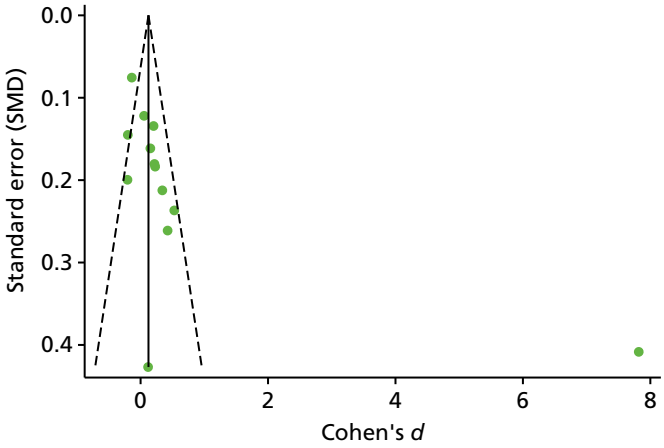

FIGURE 42 Funnel plot of publication bias for QoL in studies of T2DM.

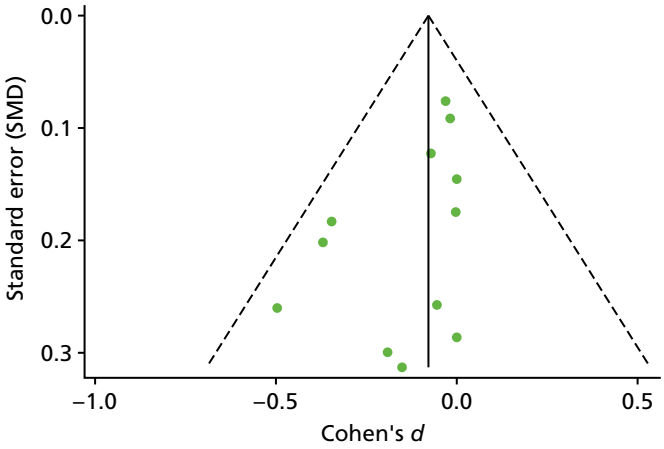

FIGURE 43 Funnel plot of publication bias for BMI in studies of T2DM.

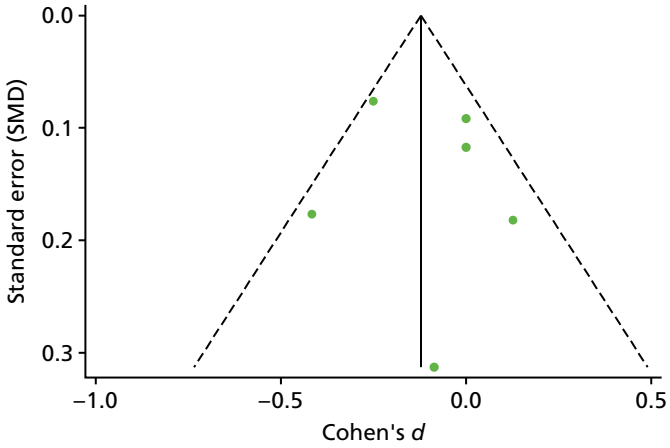

FIGURE 44 Funnel plot of publication bias for SBP in studies of adults with T2DM.

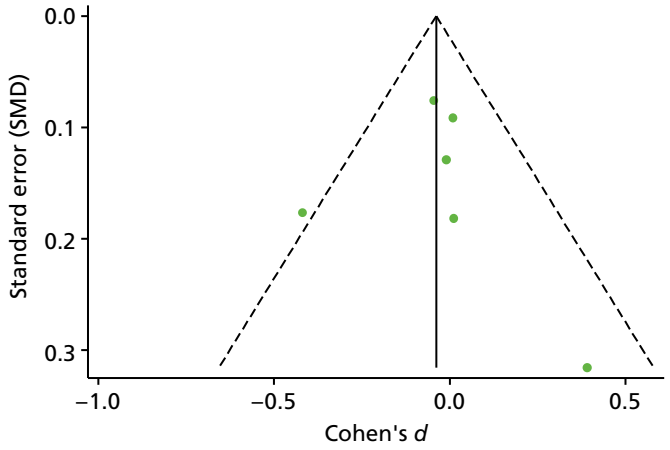

FIGURE 45 Funnel plot of publication bias for DBP in studies of adults with T2DM.

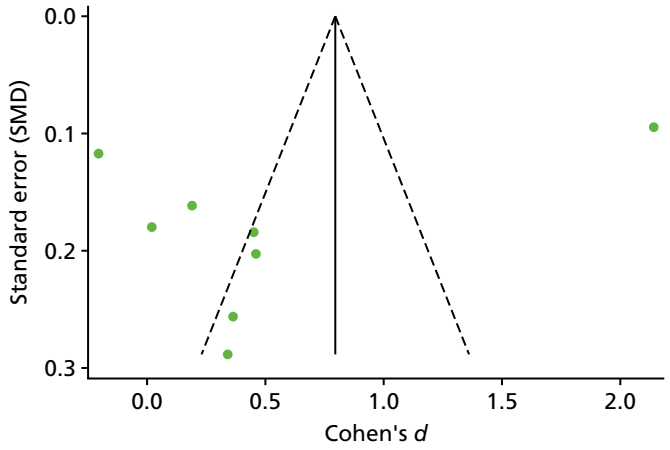

FIGURE 46 Funnel plot of publication bias for general diet behaviour in studies of adults with T2DM.

Appendix 13 Additional tables and figures for the network meta-analyses

TABLE 26 Mean rank and SUCRA for studies of adults with T1DM, derived from ranking probabilities

Treatment	Mean rank	SUCRA	Order of treatment
Usual care	3.9	0	4
CBT	2.0	0.7	3
Counselling	3.1	0.3	2
Attention control	1.1	1	1

Note
The lower the mean rank and the higher the SUCRA, the better the rank of the treatment. Order of treatment is final approximate rank of treatment effect based on SUCRA.

TABLE 27 Mean rank and SUCRA, derived from ranking probabilities of studies of adults with T2DM

Treatment	Mean rank	SUCRA	Order of treatment
Usual care	3.4	0.4	4
CBT	1.7	0.8	1.5
Counselling	1.9	0.8	1.5
Psychotherapy	3.2	0.5	3
Attention control	4.7	0.1	5

Note
The lower the mean rank and the higher the SUCRA, the better the rank of the treatment. Order of treatment is final approximate rank of treatment effect based on SUCRA.

TABLE 28 Summary of all pairwise comparisons of treatment effects, assuming common heterogeneity estimate for all treatment design comparisons, for studies of adults with T1DM

Treatment comparison		b	95% CI	SE	*z*-value	*p*-value
Usual care	CBT	–0.312	–0.499 to –0.126	0.095	–3.29	0.001
Usual care	Counselling	–0.121	–0.307 to 0.066	0.095	–1.27	0.21
Usual care	Attention control	–0.513	–0.848 to –0.177	0.1701	–3	0.003
Counselling	CBT	0.192	–0.027 to 0.410	0.111	1.72	0.085
CBT	Attention control	–0.2	–0.479 to 0.078	0.142	–1.41	0.078
Counselling	Attention control	–0.392	–0.746 to –0.038	0.181	–2.17	0.03

SE, standard error.

TABLE 29 Number of studies and arms included in the NMAs of studies of adolescents/children with T1DM

Treatment	Studies (*n*)	Studies (%)	Arm	Sample size (*n*)
CBT	4	11.1	T	167
Counselling	8	22.2	T	714
Family therapy	6	16.7	T	443
Usual care	11	30.6	C	1002
Attention control	5	13.9	C	183
Less intensive psychological intervention	2	5.7	C	74
Total	36	100		2583

C, arm was defined as control group in the original study; T, arm was defined as treatment arm in the original study.

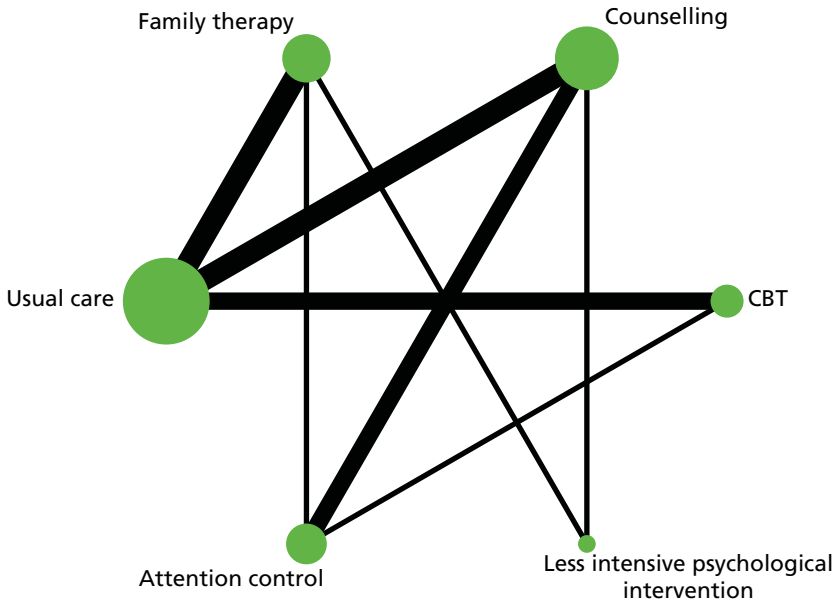

FIGURE 47 Network plots for all studies. Network plots of direct comparisons for the NMA of studies of adolescents/children with T1DM. The width of the lines is proportional to the number of trials comparing each pair of treatments and the size of each node is proportional to the number of studies testing that specific treatment. It shows, roughly, how much information is available for each treatment and for each treatment comparison.

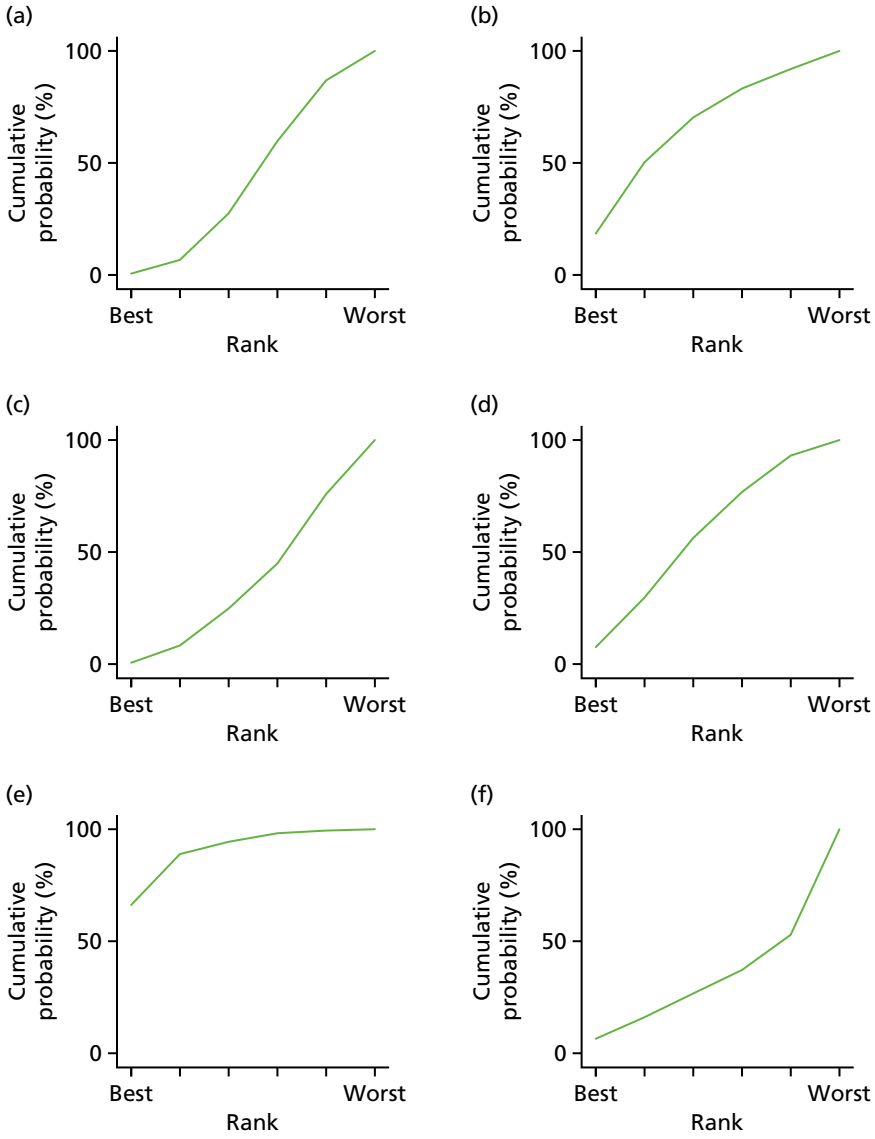

FIGURE 48 Rankogram for all treatments. The plot shows the SUCRA curves for all treatments for adolescents/children with T1DM. (a) Usual care; (b) CBT; (c) counselling; (d) family therapy; (e) attention control; and (f) less intensive psychological intervention. For example, usual care has a very low probability of being among the best treatments but a very high probability of being one of the worst.

TABLE 30 Mean rank and SUCRA derived from ranking probabilities of *Figure 48* for adolescents/children with T1DM

Treatment	Mean rank	SUCRA	Order of treatment
Usual care	4.2	0.4	4
CBT	2.9	0.6	2
Counselling	4.5	0.3	5.5
Family therapy	3.4	0.5	3
Attention control	1.5	0.9	1
Less intensive psychological intervention	4.6	0.3	5.5

Note
The lower the mean rank and the higher the SUCRA, the better the rank of the treatment. Order of treatment is final approximate rank of treatment effect based on SUCRA.

TABLE 31 Mean rank and SUCRA derived from ranking probabilities for adolescents/children with T1DM

Treatment	Mean rank	SUCRA	Order of treatment
Usual care	3.8	0.3	4
CBT	2.7	0.6	2.5
Counselling	4.2	0.2	5
Family therapy	2.9	0.5	2.5
Attention control	1.5	0.9	1

Note
The lower the mean rank and the higher the SUCRA, the better the rank of the treatment. Order of treatment is final approximate rank of treatment effect based on SUCRA.

TABLE 32 Summary of pairwise comparisons of all treatments, assuming a common heterogeneity estimate for all treatment design comparisons, for studies of adolescents/children with T1DM

Treatment comparison		b	95% CI	SE	*z*-value	*p*-value
CBT	Counselling	0.417	–0.628 to 1.462	0.533	0.78	0.43
CBT	Family therapy	0.145	–0.946 to 1.236	0.557	0.26	0.8
CBT	Usual care	0.329	–0.538 to 1.196	0.442	0.74	0.46
CBT	Attention control	–0.439	–1.525 to 0.648	0.554	–0.79	0.43
CBT	Less intensive psychological intervention	0.549	–0.967 to 2.066	0.774	0.71	0.48
Counselling	Family therapy	–0.275	–1.194 to 0.645	0.469	–0.59	0.56
Counselling	Usual care	–0.09	–0.804 to 0.625	0.365	–0.25	0.81
Counselling	Attention control	–0.864	–1.732 to 0.005	0.443	–1.95	0.05
Counselling	Less intensive psychological intervention	0.131	–1.137 to 1.399	0.647	0.2	0.84
Family therapy	Usual care	0.184	–0.548 to 0.916	0.374	0.49	0.62
Family therapy	Attention control	–0.584	–1.598 to 0.431	0.518	–1.13	0.26
Family therapy	Less intensive psychological intervention	0.404	–0.848 to 1.657	0.639	0.63	0.53
Usual care	Attention control	–0.768	–1.704 to 0.169	0.478	–1.61	0.11
Usual care	Less intensive psychological intervention	0.22	–1.076 to 1.516	0.661	0.33	0.74
Attention control	Less intensive psychological intervention	0.993	–0.449 to 2.435	0.736	1.35	0.18

SE, standard error.

TABLE 33 Summary of pairwise comparisons of all treatments, assuming a common heterogeneity estimate for all treatment design comparisons, for studies of adolescents/children with T1DM

Treatment comparison		b	95% CI	SE	*z*-value	*p*-value
CBT	Counselling	0.47	–0.649 to 1.59	0.571	0.82	0.41
CBT	Family therapy	0.09	–1.088 to 1.267	0.601	0.15	0.88
CBT	Usual care	0.329	–0.588 to 1.246	0.468	0.7	0.48
CBT	Attention control	–0.438	–1.587 to 0.711	0.586	–0.75	0.46
Counselling	Family therapy	–0.383	–1.439 to 0.672	0.538	–0.71	0.48
Counselling	Usual care	–0.143	–0.924 to 0.639	0.399	–0.36	0.72
Counselling	Attention control	–0.915	–1.835 to 0.005	0.469	–1.95	0.05
Family therapy	Usual care	0.24	–0.565 to 1.044	0.41	0.58	0.56
Family therapy	Attention control	–0.528	–1.634 to 0.579	0.565	–0.93	0.35
Usual care	Attention control	–0.767	–1.757 to 0.222	0.505	–1.52	0.13

SE, standard error.

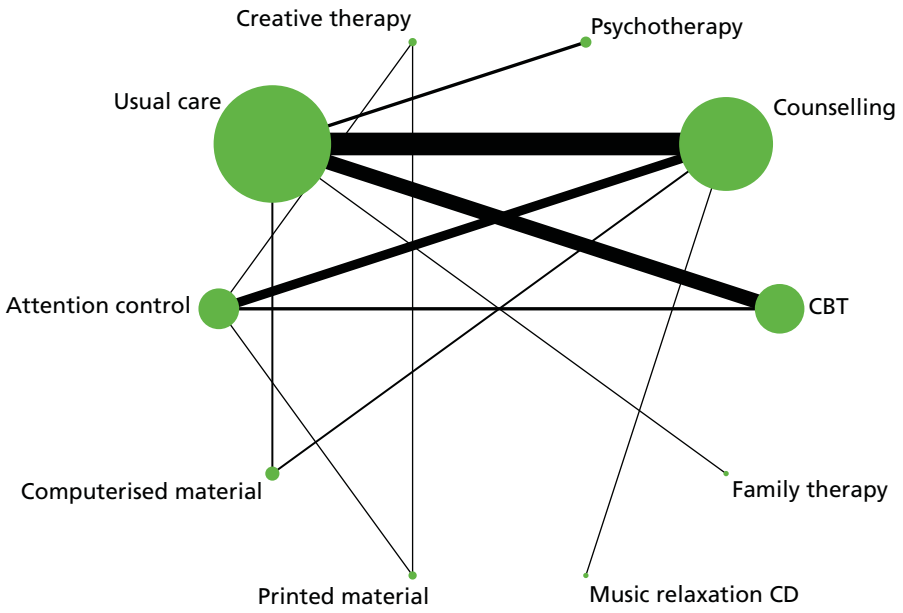

FIGURE 49 Network plots for all studies. Network plots of direct comparisons for the NMA for adults with T2DM. The width of the lines is proportional to the number of trials comparing each pair of treatments and the size of each node is proportional to the number of studies testing the specific treatment. It shows roughly how much information is available for each treatment and for each treatment comparison.

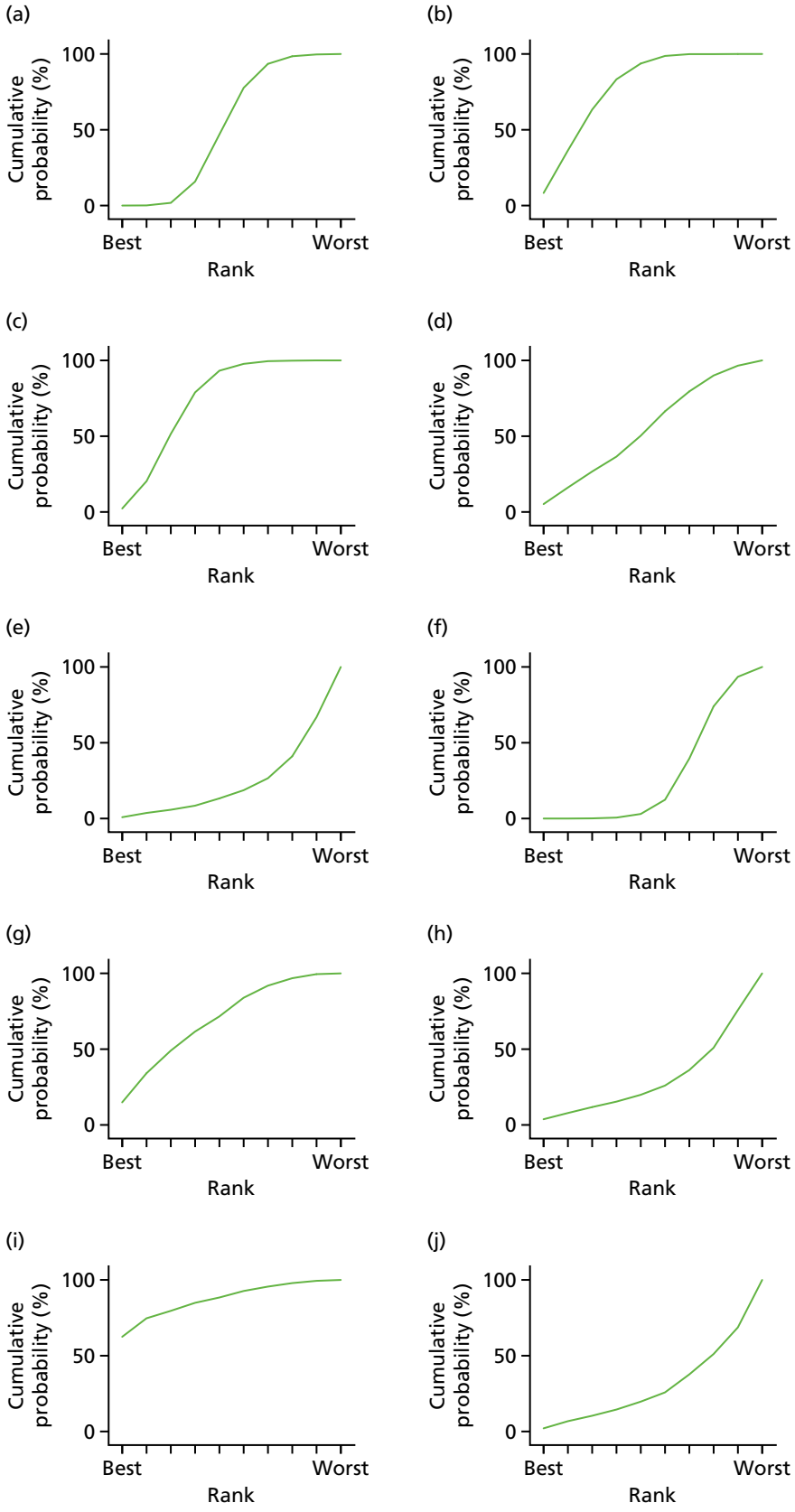

FIGURE 50 Rankogram for all treatments in studies of adults with T2DM. (a) Usual care; (b) CBT; (c) counselling; (d) psychotherapy; (e) creative therapy; (f) attention control; (g) computerised material; (h) printed material; (i) music relaxation CD; and (j) family therapy. The plot shows the SUCRA curves for all treatments. For example, usual care has a very low probability of being among the best treatments, but a very high probability of being one of the worst treatments.

TABLE 34 The mean rank and SUCRA derived from ranking probabilities of *Figure 55* for adults with T2DM

Treatment	Mean rank	SUCRA	Order of treatment
Usual care	5.7	0.5	5.5
CBT	3.2	0.8	2
Counselling	3.6	0.7	3.5
Psychotherapy	5.3	0.5	5.5
Creative therapy	8.1	0.2	9.5
Attention control	7.8	0.2	9.5
Computerised material	4.0	0.7	3.5
Printed material	7.5	0.3	7.5
Music relaxation CD	2.2	0.9	1
Family therapy	7.6	0.3	7.5

CD, compact disc.
Note
The lower the mean rank and the higher the SUCRA, the better the rank of the treatment. Order of treatment is final approximate rank of treatment effect based on SUCRA.

TABLE 35 Summary of pairwise comparisons of all treatment assuming common heterogeneity estimate for all treatment design comparisons for adults with T2DM

Number	Treatment comparison		b	95% CI	SE	*z*-value	*p*-value
1	CBT	Counselling	0.046	–0.249 to 0.342	0.151	0.31	0.76
2	CBT	Psychotherapy	0.222	–0.376 to 0.819	0.305	0.73	0.47
3	CBT	Creative therapy	0.703	–0.263 to 1.67	0.493	1.43	0.15
4	CBT	Usual care	0.213	–0.035 to 0.46	0.126	1.68	0.09
5	CBT	Attention control	0.483	0.13 to 0.835	0.18	2.68	0.01
6	CBT	Computerised material	0.057	–0.527 to 0.641	0.298	0.19	0.85
7	CBT	Printed material	0.586	–0.38 to 1.551	0.493	1.19	0.23
8	CBT	Music relaxation CD	–0.349	–1.305 to 0.608	0.488	–0.71	0.48
9	CBT	Family therapy	0.591	–0.329 to 1.511	0.469	1.26	0.21
10	Counselling	Psychotherapy	0.175	–0.402 to 0.753	0.295	0.6	0.55
11	Counselling	Creative therapy	0.657	–0.287 to 1.602	0.482	1.36	0.17
12	Counselling	Usual care	0.166	–0.027 to 0.36	0.099	1.68	0.09
13	Counselling	Attention control	0.436	0.15 to 0.723	0.146	2.98	0
14	Counselling	Computerised material	0.01	–0.524 to 0.545	0.273	0.04	0.97
15	Counselling	Printed material	0.54	–0.404 to 1.483	0.481	1.12	0.26
16	Counselling	Music relaxation CD	–0.395	–1.305 to 0.515	0.464	–0.85	0.4
17	Counselling	Family therapy	0.545	–0.362 to 1.452	0.463	1.18	0.24
18	Psychotherapy	Creative therapy	0.482	–0.616 to 1.58	0.56	0.86	0.39
19	Psychotherapy	Usual care	–0.009	–0.551 to 0.534	0.277	–0.03	0.98
20	Psychotherapy	Attention control	0.261	–0.369 to 0.892	0.322	0.81	0.42
21	Psychotherapy	Computerised material	–0.165	–0.926 to 0.597	0.389	–0.42	0.67
22	Psychotherapy	Printed material	0.365	–0.733 to 1.462	0.56	0.65	0.52
23	Psychotherapy	Music relaxation CD	–0.57	–1.647 to 0.506	0.549	–1.04	0.3

continued

TABLE 35 Summary of pairwise comparisons of all treatment assuming common heterogeneity estimate for all treatment design comparisons for adults with T2DM (*continued*)

Number	Treatment comparison		b	95% CI	SE	*z*-value	*p*-value
24	Psychotherapy	Family therapy	0.37	–0.669 to 1.409	0.53	0.7	0.49
25	Creative therapy	Usual care	–0.485	–1.435 to 0.465	0.485	–1	0.32
26	Creative therapy	Attention control	–0.215	–1.11 to 0.679	0.456	–0.47	0.64
27	Creative therapy	Computerised material	–0.641	–1.717 to 0.436	0.549	–1.17	0.24
28	Creative therapy	Printed material	–0.115	–1.011 to 0.781	0.457	–0.25	0.8
29	Creative therapy	Music relaxation CD	–1.046	–2.353 to 0.261	0.667	–1.57	0.12
30	Creative therapy	Family therapy	–0.106	–1.405 to 1.193	0.663	–0.16	0.87
31	Usual care	Attention control	0.27	–0.051 to 0.591	0.164	1.65	0.1
32	Usual care	Computerised material	–0.156	–0.69 to 0.379	0.273	–0.57	0.57
33	Usual care	Printed material	0.373	–0.581 to 1.328	0.487	0.77	0.44
34	Usual care	Music relaxation CD	–0.562	–1.492 to 0.369	0.475	–1.18	0.24
35	Usual care	Family therapy	0.379	–0.507 to 1.265	0.452	0.84	0.4
36	Attention control	Computerised material	–0.426	–1.025 to 0.174	0.306	–1.39	0.16
37	Attention control	Printed material	0.103	–0.796 to 1.002	0.459	0.23	0.82
38	Attention control	Music relaxation CD	–0.831	–1.785 to 0.123	0.487	–1.71	0.09
39	Attention control	Family therapy	0.109	–0.834 to 1.051	0.481	0.23	0.82
40	Computerised material	Printed material	0.529	–0.551 to 1.608	0.551	0.96	0.34
41	Computerised material	Music relaxation CD	–0.406	–1.46 to 0.648	0.538	–0.75	0.45
42	Computerised material	Family therapy	0.534	–0.5 to 1.568	0.528	1.01	0.31
43	Printed material	Music relaxation CD	–0.93	–2.237 to 0.376	0.667	–1.4	0.16
44	Printed material	Family therapy	0.01	–1.288 to 1.308	0.662	0.02	0.99
45	Music relaxation CD	Family therapy	0.935	–0.346 to 2.215	0.653	1.43	0.15

CD, compact disc; SE, standard error.

TABLE 36 Summary of pairwise comparisons of all treatments, assuming a common heterogeneity estimate for all treatment design comparisons, for studies of adults with T2DM

Number	Treatment comparison		b	95% CI	SE	*z*-value	*p*-value
1	CBT	Counselling	0.047	–0.253 to 0.347	0.153	0.31	0.76
2	CBT	Psychotherapy	0.222	–0.384 to 0.828	0.309	0.72	0.47
3	CBT	Usual care	0.213	–0.038 to 0.464	0.128	1.66	0.1
4	CBT	Attention control	0.483	0.125 to 0.841	0.183	2.65	0.01
5	Counselling	Psychotherapy	0.175	–0.411 to 0.76	0.299	0.58	0.56
6	Counselling	Usual care	0.166	–0.031 to 0.362	0.1	1.66	0.1
7	Counselling	Attention control	0.436	0.146 to 0.727	0.148	2.94	0
8	Psychotherapy	Usual care	–0.009	–0.559 to 0.542	0.281	–0.03	0.98
9	Psychotherapy	Attention control	0.262	–0.378 to 0.901	0.326	0.8	0.42
10	Usual care	Attention control	0.27	–0.056 to 0.596	0.166	1.63	0.1

SE, standard error.

Note

'b' is the SMD using TAU as the control group. The formulas for Hedges' *g* in White and Thomas[87] are used.

Appendix 14 Additional tables and figures for the individual patient data meta-analysis

TABLE 37 Study ID against reference for IPD studies

Reference	ID
Studies of only adults with T1DM	
Ismail K, Thomas SM, Maissi E, Chalder T, Schmidt U, Bartlett J, *et al.* Motivational enhancement therapy with and without cognitive behavior therapy to treat type 1 diabetes: a randomized trial. *Ann Intern Med* 2008;**149**:708–19[163]	ITM08
Snoek FJ, van der Ven NC, Twisk JW, Hogenelst MH, Tromp-Wever AM, van der Ploeg HM, Heine RJ. Cognitive behavioural therapy (CBT) compared with blood glucose awareness training (BGAT) in poorly controlled type 1 diabetic patients: long-term effects on HbA moderated by depression. A randomized controlled trial. *Diabet Med* 2008;**25**:1337–42[164]	SVT08
Studies of adolescents/children with T1DM	
Channon SJ, Huws-Thomas MV, Rollnick S, Hood K, Cannings-John RL, Rogers C, Gregory JW. A multicenter randomized controlled trial of motivational interviewing in teenagers with diabetes. *Diabetes Care* 2007;**30**:1390–5[168]	CHR07
Ellis DA, Templin T, Naar-King S, Frey MA, Cunningham PB, Podolski CL, Cakan N. Multisystemic therapy for adolescents with poorly controlled type I diabetes: stability of treatment effects in a randomized controlled trial. *J Consult Clin Psychol* 2007;**75**:168–74[169]	ETN07
Grey M, Whittemore R, Jaser S, Ambrosino J, Lindemann E, Liberti L, *et al.* Effects of coping skills training in school-age children with type 1 diabetes. *Res Nurs Health* 2009;**32**:405–18[171]	GWJ09
Nansel TR, Iannotti RJ, Liu A. Clinic-integrated behavioral intervention for families of youth with type 1 diabetes: randomized clinical trial. *Pediatrics* 2012;**129**:e866–73[176]	NIL12 aka FMOD
Jaser SS, Patel N, Rothman RL, Choi L, Whittemore R. Check it! A randomized pilot of a positive psychology intervention to improve adherence in adolescents with type 1 diabetes. *Diabetes Educ* 2014;**40**:659–67[179]	JPR14
Nansel TR, Laffel LM, Haynie DL, Mehta SN, Lipsky LM, Volkening LK, *et al.* Improving dietary quality in youth with type 1 diabetes: randomized clinical trial of a family-based behavioral intervention. *Int J Behav Nutr Phys Act* 2015;**12**:58[183]	NLH15 aka CHEF
Serlachius AS, Scratch SE, Northam EA, Frydenberg E, Lee KJ, Cameron FJ. A randomized controlled trial of cognitive behaviour therapy to improve glycaemic control and psychosocial wellbeing in adolescents with type 1 diabetes. *J Health Psychol* 2016;**21**:1157–69[184]	SSN16
Nansel TR, Iannotti RJ, Simons-Morton BG, Cox C, Plotnick LP, Clark LM, Zeitzoff L. Diabetes personal trainer outcomes: short-term and 1-year outcomes of a diabetes personal trainer intervention among youth with type 1 diabetes. *Diabetes Care* 2007;**30**:2471–7[170]	NIS07 aka DPT study
Christie D, Thompson R, Sawtell M, Allen E, Cairns J, Smith F, *et al.* Structured, intensive education maximising engagement, motivation and long-term change for children and young people with diabetes: a cluster randomised controlled trial with integral process and economic evaluation – the CASCADE study. *Health Technol Assess* 2014;**18**(20)[181]	CTS14
Studies of adults with T2DM	
Chiu CJ, Hu YH, Wray LA, Beverley EA, Yang YC, Wu JS, Lu FH. Dissemination of evidence-base minimal psychological intervention for diabetes management in Taiwan adults with type 2 diabetes. *Int J Clin Exp Med* 2016;**9**:14489–98[151]	CHW16
D'Eramo Melkus G, Chyun D, Vorderstrasse A, Newlin K, Jefferson V, Langerman S. The effect of a diabetes education, coping skills training, and care intervention on physiological and psychosocial outcomes in black women with type 2 diabetes. *Biol Res Nurs* 2010;**12**:7–19[118]	ECV10

continued

TABLE 37 Study ID against reference for IPD studies (*continued*)

Reference	ID
Keogh KM, Smith SM, White P, McGilloway S, Kelly A, Gibney J, O'Dowd T. Psychological family intervention for poorly controlled type 2 diabetes. *Am J Manag Care* 2011;**17**:105–13[123]	KSW11
Hartmann M, Kopf S, Kircher C, Faude-Lang V, Djuric Z, Augstein F, *et al.* Sustained effects of a mindfulness-based stress-reduction intervention in type 2 diabetic patients: design and first results of a randomized controlled trial (the Heidelberger Diabetes and Stress-study). *Diabetes Care* 2012;**35**:945–7[132]	HKK12
Safren SA, Gonzalez JS, Wexler DJ, Psaros C, Delahanty LM, Blashill AJ, *et al.* A randomized controlled trial of cognitive behavioral therapy for adherence and depression (CBT-AD) in patients with uncontrolled type 2 diabetes. *Diabetes Care* 2014;**37**:625–33[140]	SGW14
Welschen LM, van Oppen P, Bot SD, Kostense PJ, Dekker JM, Nijpels G. Effects of a cognitive behavioural treatment in patients with type 2 diabetes when added to managed care; a randomised controlled trial. *J Behav Med* 2013;**36**:556–66[135]	WOB13
Eakin EG, Winkler EA, Dunstan DW, Healy GN, Owen N, Marshall AM, *et al.* Living well with diabetes: 24-month outcomes from a randomized trial of telephone-delivered weight loss and physical activity intervention to improve glycemic control. *Diabetes Care* 2014;**37**:2177–85[143]	EWD14
Chlebowy DO, El-Mallakh P, Myers J, Kubiak N, Cloud R, Wall MP. Motivational interviewing to improve diabetes outcomes in African Americans adults with diabetes. *West J Nurs Res* 2015;**37**:566–80[145]	CEM15
Kasteleyn MJ, Vos RC, Rijken M, Schellevis FG, Rutten GE. Effectiveness of tailored support for people with type 2 diabetes after a first acute coronary event: a multicentre randomized controlled trial (the Diacourse-ACE study). *Diabet Med* 2016;**33**:125–33[150]	KVR16
Griffin SJ, Simmons RK, Prevost AT, Williams KM, Hardeman W, Sutton S, *et al.* Multiple behaviour change intervention and outcomes in recently diagnosed type 2 diabetes: the ADDITION-Plus randomised controlled trial. *Diabetologia* 2014;**57**:1308–19[142]	GSP14
Mandel SE, Davis BA, Secic M. Effects of music therapy and music-assisted relaxation and imagery on health-related outcomes in diabetes education: a feasibility study. *Diabetes Educ* 2013;**39**:568–81[136]	MDS13
Jansink R, Braspenning J, Keizer E, van der Weijden T, Elwyn G, Grol R. No identifiable HbA1c or lifestyle change after a comprehensive diabetes programme including motivational interviewing: a cluster randomised trial. *Scand J Prim Health Care* 2013;**31**:119–27[137]	JBK13
Dale J, Caramlau I, Sturt J, Friede T, Walker R. Telephone peer-delivered intervention for diabetes motivation and support: the telecare exploratory RCT. *Patient Educ Couns* 2009;**75**:91–8[113]	DCS09
Ell K, Katon W, Xie B, Lee PJ, Kapetanovic S, Guterman J, Chou CP. One-year postcollaborative depression care trial outcomes among predominantly Hispanic diabetes safety net patients. *Gen Hosp Psychiatry* 2011;**33**:436–42[129]	EKX11
Pibernik-Okanović M, Hermanns N, Ajduković D, Kos J, Prašek M, Šekerija M, Lovrenčić MV. Does treatment of subsyndromal depression improve depression-related and diabetes-related outcomes? A randomised controlled comparison of psychoeducation, physical exercise and enhanced treatment as usual. *Trials* 2015;**16**:305[147]	PHA15
Studies of adults with a T1DM and T2DM population	
Hermanns N, Schmitt A, Gahr A, Herder C, Nowotny B, Roden M, *et al.* The effect of a Diabetes-Specific Cognitive Behavioral Treatment Program (DIAMOS) for patients with diabetes and subclinical depression: results of a randomized controlled trial. *Diabetes Care* 2015;**38**:551–60[105]	HSG15
van Son J, Nyklíček I, Pop VJ, Blonk MC, Erdtsieck RJ, Pouwer F. Mindfulness-based cognitive therapy for people with diabetes and emotional problems: long-term follow-up findings from the DiaMind randomized controlled trial. *J Psychosom Res* 2014;**77**:81–4[104]	VNP14
Petrak F, Herpertz S, Albus C, Hermanns N, Hiemke C, Hiller W, *et al.* Cognitive behavioral therapy versus sertraline in patients with depression and poorly controlled diabetes: the Diabetes and Depression (DAD) study: a randomized controlled multicenter trial. *Diabetes Care* 2015;**38**:767–75[106]	PET15

TABLE 38 Comparison of characteristics between all studies and studies included in the IPD meta-analysis

Variable	Included in IPD	All studies ($n = 74$)	Difference between studies included in IPD and all studies (p-value)
Population, mean (SD); range	160.03 (111.85); 40–478	202.62 (469.74), 22–3946	0.63
Location, *n* (%)			
Asia	1 (3.45)	9 (12.16)	0.62
Australia	2 (6.90)	3 (4.05)	
Europe (non-UK)	10 (34.48)	24 (32.43)	
North America	5 (17.24)	19 (25.68)	
South America	0 (0)	1 (1.35)	
UK	5 (17.24)	8 (10.81)	
USA	6 (20.69)	10 (13.51)	
Year, range	2007–2016	2004–2016	0.45
Type of psychological intervention, *n* (%)			
CBT	11 (37.93)	26 (35.14)	0.95
Counselling	13 (44.83)	37 (50)	
Creative therapy	1 (3.45)	1 (1.35)	
Family therapy	3 (10.34)	7 (9.46)	
Psychotherapy	1 (3.45)	3 (4.05)	
RoB assessment, *n* (%)			
Low	18 (62.07)	37 (50)	0.48
Unclear	11 (37.03)	36 (48.65)	
High	0 (0)	1 (1.35)	

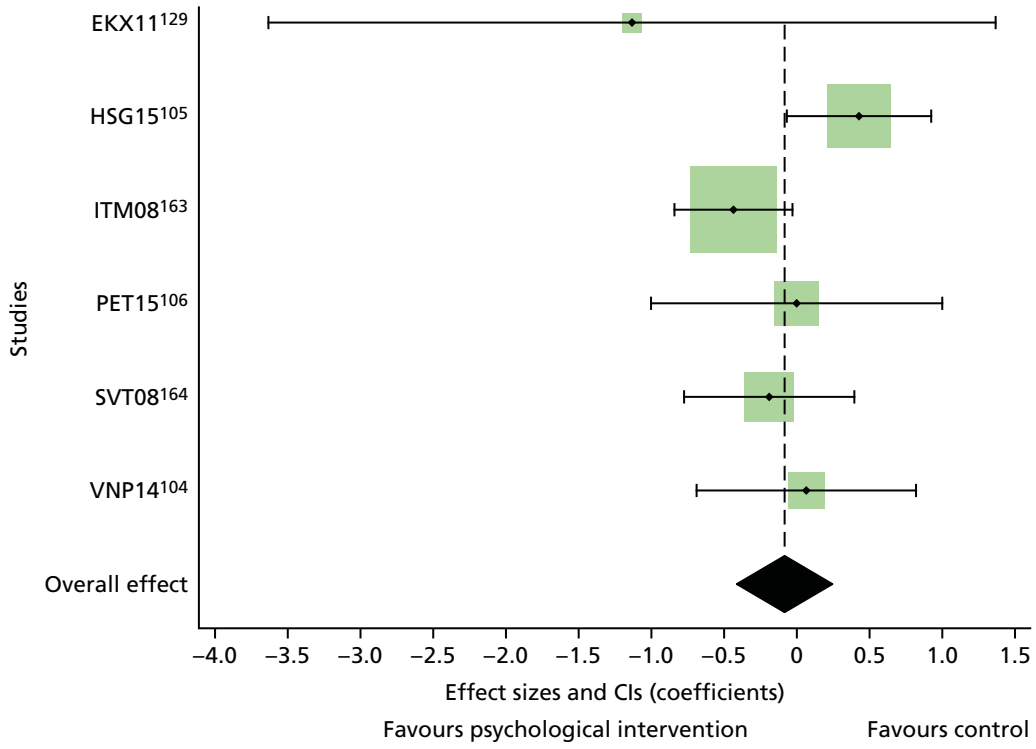

FIGURE 51 The IPD meta-analysis comparing treatment arms with control arms in terms of HbA_{1c} response at follow-up for adults with T1DM. Effect sizes are unstandardized differences in mmol HbA_{1c} at follow-up between treatment and control arms after controlling for baseline HbA_{1c} values (six study sites).

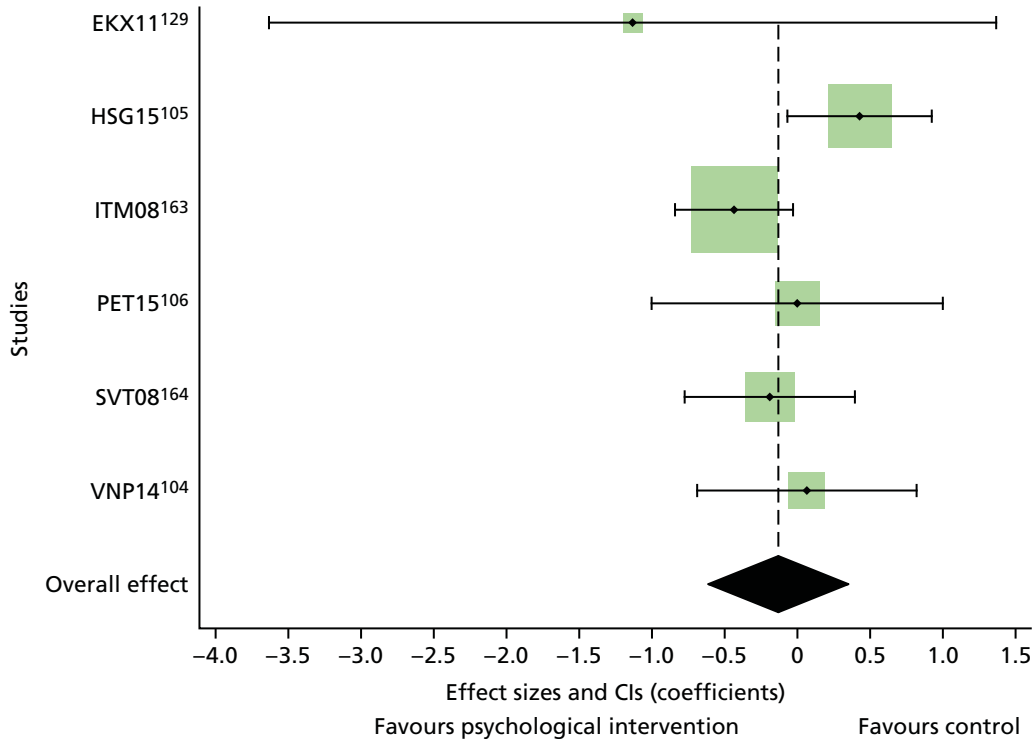

FIGURE 52 The IPD meta-analysis comparing treatment arms with control arms in terms of HbA_{1c} levels at follow-up for adults with T1DM. Effect sizes are unstandardized differences in % HbA_{1c} at follow-up between treatment and control arms after controlling for baseline HbA_{1c} values and age (six study sites).

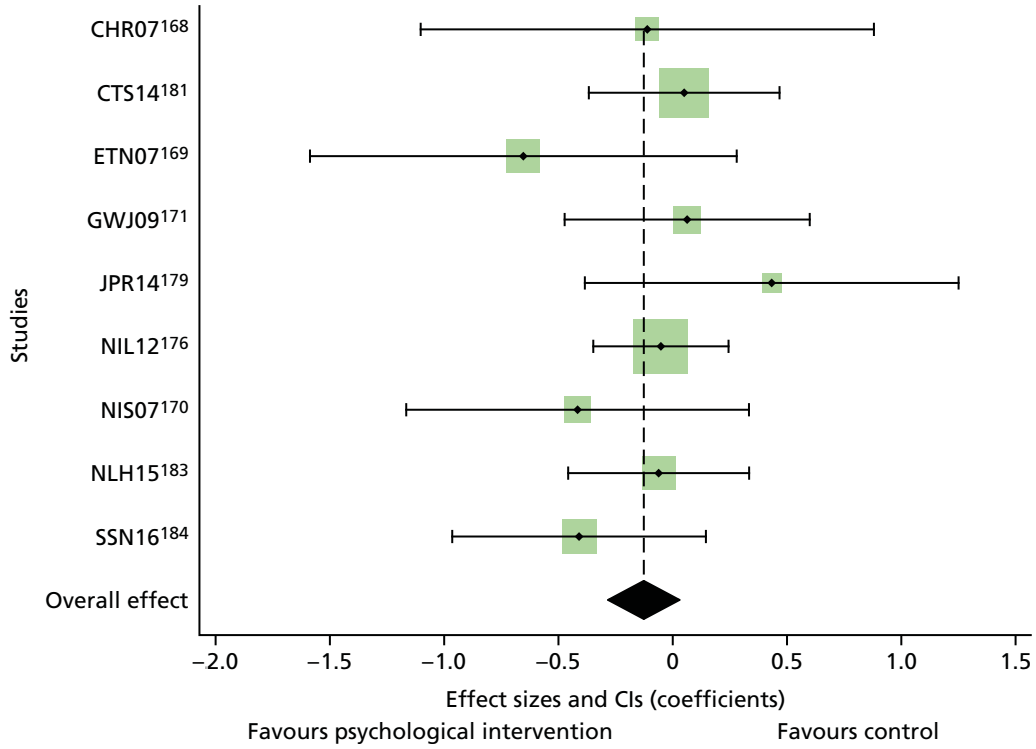

FIGURE 53 The IPD meta-analysis comparing treatment arms with control arms in terms of HbA_{1c} levels at follow-up for adolescents and children with T1DM. Effect sizes are unstandardized differences in % HbA_{1c} at follow-up between treatment and control arms after controlling for baseline HbA_{1c} values.

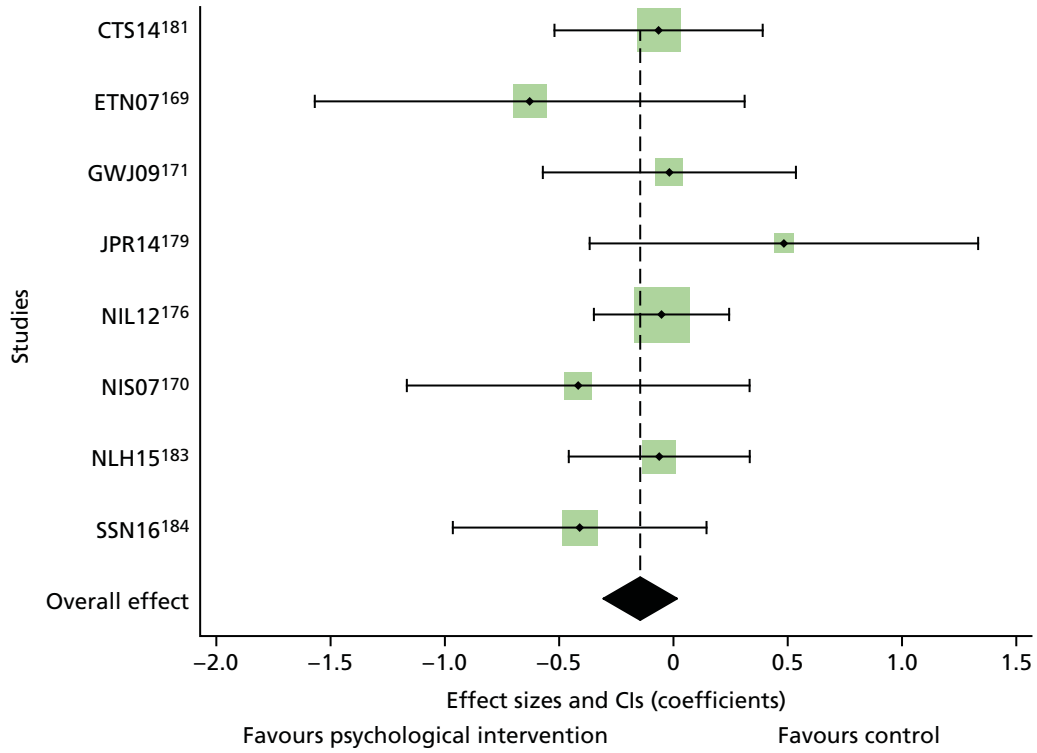

FIGURE 54 The IPD meta-analysis comparing treatment arms with control arms in terms of HbA_{1c} levels at follow-up for adolescents and children with T1DM. Effect sizes are unstandardized differences in mmol HbA_{1c} at follow-up between treatment and control arms after controlling for baseline HbA_{1c} values, age and duration of diabetes (eight study sites).

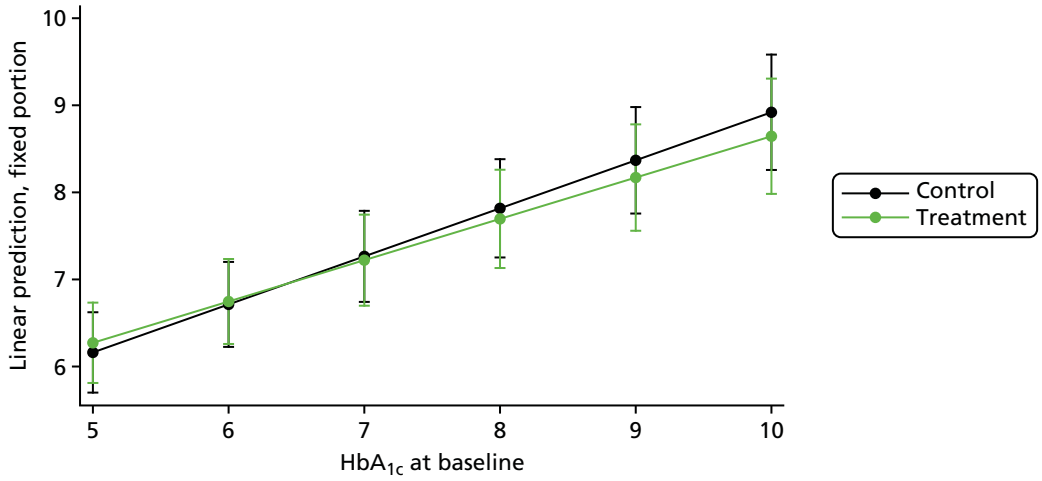

FIGURE 55 The HbA_{1c} levels (%) at follow-up, adjusted for HbA_{1c} baseline values for each treatment arm separately for adults with T2DM.

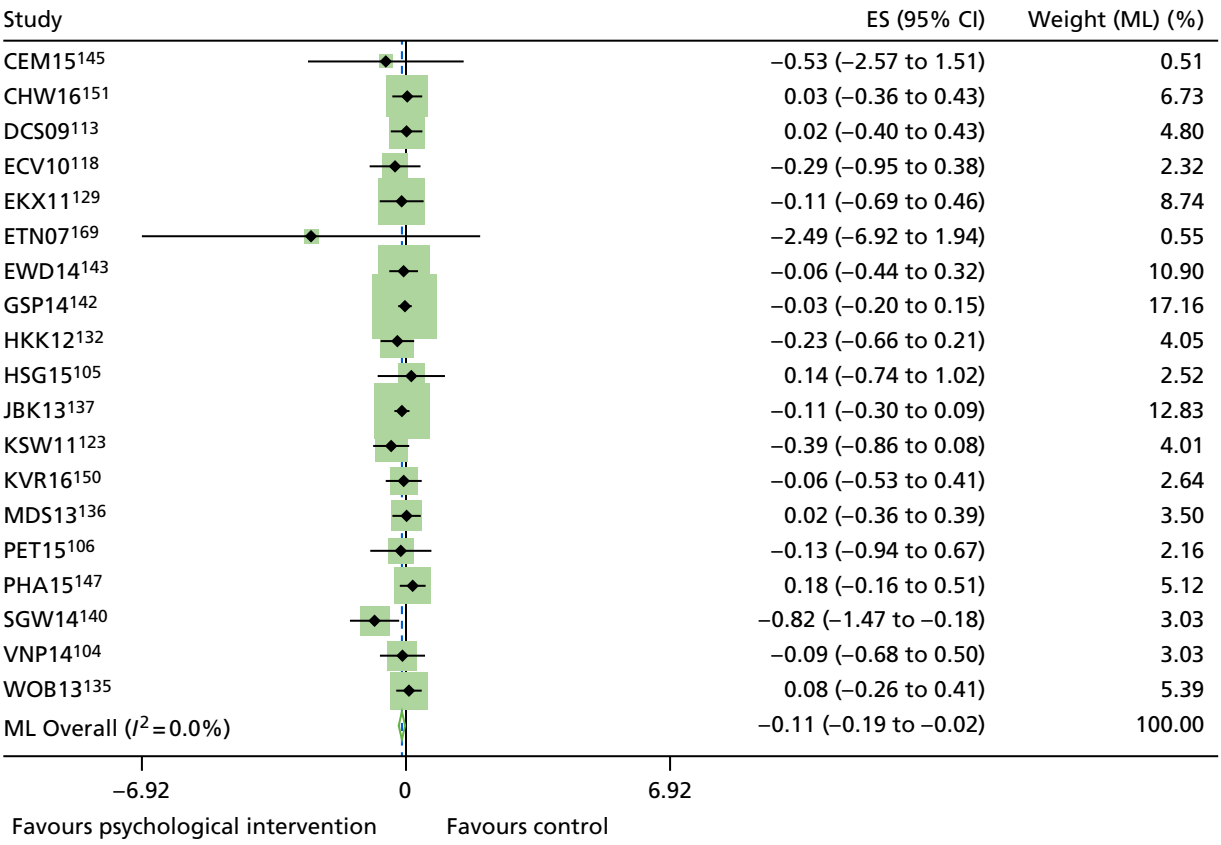

FIGURE 56 The IPD meta-analysis comparing treatment arms with control arms in terms of HbA_{1c} response at follow-up for adults with T2DM. Effect sizes are unstandardized differences in % HbA_{1c} at follow-up between treatment and control arms after controlling at an average baseline HbA_{1c} values of 7.8% (19 study sites).

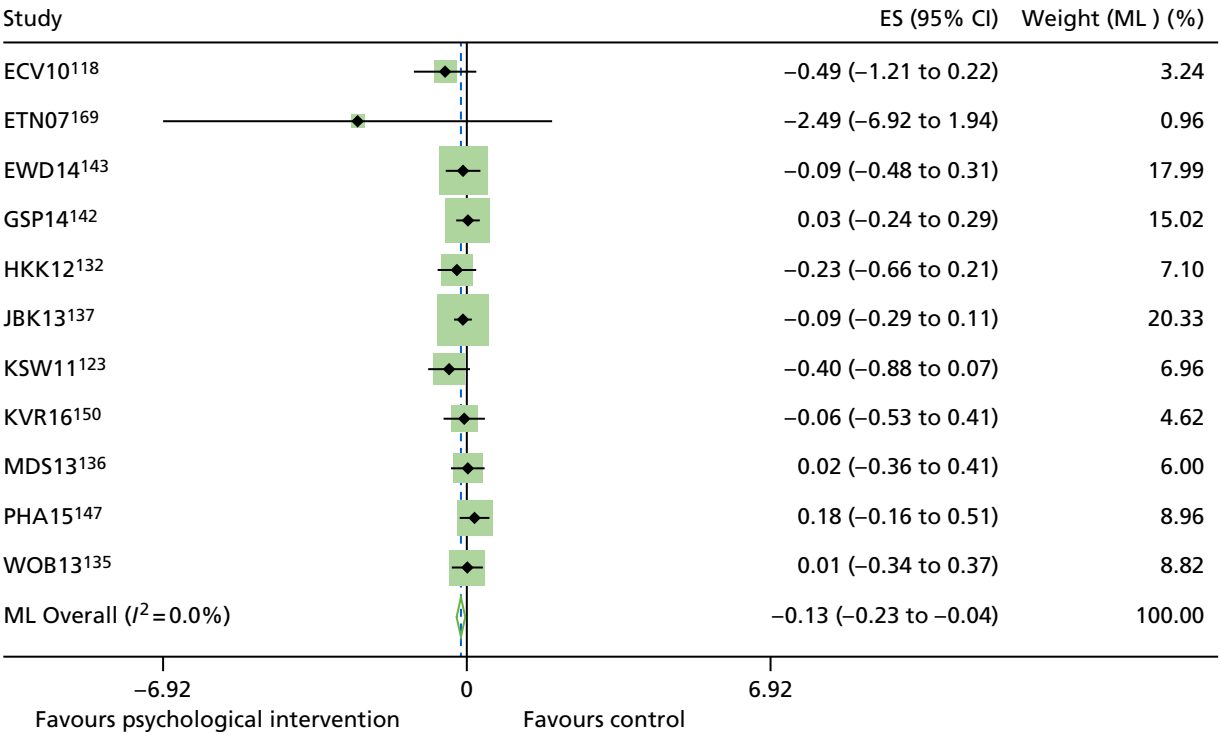

FIGURE 57 The IPD meta-analysis comparing treatment arms with control arms in terms of HbA_{1c} response at follow-up for adults with T2DM. Effect sizes are unstandardized differences in mmol HbA_{1c} at follow-up between treatment and control arms after controlling at an average baseline HbA_{1c} values of 7.8% (19 study sites), age and duration of illness.

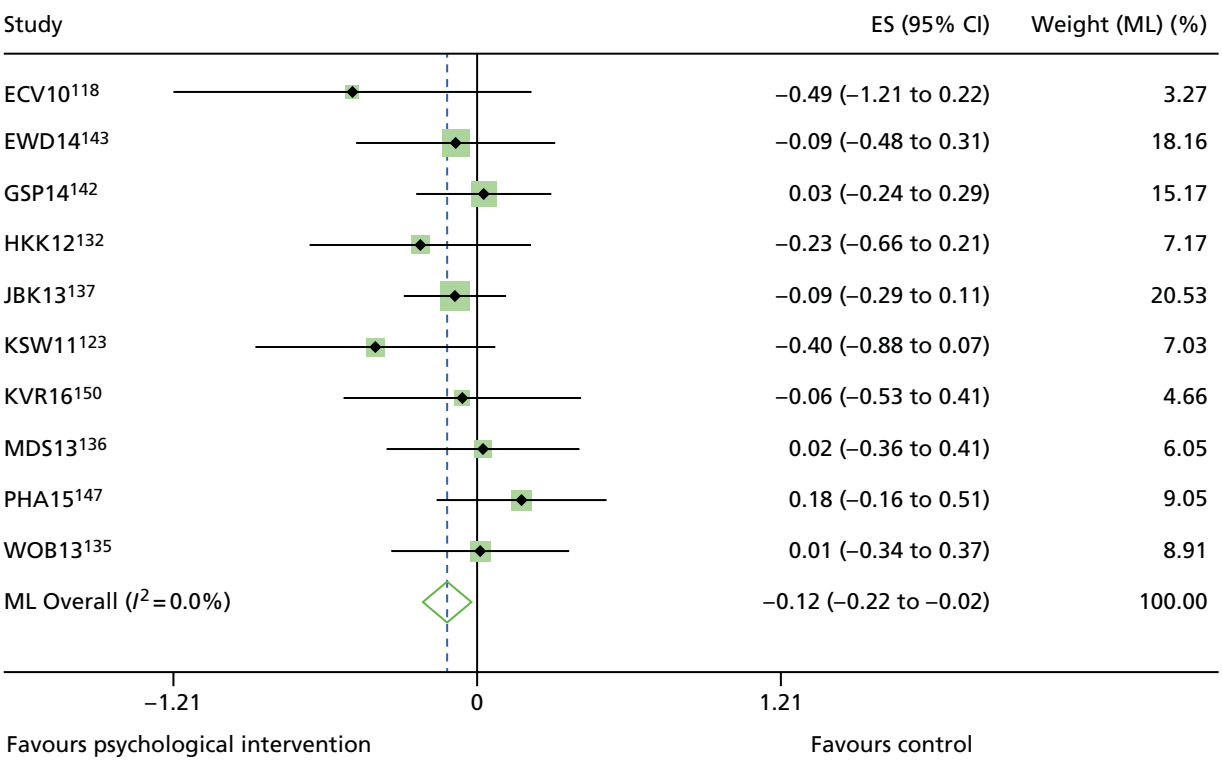

FIGURE 58 Sensitivity analyses: IPD meta-analysis comparing treatment arms with control arms in terms of HbA_{1c} response at follow-up for adults with T2DM without the Ellis *et al.*[169] study. Effect sizes are unstandardized differences in mmol HbA_{1c} at follow-up between treatment and control arms after controlling at an average baseline HbA_{1c} values of 7.8% (19 study sites), age and duration of illness.

Appendix 15 Additional tables for non-randomised controlled trials

TABLE 39 Risk of bias assessment: grading biases observed in seven domains for individual nRCT studies

Year, country, reference	Confounding	Selection of participants	Classification of interventions	Deviations from intended interventions	Missing data	Measurement of outcomes	Selection of reported results	Overall assessment
T2DM studies								
2004, South Korea, Kim *et al.*[233]	Moderate	Low	Low	NI	NI	Moderate	Moderate	NI
2007, South Korea, Song and Kim[234]	Low	Low	Low	NI	NI	Moderate	Moderate	NI
2009, Italy, Forlani *et al.*[235]	Serious	Moderate	Low	Low	NI	Moderate	Moderate	Serious
2011, South Korea, Lee *et al.*[236]	Low	Low	Moderate	Low	NI	Moderate	Moderate	Moderate
2013, Spain, Cervantes Cuesta *et al.*[237]	Moderate	Low	Low	NI	NI	Moderate	Moderate	NI
2014, Thailand, Ounnapiruk *et al.*[238]	Low	Low	Low	NI	NI	Moderate	Moderate	NI
2014, Taiwan, Wu *et al.*[240]	Critical	Moderate	Moderate	NI	NI	Moderate	Moderate	Critical
T1DM studies								
2003, USA, Ellis *et al.*[229]	Serious	Serious	Moderate	Serious	NI	Serious	Critical	Critical
2003, Japan, Takii *et al.*[226]	Moderate	Moderate	Moderate	NI	NI	Moderate	Moderate	NI
2006, Germany, Kubiak *et al.*[228]	Moderate	Low	Moderate	NI	NI	Moderate	Moderate	NI
2006, Iran, Attari *et al.*[227]	Moderate	Low	Moderate	NI	NI	Moderate	Moderate	NI
2010, Spain, García-Pérez *et al.*[230]	Moderate	Low	Low	NI	NI	Moderate	Moderate	NI
2013, USA, Bitsko *et al.*[231]	Serious	Low	Low	NI	NI	Moderate	Moderate	Serious
Studies including a T2DM and T1DM population								
2009, USA, Harris *et al.*[232]	Critical	Serious	Low	NI	NI	Moderate	Moderate	Critical

NI, no information.

TABLE 40 Comparison of HbA_{1c} levels between intervention and control groups in nRCT studies

Year, country, reference	Follow-up period (months)	Intervention group		Control group		*p*-value
		Baseline	Follow-up	Baseline	Follow-up	
T2DM studies						
2004, South Korea, Kim *et al.*[233]	Post intervention	7.84 ± 1.63	6.96 ± 1.19	7.78 ± 1.72	8.19 ± 2.07	0.02
2007, South Korea, Song and Kim[234]	3	9.4 ± 1.8	7.1 ± 1.2	9.0 ± 1.2	8.6 ± 71.3	0.001
2009, Italy, Forlani *et al.*[235]	48	7.4 ± 1.8	7.0 (2.3)	7.9 ± 1.9	7.5 (1.9)	NR
2011, South Korea, Lee *et al.*[236]	6	7.95 ± 1.43	7.33 ± 1.22	7.42 ± 1.67	7.08 ± 1.79	NR
2013, Spain, Cervantes Cuesta *et al.*[237]	3	6.89 ± 1.16	6.38 ± 0.88	7.03 ± 1.20	6.97 ± 1.30	0.04
2014, Thailand, Ounnapiruk *et al.*[238]	3	8.17 ± 0.44	7.71 ± 0.28	7.99 ± 0.42	8.24 ± 0.41	0.292
2014, Taiwan, Wu *et al.*[240]	1	8.18 ± 1.76	7.79 ± 1.62	8.49 ± 1.99	8.60 ± 2.02	**
T1DM studies						
2003, USA, Ellis *et al.*[229]	• Controls[a] 1 and 2: 3 • Control 3: 2 • Control 4: 9	NR	NR	NR	NR	NR
2003, Japan, Takii *et al.*[226]	36	12.2 ± 1.7	NR	12.8 ± 2.9	NR	NR
2006, Germany, Kubiak *et al.*[228]	6	6.8 ± 1.6	6.3 ± 0.9	6.8 ± 1.5	6.2 ± 1.3	0.67
2006, Iran, Attari *et al.*[227]	Post intervention	11.7 ± 2.9	8.5 ± 1.7	10.9 ± 2.1	10.3 ± 2.1	**
2010, Spain, García-Pérez *et al.*[230]	3	8.63 ± 1.75	9.19 ± 1.89	9.06 ± 1.37	9.42 ± 1.87	.646
2013, USA, Bitsko *et al.*[231]	12					
10.40 ± 2.21	9.67 ± 2.19	8.65 ± 1.99	9.34 ± 1.79	0.459		
Studies including a T2DM and T1DM population						
2009, USA, Harris *et al.*[232]	Post intervention	11.4 ± 1.4	11.1 ± 1.4	11.1 ± 1.6	NR	NR

**$p < 0.001$.
NR, not reported.
a Follow-period for individual cases.
Note
Data are means ± SD or median (interquartile range).

TABLE 41 Comparison of psychological scores between intervention and control groups in nRCT studies

Year, country, reference	Psychological measures	Follow-up period (months)	Intervention group		Control group		*p*-value
			Baseline	Follow-up	Baseline	Follow-up	
T2DM studies							
2004, South Korea, Kim *et al.*[233]	Stages of Readiness Exercise Behavior Scale	Psychological intervention	3.41 ± 1.33	4.36 ± 0.66	3.22 ± 1.35	3.22 ± 1.38	0.001
2011, South Korea, Lee *et al.*[236]	Jalowiec Coping Scale	6					
	Affective-oriented		59.52 ± 9.98	58.45 ± 10.74	61.00 ± 9.65	61.71 ± 10.07	0.643
	Problem-oriented		42.03 ± 10.50	43.41 ± 9.04	47.00 ± 10.12	46.18 ± 11.64	0.112
2014, Thailand, Ounnapiruk *et al.*[238]	Diabetes Management Self-Efficacy Scale	3	28.86 ± 0.71	30.63 ± 0.51	28.96 ± 0.67	27.73 ± 0.63	0.001
2014, Taiwan, Wu *et al.*[240]	Perceived Therapeutic Efficacy Scale	1					
	Self-efficacy		75.22 ± 18.97	81.90 ± 15.65	75.09 ± 16.62	76.24 ± 16.00	**
	Self-care		37.33 ± 14.20	56.20 ± 14.21	37.58 ± 12.33	48.55 ± 14.66	**
	Depression, Anxiety and Stress Scale		16.51 ± 13.68	15.50 ± 14.29	16.49 ± 13.88	16.56 ± 13.95	**
	WHO Well-Being Index		16.60 ± 5.65	17.17 ± 5.66	15.06 ± 5.17	15.42 ± 5.36	0.21
T1DM studies							
2003, Japan, Takii *et al.*[226]	Eating Disorder Inventory	• Intervention: 36 • Control: 24	102.3 ± 19.2	40.6 ± 32.6	78.7 ± 25.6	75.0 ± 23.8	NR
	Self-Rating Depression Scale		52.8 ± 05.7	36.8 ± 13.4	49.9 ± 5.2	51.2 ± 4.0	NR
	STAI		58.8 ± 05.7	44.1 ± 14.0	53.9 ± 4.6	57.9 ± 5.9	NR
2006, Germany, Kubiak *et al.*[228]	Zerssen-d-Scale (Depression)	6	7.9 ± 6.1	6.8 ± 6.1	6.5 ± 6.2	7.9 ± 6.8	0.09
	STAI		36.5 ± 10.1	38.1 ± 11.5	36.2 ± 8.5	36.5 ± 10.5	0.83

Year, country, reference	Psychological measures	Follow-up period (months)	Intervention group		Control group		*p*-value
			Baseline	Follow-up	Baseline	Follow-up	
	Control beliefs: IPC-D Q						
	Internal control		38.4 ± 7.0	38.2 ± 5.7	37.7 ± 6.0	38.7 ± 7.1	0.12
	External control		23.1 ± 7.1	21.7 ± 8.2	22.5 ± 7.0	19.5 ± 7.4	0.26
	Unpredictability		26.7 ± 7.7	28.1 ± 7.8	25.2 ± 8.1	24.4 ± 8.2	0.41
	Luck and chance		7.9 ± 3.3	8.8 ± 4.3	7.8 ± 4.0	7.5 ± 3.4	0.43
	Visual Analogue scales						
	Fear of hypoglycemia		6.0 ± 6.1	5.3 ± 3.9	5.1 ± 4.2	4.3 ± 3.7	0.83
	Fear of diabetes complications		13.5 ± 2.5	8.2 ± 3.9	13.9 ± 1.6	9.8 ± 5.2	0.17
2006, Iran, Attari *et al.*[227]	Stress Management Questionnaire: applied positive coping	Psychological intervention	5.06 ± 2.75	8.13 ± 2.44	5.63 ± 2.97	5.8 ± 2.09	0.001
2010, Spain, García-Pérez *et al.*[230]	STAI (State)	3	35 (54)	28 (60)	20 (34)	10 (28)	0.347
	STAI-C (Trait)		48 (43)	53 (71)	21 (51)	18 (41)	0.091
Studies including a T2DM and T1DM population							
2009, USA, Harris *et al.*[232]	Diabetes Responsibility and Conflict Scale	Psychological intervention					
	Adolescents		30.7 ± 15.0	25.4 ± 12.8	NR	37.7 ± 12.3	**
	Mothers		29.7 ± 15.0	23.9 ± 6.9	NR	37.6 ± 13.5	*
	Fathers		27.1 ± 08.1	26.6 ± 7.6	NR	36.3 ± 11.2	Non-significant
	Conflict Behaviour Questionnaire						
	Adolescents		06.1 ± 5.7	4.5 ± 4.5	NR	6.6 ± 5.5	*
	Mothers		9.5 ± 4.7	5.1 ± 5.0	NR	7.3 ± 6.1	*
	Fathers		9.9 ± 6.1	6.8 ± 7.2	NR	7.3 ± 6.3	*

IPC-D Q, diabetes-specific control beliefs questionnaire; STAI, State–Trait Anxiety Inventory.

Note

Data are means ± SD.

Appendix 16 Technical appendices to the health economic analysis

Technical appendix on details of baseline characteristics used for modelling type 1 diabetes patients

TABLE 42 Distributions used to generate baseline characteristics for patients included in the T1DM simulation

What is needed	Key	Transformations applied for sampling	Values used		Source
			Mean	SD	
Age	Years	None	40.9819	13.59232	DAFNE research database
Duration of diabetes	Years	None	16.92	13.31	National Diabetes Audit
Gender	0 = female, 1 = male		0.57	0.50006	National Diabetes Audit (mean) DAFNE research database (SD)
Smoker	1 = current smoker, 2 = former smoker, 3 = non-smoker		2.380388	0.780509	DAFNE research database
Systolic blood pressure	mmHg	LN	4.854137	0.132766	National Diabetes Audit (mean) DAFNE research database (SD)
LDL cholesterol	mmol/l	None	2.84	0.75	National Diabetes Audit
HDL cholesterol	mmol/l	LN	0.41996	0.278074	DAFNE research database
Total cholesterol	mmol/l	LN	1.507881	0.20003	DAFNE research database
Triglycerides	mmol/l	LN	0.032197	0.575833	DAFNE research database
Physical activity					
Race	0 = white, 1 = Hispanic, 2 = black		0.1	0.369242	National Diabetes Audit (mean) DAFNE research database (SD)
Baseline insulin costs	£		–	–	
Baseline diabetes-related costs	£		–	–	
HbA_{1c} level	DCCT aligned	LN (HbA_{1c})	2.151762	0.172024	National Diabetes Audit (mean) DAFNE research database (SD)

continued

TABLE 42 Distributions used to generate baseline characteristics for patients included in the T1DM simulation (*continued*)

What is needed	Key	Transformations applied for sampling	Values used		Source
			Mean	SD	
Nephropathy	1 = no comps/missing, 2 = microalbumuria, 3 = macroalbumuria, 4 = dialysis/transplant		1.103301	0.431909	DAFNE research database
Neuropathy	1 = no comps/missing, 2 = neuropathy or ulcers, 5 = reported amputation (above or below the toe)	3 = amputation (above or below toe)	1.055378	0.62177	DAFNE research database
Retinopathy	1 = no comps/missing, 2 = BDR, 3 = PDR, 4 = partially sighted/blind		1.339723	0.62177	DAFNE research database
Myocardial infarction	1 = no comps/missing, 2 = myocardial infarction		1.014909	0.233451	DAFNE research database
Stroke	1 = no comps/missing, 2 = stroke		1.007455	0.121255	DAFNE research database
Heart failure	1 = no comps/missing, 2 = hear failure		1	NR	DAFNE research database
Angina	1 = no comps/missing, 2 = angina		1.011715	0.107655	DAFNE research database

DCCT, Diabetes Control and Complications Trial; NR, not reported.

TABLE 43 Correlation matrix from the DFANE research database used in conjunction with *Table 42* to generate characteristics for patients included in the T1DM simulation

Characteristic	Age	Duration	Gender	Smoke	ldl_mol_result	eth	neph	neuro	ret	Myocardial infarction	Stroke	Angina	l_A1c	l_SBP	l_HDL	l_tri	l_chol
Age	1	0.461557	0.077086	–0.05265	–0.20529	–0.05886	0.064699	0.127438	0.166778	0.125375	0.06462	0.160945	–0.0713	0.316724	0.110877	–0.02584	–0.13275
Duration	0.461557	1	0.002752	0.066821	–0.11464	–0.02671	0.1989	0.187423	0.441926	0.151865	0.106954	0.169587	0.000766	0.258778	0.121674	–0.08435	–0.08116
Gender	0.077086	0.002752	1	–0.0821	–0.04005	0.05245	0.014266	0.000739	0.062288	0.033366	0.023498	0.047723	–0.07077	0.091767	–0.31077	0.081835	–0.17903
Smoke	–0.05265	0.066821	–0.0821	1	–0.0406	0.02119	–0.03963	–0.04292	–0.03751	0.015813	–0.09482	0.023793	–0.17369	0.043068	0.088948	–0.13688	–0.03202
ldl_mol_result	–0.20529	–0.11464	–0.04005	–0.0406	1	–0.00499	0.029985	–0.0176	–0.05926	–0.04299	0.005286	–0.04058	0.138707	–0.06789	–0.12822	0.21733	0.816337
eth	–0.05886	–0.02671	0.05245	0.02119	–0.00499	1	0.024462	0.018193	–0.00289	–0.02692	0.06937	–0.02552	0.137036	–0.02343	–0.10038	0.064053	–0.03019
neph	0.064699	0.1989	0.014266	–0.03963	0.029985	0.024462	1	0.264598	0.260778	0.089258	0.021153	–0.02767	0.046666	0.104641	0.017395	0.070919	0.054139
neuro	0.127438	0.187423	0.000739	–0.04292	–0.0176	0.018193	0.264598	1	0.267284	0.079597	0.056058	0.029498	0.127995	0.100522	0.044187	–0.00618	0.012525
ret	0.166778	0.441926	0.062288	–0.03751	–0.05926	–0.00289	0.260778	0.267284	1	0.134453	0.037145	0.105935	0.107738	0.107083	–0.05104	0.057722	–0.0549
Myocardial infarction	0.125375	0.151865	0.033366	0.015813	–0.04299	–0.02692	0.089258	0.079597	0.134453	1	0.131752	0.519815	0.023971	0.009747	–0.03703	0.014236	–0.0947
Stroke	0.06462	0.106954	0.023498	–0.09482	0.005286	0.06937	0.021153	0.056058	0.037145	0.131752	1	–0.01078	0.11291	0.002222	0.020342	–0.00582	0.0119
Angina	0.160945	0.169587	0.047723	0.023793	–0.04058	–0.02552	–0.02767	0.029498	0.105935	0.519815	–0.01078	1	–0.00576	0.121203	–0.11386	0.062528	–0.10244
l_A1c	–0.0713	0.000766	–0.07077	–0.17369	0.138707	0.137036	0.046666	0.127995	0.107738	0.023971	0.11291	–0.00576	1	0.041214	–0.06577	0.245816	0.148099
l_SBP	0.316724	0.258778	0.091767	0.043068	–0.06789	–0.02343	0.104641	0.100522	0.107083	0.009747	0.002222	0.121203	0.041214	1	0.002022	0.142123	–0.01014
l_HDL	0.110877	0.121674	–0.31077	0.088948	–0.12822	–0.10038	0.017395	0.044187	–0.05104	–0.03703	0.020342	–0.11386	–0.06577	0.002022	1	–0.32514	0.282313
l_tri	–0.02584	–0.08435	0.081835	–0.13688	0.21733	0.064053	0.070919	–0.00618	0.057722	0.014236	–0.00582	0.062528	0.245816	0.142123	–0.32514	1	0.29572
l_chol	–0.13275	–0.08116	–0.17903	–0.03202	0.816337	–0.03019	0.054139	0.012525	–0.0549	–0.0947	0.0119	–0.10244	0.148099	–0.01014	0.282313	0.29572	1

TABLE 44 The costs (£) used in the economic model, part a. Seemingly unrelated regression functions for estimated costs in year 1 and ongoing based on REPOSE trial data (Multivariate normal distributions[a])

	Annual cost of insulin and MDI consumables (year 1)	Annual cost of insulin and MDI consumables (ongoing)	Annual cost of DRC (year 1)	Annual cost of DRC (ongoing)	Source
Multiplier for the baseline DRC cost (β_1)	[b]	[b]	–0.11	0.03	Heller *et al.*[245]
Multiplier for the baseline insulin cost (β_2)	–0.99	–1.07	[b]	[b]	
Multiplier for the baseline HbA_{1c} (DCCT % scale) (β_3)	–5.19	–13.10	–22.15	–12.42	
Constant (β_0)	379.14	303.60	472.43	179.73	

DCCT, Diabetes Control and Complications Trial; MDI, multiple daily injections.

a The variance–covariance matrices used to parameterise the multivariate normal distribution are provided in the supplementary material B in Pollard *et al.*[244]

b This value was not included as a covariate in the regression formula and is taken to be a zero value in the total cost formula.

Note

The cost for each total cost is calculated using the following formula:
Total cost = $\beta_0 + \beta_1 \times$ Individual's baseline diabetes-related contact cost + $\beta_2 \times$ Individual's baseline insulin cost + $\beta_3 \times$ Individual's baseline HbA_{1c} (DCCT % scale) + $\beta_4 \times$ Individual's treatment at the start of the year (1 = pump, 0 = MDI) + $\beta_5 \times$ (1 = switched from pump to MDI, 0 = did not switch from pump to MDI) + $\beta_6 \times$ (1 = switched from MDI to pump, 0 = did not switch from MDI to pump).

TABLE 45 The costs (£) used in the economic model, part c. Costs of adverse events, comorbidities and complications; gamma distributions

Health state	Mean cost (£)	SE	Source	Health state	Mean cost (£)	SE	Source
Adverse events							
Hypoglycaemia	191	19	Heller *et al.*[242]	DKA	2091	197	Dhatariya *et al.*[301]
Nephropathy							
Ongoing yearly cost of microalbuminuria	36	4	BNF[265] and McEwan *et al.*[302]	Ongoing yearly cost of microalbuminuria – ongoing	36	4	BNF[265] and McEwan *et al.*[302]
Ongoing yearly cost of ESRD	24,983	2498	NHS reference costs[303]	Death due to ESRD	0	0	Assumed equal to Zero
Neuropathy							
Clinically confirmed neuropathy	277	28	Currie *et al.*[304]	Clinical neuropathy	277	28	Currie *et al.*[304]
Diabetic foot syndrome	2912	291	NHS Reference costs[303]	PAD with amputation (year 1)	7383	738	NHS Reference costs[303]
Ongoing yearly cost of PAD with amputation	449	45	McEwan *et al.*[302]				

TABLE 45 The costs (£) used in the economic model, part c. Costs of adverse events, comorbidities and complications; gamma distributions (*continued*)

Health state	Mean cost (£)	SE	Source	Health state	Mean cost (£)	SE	Source
Retinopathy							
Background retinopathy	148	15	McEwan *et al.*[302]	Proliferative retinopathy	676	68	McEwan *et al.*[302]
Macular oedema (year 1)	5726	573	NICE,[305] BNF[265]	Macular oedema (year 2)	3432	343	NICE,[305] BNF[265]
Macular oedema (year 3)	2574	257	NICE,[305] BNF[265]	Macular oedema (ongoing)	280	28	NICE,[305] BNF[265]
Blindness (year 1)	2227	223	Alva *et al.*[306]	Blindness (ongoing)	207	21	Alva *et al.*[306]
Cardiovascular							
First myocardial infarction (year 1)	6565	657	Alva *et al.*[306]	Second myocardial infarction (year 1)	6565	657	Alva *et al.*[306]
Final myocardial infarction (year 1)	6565	657	Alva *et al.*[306]	Ongoing yearly cost of a myocardial infarction	862	86	Alva *et al.*[306]
Fatal myocardial infarction	1098	110	Alva *et al.*[306]	Heart failure (year 1)	3286	329	Alva *et al.*[306]
Heart failure (ongoing)	1504	150	Alva *et al.*[306]	Fatal heart failure	3286	329	Alva *et al.*[306]
First stroke (year 1)	7132	714	Alva *et al.*[306]	Second stroke	7132	713	Alva *et al.*[306]
Fatal stroke	3613	361	Alva *et al.*[306]	First stroke (ongoing)	920	92	Alva *et al.*[306]
Angina (year 1)	9965	997	Alva *et al.*[306]	Angina (ongoing)	870	87	Alva *et al.*[306]

BNF, *British National Formulary*; ESRD, end-stage renal disease; PAD, peripheral arterial disease; SE, standard error.

TABLE 46 The utilities used in the economic model

Health state for event	Utility	SE	Beta distribution		Source
			Alpha	Beta	
Baseline utility value					
Male with type 1 diabetes and no complications	0.866	0.010	947.79	146.90	Peasgood *et al.*[250]
			Gamma distribution		
	Disutility	**SE**	**Alpha**	**Beta**	**Source**
Complications or covariates					
Female with type 1 diabetes and no complications	–0.0236	0.008	8.70	0.003	Peasgood *et al.*[250]
Age decrement (per 10 years)	–0.0214	0.003	50.88	0.0004	Peasgood *et al.*[250]
Adverse events[a]					
Severe hypoglycaemia	–0.002	–0.002	1	0.002	Peasgood *et al.*[250]
DKA	–0.0091	–0.01	0.83	0.01	Peasgood *et al.*[250]
Nephropathy					
Microalbuminuria	0				Assumption
Microalbuminuria	–0.017	0.01	2.89	0.01	Coffey *et al.*[249]
ESRD	–0.078	0.026	9	0.01	Coffey *et al.*[249]

continued

TABLE 46 The utilities used in the economic model (*continued*)

Health state for event	Utility	SE	Beta distribution		Source
			Alpha	Beta	
Neuropathy					
Clinical neuropathy	–0.055	0.01	30.25	0.002	Coffey *et al.*[249]
Clinically confirmed neuropathy	–0.055	0.01	30.25	0.002	Coffey *et al.*[249]
Diabetic foot syndrome	–0.1042	–0.119	0.77	0.14	Peasgood *et al.*[250]
PAD with amputation	–0.1172	–0.055	4.54	0.03	Peasgood *et al.*[250]
Retinopathy					
Background retinopathy	–0.0544	–0.023	5.59	0.01	Peasgood *et al.*[250]
Proliferative retinopathy	–0.0288	–0.026	1.23	0.02	Peasgood *et al.*[250]
Blindness	–0.208	0.013	256	0.001	Coffey *et al.*[249]
Cardiovascular					
Myocardial infarction (first year)[a]	–0.065	0.03	4.69	0.01	Alva *et al.*[247]
Myocardial infarction (subsequent years)	–0.057	0.03	3.61	0.02	Alva *et al.*[247]
Heart failure	–0.101	0.032	9.96	0.010	Alva *et al.*[247]
Stroke	–0.165	0.035	22.22	0.007	Alva *et al.*[247]
Angina[b]	–0.09	0.018	25	0.004	Clarke *et al.*[248]

ESRD, end stage renal disease; PAD, peripheral arterial disease; SE, standard error.
a These disutilites are applied transiently to the number of these events in each year.
b Value is presented in *Table 5* as ischaemic heart disease.

Technical appendix on methods to model severe hypoglycaemia and diabetic ketoacidosis in people with type 1 diabetes

Data on the incidence and severe hypoglycaemia and DKA was obtained from analyses of the DAFNE research database.[242] This source was used for three reasons: first, it had the largest sample size for this data; second, it was not clinically expected that the inclusion of a bolus advisor to a DAFNE course would affect the incidence of these two serious adverse events; and third, it was expected that the REPOSE trial exclusion of people immediately eligible for a pump would have lowered the incidence of these two events compared with the population who normally receive DAFNE.

TABLE 47 The results of the negative binomial regression fitted to the DAFNE research database to predict the incidence of DKA

Parameters	Coefficient	SE	95% CI	Relative risk	95% CI	Source
Constant	–7.601	1.2041	–9.961 to –5.241	–	–	Re-analysis of data used in Heller *et al.*[242] and Thokala *et al.*[246]
DAFNE receipt (before = 0/ after = 1)	–0.943	0.3443	–1.618 to –0.268	0.006	0.198 to 0.765	
HbA_{1c} (DCCT aligned)	0.563	0.1235	0.320 to 0.805	1.755	1.376 to 2.236	
Overdispersion parameter	6.974	N/A				

DCCT, Diabetes Control and Complications Trial; N/A, not applicable; SE, standard error.
Note
The covariance matrix required to sample the coefficients from a multivariate distribution is given in *Table 48*.

TABLE 48 Covariance matrix for the negative binomial data fitted to estimate DKA

Parameters	Intercept	(After DAFNE = 1, otherwise = 0)	HbA_{1c}
Intercept	1.20397	0.19004	–0.12386
(After DAFNE = 1, otherwise = 0)	0.19004	0.12308	–0.02408
HbA_{1c}	–0.12386	–0.02408	0.01318

Risk of severe hypoglycaemia

TABLE 49 The results of the negative binomial regression fitted to the DAFNE research database

Parameters	Coefficient	SE	95% CI	Relative risk	95% CI	Source
Constant	0.912	0.5961	–0.257 to 2.080	–	–	Re-analysis of data used in Heller *et al.* (1) & Thokala *et al.*[246] (7)
DAFNE (before = 0/ after = 1)	–1.288	0.1487	–1.580 to –0.977	0.275	0.208 to 0.363	
HbA_{1c} (DCCT aligned)	–0.131	0.0689	–0.266 to 0.004	0.876	0.772 to 0.994	
Overdispersion parameter	8.525	N/A				

DCCT, Diabetes Control and Complications Trial; N/A, not applicable; SE, standard error.

TABLE 50 Covariance matrix for the negative binomial data fitted to estimate severe hypoglycaemia

Parameters	Intercept	(After DAFNE = 1, otherwise = 0)	HbA_{1c}
Intercept	0.35534	–0.02779	–0.04043
(After DAFNE = 1, otherwise = 0)	–0.02779	0.02212	0.00195
HbA_{1c}	–0.04043	0.00195	0.00475

How to sample from these negative binomial regressions

The number of events was directly sampled for each individual in the model. An example of how to estimate the number of severe hypoglycaemic events that occur in 1 year for a person with a HbA_{1c} level of 10% and post DAFNE using the central estimates of the coefficients is given below.

- The fitted value (FV) of the regression coefficients was estimated: ($FV = 0.912 + -1.288 + -0.131 \times 10$).
- The mean number of events for this individual (μ) was calculated using the following formula: $\mu = e^{FV}$.
- A parameter of the negative binomial distribution (p) was calculated using the following formula: $p = 1 - [1 / (8.525 + 1 / \mu)]$.
- A parameter of the negative binomial distribution (r) was calculated using the following formula: $r = [\mu \times (1 - p)] / p$.
- A random sample (λ) from the following gamma distribution (using a shape and scale parameterisation) was taken: $\lambda \sim$ gamma $[r, p/(1 - p)]$.
- A random sample for the number of predicted events (*N*) was taken from the following Poisson distribution: $N \sim$ Poisson(λ).
- This process was applied in the model in each year that each individual was run through the model.
- In each PSA run, the coefficients of the negative binomial regression were sampled from a multivariate normal distribution.

It should be noted that the formulae for p and r depend on the parameterisation of the variance in the negative binomial regression that an analyst is using. These formulae are valid for SPSS; the formulae may be different if other statistical software is used to fit the negative binomial regression.

Technical appendix on Sheffield Type 2 Diabetes Prevention Model adapted to this study

Whitehall II statistical model of metabolic trajectories

The metabolic trajectories used in the model are derived from statistical analysis of the longitudinal Whitehall II cohort.[258] The parameters derived from this model are described in *Tables 51–53*.

TABLE 51 Coefficient estimates for metabolic risk factor parallel growth models

Parameters	Parameter description	Estimated mean	SE	*p*-value
BMI intercept				
α_{10}	Population mean BMI intercept	2.2521	0.045	< 0.001
γ_{10}	Age at baseline coefficient for BMI intercept	0.0056	0.001	< 0.001
	Sex coefficient for BMI intercept	–0.0311	0.012	0.009
	Family history of CVD coefficient for BMI intercept	–0.0079	0.012	0.515
υ_{10}	Random error term for BMI intercept	0.1165	0.003	< 0.001
BMI linear slope				
α_{11}	Population mean BMI linear slope	0.6409	0.042	< 0.001
γ_{11}	Age at baseline coefficient for BMI linear slope	–0.0084	0.001	< 0.001
	Sex coefficient for BMI linear slope	–0.0285	0.011	0.009
	Family history of CVD coefficient for BMI linear slope	–0.0155	0.010	0.117
υ_{11}	Random error term for BMI linear slope	0.0222	< 0.001	< 0.001
BMI quadratic slope				
α_{12}	Population mean BMI quadratic slope	–0.2007	0.023	< 0.001
γ_{12}	Age at baseline coefficient for quadratic slope	0.0026	< 0.001	< 0.001
	Sex coefficient for quadratic slope	0.0089	0.006	0.147
	Family history of CVD coefficient for quadratic slope	0.0104	0.006	0.061
ϵ_1	Random error term for BMI	0.0104	< 0.001	< 0.001
Glycaemic intercept				
α_{20}	Population mean glycaemic intercept	0	NA	NA
γ_{20}	Smoker coefficient for glycaemic intercept	–0.1388	0.029	< 0.001
τ_{20}	Association between BMI intercept and glycaemic intercept	0.2620	0.024	< 0.001
υ_{20}	Random error term for glycaemic intercept	0.0851	0.008	< 0.001
Glycaemic linear slope				
α_{21}	Population mean glycaemic linear slope	–0.4255	0.071	< 0.001
γ_{21}	Sex coefficient for glycaemic linear slope	0.1486	0.045	0.001
	Ethnicity coefficient for glycaemic linear slope	–0.0218	0.081	0.786
	Family history of T2DM coefficient for glycaemic linear slope	–0.0512	0.054	0.345
	Smoker coefficient for glycaemic linear slope	0.1796	0.066	0.007

TABLE 51 Coefficient estimates for metabolic risk factor parallel growth models (*continued*)

Parameters	Parameter description	Estimated mean	SE	*p*-value
τ_{21}	Association between BMI intercept and glycaemic linear slope	0.0821	0.024	0.001
τ_{22}	Association between BMI linear slope and glycaemic linear slope	0.1984	0.073	0.007
υ_{21}	Random error term for glycaemic linear slope	0.0222	0.011	0.053
Glycaemic quadratic slope				
α_{22}	Population mean glycaemic quadratic slope	0.1094	0.025	< 0.001
γ_{22}	Sex coefficient for glycaemic quadratic slope	–0.0855	0.027	0.002
	Ethnicity coefficient for glycaemic quadratic slope	0.0899	0.049	0.067
	Family history of T2DM coefficient for glycaemic quadratic slope	0.0633	0.033	0.052
	Smoker coefficient for glycaemic quadratic slope	–0.0390	0.040	0.330
υ_{22}	Random error term for glycaemic quadratic slope	0.0107	0.003	0.002
ϵ_2	Glycaemic measurement error	0.0707	0.005	< 0.001
SBP intercept				
α_{30}	Population mean SBP intercept	0.6934	0.021	< 0.001
γ_{30}	Age at baseline coefficient for SBP intercept	0.0043	< 0.001	< 0.001
	Sex coefficient for SBP intercept	0.0380	0.004	< 0.001
	Smoking coefficient for SBP intercept	–0.0243	0.006	< 0.001
	Ethnicity coefficient for SBP intercept	0.0078	0.007	0.300
	Family history of CVD coefficient for SBP intercept	0.0061	0.004	0.160
τ_{31}	Association between BMI intercept and SBP intercept	0.1080	0.006	< 0.001
υ_{30}	Random error term for SBP intercept	0.0085	0.00	< 0.001
SBP linear slope				
α_{31}	Population mean SBP linear slope	–0.0227	0.021	0.278
γ_{31}	Age at baseline coefficient for SBP linear slope	0.0024	< 0.001	< 0.001
	Sex coefficient for SBP linear slope	–0.0004	0.004	0.927
	Smoking coefficient for SBP linear slope	0.0205	0.005	< 0.001
	Ethnicity coefficient for SBP linear slope	0.0224	0.007	0.001
	Family history of CVD coefficient for SBP linear slope	–0.0013	0.004	0.748
τ_{31}	Association between BMI intercept and SBP linear slope	–0.0396	0.006	< 0.001
	Association between BMI linear slope and SBP linear slope	0.2325	0.019	< 0.001
υ_{31}	Random error term for SBP linear slope	0.0024	< 0.001	< 0.001
ϵ_3	SBP measurement error variance	0.0093	< 0.001	< 0.001
TC intercept				
α_{40}	Population mean TC intercept	2.9956	0.176	< 0.001
γ_{40}	Age at baseline coefficient for TC intercept	0.0456	0.003	< 0.001
	Sex coefficient for TC intercept	0.0660	0.036	0.070
τ_{40}	Association between BMI intercept and TC intercept	0.4459	0.049	< 0.001
υ_{40}	Random error term for TC intercept	0.8960	0.025	< 0.001

continued

TABLE 51 Coefficient estimates for metabolic risk factor parallel growth models (*continued*)

Parameters	Parameter description	Estimated mean	SE	*p*-value
TC linear slope				
α_{41}	Population mean TC linear slope	2.1216	0.128	< 0.001
γ_{41}	Age at baseline coefficient for TC linear slope	–0.0316	0.002	< 0.001
	Sex coefficient for TC linear slope	–0.2677	0.026	< 0.001
τ_{41}	Association between BMI intercept and TC linear slope	–0.4808	0.035	< 0.001
τ_{42}	Association between BMI linear slope and TC linear slope	0.9802	0.108	< 0.001
υ_{41}	Random error term for TC linear slope	0.1583	0.011	< 0.001
ϵ_4	TC measurement error variance	0.3426	0.006	< 0.001
HDL intercept				
α_{50}	Population mean HDL intercept	2.4124	0.054	< 0.001
γ_{50}	Age at baseline coefficient for HDL intercept	0.0032	0.011	< 0.001
	Sex coefficient for HDL intercept	–0.3710	0.001	< 0.001
τ_{51}	Association between BMI intercept and HDL intercept	–0.3514	0.015	< 0.001
υ_{50}	Random error term for HDL intercept	0.0827	–0.040	< 0.001
HDL linear slope				
α_{51}	Population mean HDL linear slope	0.1241	0.034	< 0.001
γ_{51}	Age at baseline coefficient for HDL linear slope	0.0020	0.001	< 0.001
	Sex coefficient for HDL linear slope	0.0041	0.007	0.558
τ_{51}	Association between BMI intercept and HDL linear slope	–0.0400	0.010	< 0.001
υ_{51}	Random error term for HDL linear slope	0.0090	0.001	< 0.001
ϵ_5	HDL measurement error variance	0.0333	0.001	< 0.001

HDL, high-density lipoprotein; SE, standard error; TC, total cholesterol.

TABLE 52 Coefficient estimates for latent glycaemic measurement model

Parameters	Parameter description	Estimated mean	SE	*p*-value
μ_0	FPG intercept	4.2903	0.089	< 0.001
θ_{01}	Glycaemic factor to FPG	1	NA	NA
θ_{02}	Age to FPG	0.0031	0.001	0.022
θ_{03}	Sex to FPG	0.2129	0.021	< 0.001
θ_{04}	Ethnicity to FPG	0.0100	0.037	0.786
θ_{05}	Family history of diabetes to FPG	0.1168	0.025	< 0.001
ϵ_0	FPG measurement error variance	0.1649	0.007	< 0.001
μ_1	Two-hour glucose intercept	0.5707	0.223	0.011
θ_{11}	Glycaemic factor to 2-hour glucose	2.4384	0.078	< 0.001
θ_{12}	Age to 2-hour glucose	0.0716	0.003	< 0.001
θ_{13}	Sex to 2-hour glucose	–0.1411	0.058	0.014
θ_{14}	Ethnicity to 2-hour glucose	0.3047	0.100	0.002

TABLE 52 Coefficient estimates for latent glycaemic measurement model (*continued*)

Parameters	Parameter description	Estimated mean	SE	*p*-value
θ_{15}	Family history of diabetes to 2-hour glucose	0.3496	0.068	< 0.001
ϵ_1	2-hour measurement error variance	2.3679	0.054	< 0.001
μ_2	HbA_{1c} intercept	4.4769	0.073	< 0.001
θ_{21}	Glycaemic factor to HbA_{1c}	0.5074	0.016	< 0.001
θ_{22}	Age to HbA_{1c}	0.0101	0.001	< 0.001
θ_{23}	Sex to HbA_{1c}	–0.0457	0.001	< 0.001
θ_{24}	Ethnicity to HbA_{1c}	0.1854	0.030	< 0.001
θ_{25}	Family history of diabetes to HbA_{1c}	0.0563	0.020	0.004
ϵ_2	HbA_{1c} measurement error variance	0.1166	0.003	< 0.001

FPG, fasting plasma glucose; SE, standard error.

TABLE 53 Covariance matrix Ω for individual random error

Parameters	υ_{10}	υ_{11}	υ_{20}	υ_{21}	υ_{22}	υ_{30}	υ_{31}	υ_{40}	υ_{41}	υ_{50}	υ_{51}
υ_{10}	0.1165										
υ_{11}	0.0095	0.0131									
υ_{20}	< 0.0010	< 0.0010	0.0851								
υ_{21}	< 0.0010	< 0.0010	0.0222	0.0209							
υ_{22}	< 0.0010	< 0.0010	< 0.0010	< 0.0010	0.0107						
υ_{30}	< 0.0010	< 0.0010	0.0080	< 0.0010	< 0.0010	0.0085					
υ_{31}	< 0.0010	< 0.0010	< 0.0010	0.0018	< 0.0010	< 0.0017	0.0024				
υ_{40}	< 0.0010	< 0.0010	0.0324	< 0.0010	< 0.0010	0.0031	< 0.0010	0.8960			
υ_{41}	< 0.0010	< 0.0010	< 0.0010	< 0.0012	< 0.0010	< 0.0010	0.0066	–0.2229	0.1583		
υ_{50}	< 0.0010	< 0.0010	–0.0118	< 0.0010	< 0.0010	0.0010	< 0.0010	0.0273	< 0.0010	0.0827	
υ_{51}	< 0.0010	< 0.0010	< 0.0010	–0.0059	< 0.0010	< 0.0010	0.0020	< 0.0010	0.0159	0.0061	0.0090

Glycated haemoglobin trajectory in individuals diagnosed with type 2 diabetes mellitus

The input parameters for the initial reduction in HbA_{1c} level and long-term trend in HbA_{1c} level following diagnosis, derived from analysis of the UKPDS outcomes model, are reported in *Tables 54* and *55*.

TABLE 54 Estimated change in HbA_{1c} level in the first year following diabetes diagnosis

Parameters	Distribution	Parameter 1	Parameter 2	Central estimate
Change in HbA_{1c} intercept	Normal	–2.9465	0.0444513	–2.9465
HbA_{1c} at baseline	Normal	0.5184	0.4521958	0.5184

TABLE 55 Estimated change in HbA_{1c} level following diabetes diagnosis over the long term

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate
Longitudinal HbA_{1c} for diabetes intercept	Normal	–0.024	0.017	–0.024
Longitudinal HbA_{1c} for diabetes log (time since diagnosis)	Normal	0.144	0.009	0.144
Longitudinal HbA_{1c} for diabetes second year	Normal	–0.333	0.05	–0.333
Longitudinal HbA_{1c} for diabetes lag HbA_{1c}	Normal	0.759	0.004	0.759
Longitudinal HbA_{1c} for diabetes HbA_{1c} at diagnosis	Normal	0.085	0.004	0.0896

Microvascular complications

The parameter distributions for the risk models for foot ulcer, blindness, renal failure, first amputation and second amputation are reported in *Table 56*. Parameters for renal failure were based on the UKPDS Outcomes Model 1,[261] whereas parameters for other microvascular complications were based on the UKPDS Outcomes Model 2.[262]

Cancer

The parameter distributions for the incidence and hazard ratios for breast cancer and colorectal cancer are reported in *Table 57*.

The parameter distributions for breast and colorectal cancer mortality are reported in *Table 58*.

TABLE 56 Input parameters for microvascular complications

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate
Renal failure baseline hazard	Normal	–10.016	0.939	–10.016
Renal failure Weibull shape	Normal	1.865	1.4352	1.865
Renal failure SBP	Normal	0.404	0.106	0.404
Renal failure blindness	Normal	2.082	0.551	2.082
Foot ulcer baseline hazard	Normal	–11.295	1.13	–11.295
Foot ulcer age at diagnosis	Normal	0.043	0.014	0.043
Foot ulcer female	Normal	–0.962	0.255	–0.962
Foot ulcer BMI	Normal	0.053	0.019	0.053
Foot ulcer HbA_{1c}	Normal	0.16	0.056	0.16
Foot ulcer PVD	Normal	0.968	0.258	0.968
Amputation baseline hazard	Normal	–14.844	1.205	–14.844
Amputation age at diagnosis	Normal	0.023	0.011	0.023
Amputation female	Normal	–0.445	0.189	–0.445
Amputation atrial fibrillation	Normal	1.088	0.398	1.088
Amputation HbA_{1c}	Normal	0.248	0.042	0.248
Amputation HDL	Normal	–0.059	0.032	–0.059

TABLE 56 Input parameters for microvascular complications (*continued*)

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate
Amputation heart rate	Normal	0.098	0.05	0.098
Amputation MMALB	Normal	0.602	0.18	0.602
Amputation PVD	Normal	1.01	0.189	1.01
Amputation white blood count	Normal	0.04	0.017	0.04
Amputation stroke	Normal	1.299	0.245	1.299
Amputation shape	Normal	2.067	0.193	2.067
Amputation with ulcer lambda	Normal	–0.881	0139	–0.881
Amputation with ulcer age at diagnosis	Normal	–0.065	0.027	–0.065
Amputation with ulcer PVD	Normal	1.769	0.449	1.769
Second amputation baseline hazard	Normal	–3.455	0.565	–3.455
Second amputation HbA_{1c}	Normal	0.127	0.06	0.127
Blindness baseline hazard	Normal	–10.6774	0.759	–10.6774
Blindness age at diagnosis	Normal	0.047	0.009	0.047
Blindness HbA_{1c}	Normal	0.171	0.032	0.171
Blindness heart rate	Normal	0.08	0.039	0.08
Blindness SBP	Normal	0.068	0.032	0.068
Blindness white blood cells	Normal	0.052	0.019	0.052
Blindness CHF	Normal	0.841	0.287	0.841
Blindness IHD	Normal	0.61	0.208	0.61

CHF, chronic heart failure; HDL, high-density lipoprotein; IHD, ischaemic heart disease; MMALB, micro-/macro-albuminuria PVD, peripheral vascular disease.

TABLE 57 Input parameters for breast cancer and colorectal cancer risk models

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source
Colorectal cancer men	Normal	0.0011	0.0001	0.0011	Pischon *et al.*[307]
Colorectal cancer women	Normal	0.0005	0.0000	0.0005	Pischon *et al.*[307]
Breast cancer pre menopause	Normal	0.0010	0.0001	0.0010	Lahmann *et al.*[308]
Breast cancer post menopause	Normal	0.0028	0.0002	0.0028	Lahmann *et al.*[308]
Colorectal cancer BMI relative risk for men	Lognormal	0.1906	0.0111	1.21	Renehan *et al.*[309]
Colorectal cancer BMI relative risk for women	Lognormal	0.0392	0.0151	1.04	Renehan *et al.*[309]
Breast cancer BMI relative risk for pre menopause	Lognormal	–0.1165	0.0251	0.89	Renehan *et al.*[309]
Breast cancer BMI relative risk for post menopause	Lognormal	0.0862	0.0205	1.09	Renehan *et al.*[309]

TABLE 58 Input parameters for breast cancer and colorectal cancer mortality

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate
Breast cancer 5-year survival	Beta	439.69	2354.44	0.157
Colorectal cancer 5-year survival	Beta	1457.56	1806.35	0.447

Osteoarthritis

The parameter distributions for the incidence and hazard ratios for osteoarthritis are reported in *Table 59*.

Depression

The parameter distributions for the incidence and hazard ratios for depression are reported in *Table 60*.

Utilities

The parameter distributions used to estimate health state utilities in the model are reported in *Table 61*.

Unit health-care costs

The parameter distributions used to estimate health state utilities in the model are reported in *Table 62*.

TABLE 59 Input parameters for the osteoarthritis risk model

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate
Osteoarthritis incidence	Normal	0.0053	0.0000004	0.0053
Osteoarthritis relative risk of diabetes mellitus	Lognormal	0.723	0.317	2.06
Osteoarthritis relative risk of BMI	Lognormal	0.073	0.026	1.076

Note
The parameters in this table have been sourced from Schett *et al.*[310]

TABLE 60 Input parameters for the depression risk model

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source
Odds of depression	Beta	336	8803	0.0397	Golden *et al.*[311]
Odds ratio for diabetes	Lognormal	0.4187	0.1483	1.52	Golden *et al.*[311]
Odds ratio for stroke	Lognormal	1.8406	0.5826	6.3	Whyte *et al.*[312]

TABLE 61 Utility input parameters

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source
Renal/ulcer baseline utility	Normal	0.689	0.014	0.689	Coffey *et al.*[249]
Renal dialysis	Normal	–0.078	0.026	–0.078	Coffey *et al.*[249]
Foot ulcer	Normal	–0.099	0.013	–0.099	Coffey *et al.*[249]
Amputation/heart failure baseline utility	Normal	0.807	0.005	0.807	Hayes *et al.*[262]
Heart failure	Normal	–0.101	0.032	–0.101	Hayes *et al.*[262]
Amputation	Normal	–0.172	0.045	–0.172	Hayes *et al.*[262]
Stable angina multiplicative factor decrement	Normal	0.801	0.038	0.801	Ward *et al.*[313]

TABLE 61 Utility input parameters (*continued*)

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source
Unstable angina multiplicative factor decrement	Normal	0.77	0.038	0.77	Ward *et al.*[313]
Myocardial infarction multiplicative factor decrement	Normal	0.76	0.018	0.76	Ward *et al.*[313]
Stroke multiplicative factor decrement	Normal	0.629	0.04	0.629	Ward *et al.*[313]
Cancer baseline utility	Normal	0.8	0.0026	0.8	Yabroff *et al.*[314]
Cancer decrement	Normal	–0.06	0.008	–0.06	Yabroff *et al.*[314]
Osteoarthritis utility	Normal	0.69	0.069	0.69	Black *et al.*[315]
Depression baseline utility	Normal	0.48	0.048	0.48	Benedict *et al.*[316]
Depression remitters	Normal	0.31	0.031	0.31	Benedict *et al.*[316]
Depression responders	Normal	0.20	0.020	0.20	Benedict *et al.*[316]
Depression non-responders	Normal	0.070	0.007	0.070	Benedict *et al.*[316]
Depression drop-outs	Normal	0.050	0.005	0.050	Benedict *et al.*[316]
Age utility decrement	Normal	–0.004	0.0001	–0.004	Ward *et al.*[313]

TABLE 62 Cost input parameters

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source/reference
Diabetes costs					
Insulin (annual cost)	Gamma	3.367	408.6	£1375.72	Poole *et al.*[317]
Metformin (annual cost)	Constant	NA	NA	£28.24	Curtis[318]
Sitagliptin (annual cost)	Constant	NA	NA	£433.77	Curtis[318]
Nurse appointment (advanced)	Gamma	100	0.26	£25.52	Curtis[318]
Health-care assistant appointment	Gamma	100	0.03	£3.40	Curtis[318]
Eye screening	Gamma	15.3664	1.58219	£24.31	Burr *et al.*[319]
HbA_{1c} test	Gamma	100	0.03	£3.00	*NHS Reference Costs*[320]
Lipids test	Gamma	100	0.01	£1.00	*NHS Reference Costs*[320]
Liver function test	Gamma	100	0.03	£3.13	*NHS Reference Costs*[320]
Vitamin B12 test	Gamma	100	0.03	£3.13	*NHS Reference Costs*[320]
Nicotine replacement therapy	Gamma	100	1.03	£103.00	Curtis[318]

continued

TABLE 62 Cost input parameters (*continued*)

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source/reference
CVD costs					
Unstable angina hospital admission	Gamma	100	12.75591	£1275.59	Ara *et al.*[321]
Revascularisation in hospital	Gamma	100	60.36846	£6036.85	Ara *et al.*[321]
Myocardial infarction hospital admission	Gamma	100	15.54896	£1554.90	Ara *et al.*[321]
First outpatient appointment	Gamma	100	1.653571	£165.36	Ara *et al.*[321]
Subsequent outpatient appointments	Gamma	100	1.100574	£110.06	Ara *et al.*[321]
Fatal coronary heart disease	Gamma	100	7.125001	£712.50	Palmer *et al.*[322]
Fatal stroke	Gamma	100	44.42562	£4442.56	Youman *et al.*[323]
First year stroke	Gamma	100	126.77	£12676.60	Luengo-Fernandez *et al.*[324]
Subsequent year stroke	Gamma	100	17.399	£1739.91	Luengo-Fernandez *et al.*[324]
Transient ischaemic attack	Gamma	100	27.226	£2722.65	Luengo-Fernandez *et al.*[324]
Glyceryl Trinitrate Spray (Glytrin spray; Aspire Pharma Ltd, Petersfield, UK)	Constant	NA	NA	£12.61	Ara *et al.*[321]
Isosorbide mononitrate	Constant	NA	NA	£13.54	Ara *et al.*[321]
Verapamil	Constant	NA	NA	£50.57	Ara *et al.*[321]
(Tenormin®; AstraZeneca plc, Cambridge, UK)	Constant	NA	NA	£36.42	Ara *et al.*[321]
Aspirin	Constant	NA	NA	£8.01	Ara *et al.*[321]
Ramipril	Constant	NA	NA	£90.45	Ara *et al.*[321]
ARB	Constant	NA	NA	£253.28	Ara *et al.*[321]
Clopidogrel	Constant	NA	NA	£554.41	Ara *et al.*[321]
Chronic heart failure year 1 inpatient	Gamma	17.08787	197.607	£3376.68	Alva *et al.*[247]
Chronic heart failure year 1 non inpatient	Gamma	50.13476	20.66365	£1035.97	Alva *et al.*[247]
Chronic heart failure subsequent years inpatient	Gamma	23.46525	66.42644	£1558.71	Alva *et al.*[247]
Chronic heart failure subsequent years non inpatient	Gamma	109.7982	9.377373	£1029.62	Alva *et al.*[247]
Microvascular costs					
Blindness year 1 inpatient	Gamma	7.982428	179.6254	£1433.85	Alva *et al.*[247]
Blindness year 1 non-inpatient	Gamma	14.79887	127.9935	£1894.16	Alva *et al.*[247]
Blindness subsequent years inpatient	Gamma	41.39524	11.58007	£479.36	Alva *et al.*[247]

TABLE 62 Cost input parameters (*continued*)

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source/reference
Blindness subsequent years non-inpatient	Gamma	79.72506	9.795462	£780.94	Alva *et al.*[247]
Amputation year 1 inpatient	Gamma	35.73274	282.6952	£10101.48	Alva *et al.*[247]
Amputation year 1 outpatient	Gamma	16.81661	169.8352	£2856.05	Alva *et al.*[247]
Amputation subsequent years inpatient	Gamma	23.02322	82.36361	£1896.28	Alva *et al.*[247]
Amputation subsequent years outpatient	Gamma	57.06248	29.87502	£1704.74	Alva *et al.*[247]
Renal haemodialysis	Gamma	100	420.49	£42,049.00	Baboolal *et al.*[325]
Renal automated peritoneal dialysis	Gamma	100	272.1714	£27,217.14	Baboolal *et al.*[325]
Renal ambulatory peritoneal dialysis	Gamma	100	197.4225	£19,742.25	Baboolal *et al.*[325]
Renal transplant	Gamma	100	236.5973	£23,659.73	Organ Donation[326]
Immunosuppressants	Gamma	100	69.58745	£6958.75	Organ Donation[326]
Foot ulcer not infected	Gamma	100	1.677526	£167.75	Gordois *et al.*[327]
Foot ulcer with cellulitis	Gamma	100	4.431003	£443.10	Gordois *et al.*[327]
Foot ulcer with osteomyelitis	Gamma	100	8.215817	£821.58	Gordois *et al.*[327]
Other disease costs					
Breast cancer	Gamma	100	138.1811	£13,818.11	Madan *et al.*[328]
Colorectal cancer Dukes A	Gamma	100	100.9135	£10,091.35	Tappenden *et al.*[329]
Colorectal cancer Dukes B	Gamma	100	173.1532	£17,315.32	Tappenden *et al.*[329]
Colorectal cancer Dukes C	Gamma	100	265.5026	£26,550.26	Tappenden *et al.*[329]
Colorectal cancer Dukes D	Gamma	100	166.2553	£16,625.53	Tappenden *et al.*[329]
Osteoarthritis	Gamma	100	9.616886	£961.69	Oxford Economics[330]
Depression – Practice nurse surgery	Gamma	100	0.090154	£9.02	Chalder *et al.*[331]
Depression – Practice nurse home	Gamma	100	0.270463	27.05	Chalder *et al.*[331]
Depression – Practice nurse telephone	Gamma	100	0.090154	9.02	Chalder *et al.*[331]
Depression – health visitor	Gamma	100	0.387834	38.78	Chalder *et al.*[331]
Depression – district nurse	Gamma	100	0.377628	37.76	Chalder *et al.*[331]
Depression – other nurse	Gamma	100	0.090154	9.02	Chalder *et al.*[331]
Depression – health-care assistant phlebotomist	Gamma	100	0.034021	3.40	Chalder *et al.*[331]
Depression – other primary care	Gamma	100	0.255154	25.52	Chalder *et al.*[331]
Depression – out of hours	Gamma	100	0.268661	26.87	Chalder *et al.*[331]
Depression – NHS Direct	Gamma	100	0.25295	25.30	Chalder *et al.*[331]
Depression – walk-in centre	Gamma	100	0.388316	38.83	Chalder *et al.*[331]

continued

TABLE 62 Cost input parameters (*continued*)

Parameter description	Distribution	Parameter 1	Parameter 2	Central estimate	Source/reference
Depression – prescribed medicines	Gamma	100	0.096144	9.61	Chalder *et al.*[331]
Depression – secondary care	Gamma	100	0.81	81.00	Chalder *et al.*[331]
Diagnosis and other costs					
GP appointment	Gamma	100	0.47	£46.95	Chalder *et al.*[331]
Diabetes diagnosis	Gamma	100	0.12	£14.81	*NHS Reference Costs*[320]
Hypertension diagnosis	Gamma	100	0.57	£56.51	NICE[332]
Antihypertensives	Gamma	100	1.96	£195.94	
Simvastatin	Constant	NA	NA	£26.59	

ARB, angiotensin II receptor blockers; GP, general practitioner; NA, not applicable.

Technical appendix on network meta-analysis results used in cost-effectiveness modelling

Adults with type 1 diabetes mellitus

TABLE 63 Variance–covariance matrix for HbA_{1c} treatment effects in year 1, for adults with T1DM

	_y_A: _cons	_y_B: _cons	_y_D: _cons	tau: _cons
_y_A:_cons	0.00902538			
_y_B:_cons	0.00283336	0.0090491		
_y_D:_cons	0.0090252	0.0028333	0.02923929	
tau:_cons	1.174×10^{9}	1.189×10^{9}	1.479×10^{9}	0.00995378

A, CBT; B, counselling; C (reference): usual care; D, attention control.

Adults with type 2 diabetes mellitus

TABLE 64 Variance–covariance matrix for HbA_{1c} treatment effects in year 1, for adults with T2DM

	_y_A: _cons	_y_B: _cons	_y_C: _cons	_y_E: _cons	tau: _cons
_y_A:_cons	0.01642376				
_y_B:_cons	0.00152833	0.01004061			
_y_C:_cons	4.068×10^{-6}	3.676×10^{-6}	.0791886		
_y_E:_cons	0.00537357	0.00783819	2.476×10^{-6}	0.02765208	
tau:_cons	–0.00016284	–0.00014717	–0.00008289	–0.00009913	0.00331815

A, CBT; B, counselling; C, psychotherapy; D (reference), usual care; E attention control.

Adults with type 1 diabetes mellitus: dispersion parameters

TABLE 65 Dispersion parameters used for individual heterogeneity in HbA_{1c} year 1 effect for adults with T2DM

HbA_{1c} at 1 year (beta scale)	Coefficient	SE	*t*	$p > t$	95% CI
Dispersion parameter (phi), using a natural logarithm link function					
Baseline HbA_{1c} (beta scale)	–2.996862	0.9980645	–3	0.003	–4.954 to –1.040
Constant	4.912	0.332	14.79	0	4.261 to 5.563

SE, standard error.

See appendix 22 of supplementary materials B in Pollard *et al.*[244] to obtain the covariance matrix for these coefficients.

Technical appendix on longer-term (post 1 year) duration of treatment effect for psychological interventions

TABLE 66 Joint distribution for 1-year fall and longer-term trajectory in HbA_{1c} levels for T1DM: CBT versus usual care

Mean and SEs from the Ridge *et al.*[251] analysis	Mean	SE	Covariance matrix	
Initial fall	–0.46	0.178575	0.031888927	–0.01613
Trajectory	0.062145	0.116901	–0.016134413	0.013666

SE, standard error.

TABLE 67 Joint distribution for 1-year fall and longer-term trajectory in HbA_{1c} levels for T1DM: counselling versus usual care

Mean and SEs from the Ridge *et al.*[251] analysis	Mean	SE	Covariance matrix	
Initial fall	–0.19	0.178575	0.030984323	–0.01489
Trajectory	–0.02707	0.14901	–0.014886507	0.022204

SE, standard error.

Technical appendix on costing psychological interventions

Purpose of this section

This section details the assumptions made in estimating the cost of the different types of psychological interventions for adults with T1DM and people with T2DM. Values used in the costing are underlined.

Adults with type 1 diabetes mellitus

This section highlights the different components of intervention resource use and cost associated with the different types of psychological interventions delivered to adults with T1DM. These are broadly split into two categories: those types of resource use/cost that are assumed to be the same across interventions and those that are different. The following categories are assumed to be the same across interventions: the interventionists, the session-related non-contact time (either as a ratio of contact time or an absolute value),

the cost of consumables and the training costs. The following categories are assumed to be different: the split between individual and group sessions, the average number of people in a group session, the number of sessions and the duration of each session. These are all dealt with in the following sections.

Resources that are the same across the different psychological interventions

Interventionists

Table 68 shows the different interventionists who delivered psychological interventions for people with T1DM and associated UK full economic costs (from the PSSRU *Unit Costs of Health and Social Care* 2016[333]).

We have assumed that the person delivering the intervention is a band 7 nurse. The full economic cost of staff time will be £53 per hour worked, as most studies used nurses rather than psychologists for psychological interventions for people with T1DM.

Q1 – Is a band 7 nurse an appropriate interventionist, if a psychological intervention were to be implemented for adults with T1DM in the UK?

Session-related non-contact time

The number of hours spent on course administration was reported in only one study (ADaPT);[251] it was 0.25 hours per session. As this is only one study, there are some concerns of the applicability of this, more generally, to psychological interventions in a UK setting. Therefore, the proportion of non-contact time to contact time will be based on the ratio of direct to indirect contacts reported for band 7 hospital nurses in the PSSRU.[333] This is for every hour of face-to-face contact, there is 1.44 hours of indirect time. This was chosen as it is based on a nationally representative ratio of non-contact to contact time for this grade of nurse in the UK.

Q2 – Are you aware of any other information which gives information on the non-contact time associated with delivering a psychological intervention to adults with T1DM?

Q3 – Does the ratio of 1.44 non-contact hours per hour of contact capture all non-contact time spent delivering the session (e.g. administration, rearranging session times)? If not, what alternative assumption do you think that we should make?

TABLE 68 The staff member who delivered psychological interventions to adults with T1DM in the systematic review and the associated costs per hour of staff time in the UK

Interventionist	Number of studies	Typical NHS band (PSSRU)	Cost (£) per hour (PSSRU)
Nurse/dietitian/educator	4	Band 6 (nurse specialist)	44 (excluding standard non-patient contact)
		Band 7 (nurse advanced)	53 (excluding standard non-patient contact)
		Band 8a (modern matron)	62
Psychologist	2	Band 7 (clinical psychologist)	52
		Band 8a–b (clinical psychologist principle)	62
		Band 8d–9 (clinical psychologist consultant)	Not stated
Nurse and psychologist	1	Combination of the two above categories	
Nurse or psychologist	1	Combination of the two above categories	

Consumable cost per session

Only one study reported the cost of consumables per session (ADaPT); this was £0.72 in 2005–06 prices. After inflating these to 2015–16 prices using the Hospital and Community Health Service (HCHS) pay and prices index,[333] this gives a consumable cost per session of £0.89.

Q4 – Are you aware of any other studies that give a cost of consumables spent delivering psychological interventions in T1DM adults?

Training duration

The mean duration of training for interventionists to deliver a group session across all psychological interventions for adults with T1DM was 40 hours of contact time. The mean duration of training for individual sessions was 30 hours of contact time.

We will assume that both sessions were delivered by a band 8 clinical psychologist (£62 per hour) to band 7 nurses. We will assume that the training session is delivered to, on average, 15 nurses at the same time. This is based on the DAFNE activity report from 2014–15 in which 46 educators were trained in three courses (DAFNE programme activity, 1 April 2014–31 March 2015). Furthermore, based on the costings conducted for DAFNE, we will assume that each site will train three trainees, and that there will be a 10% depletion of staff per year (DAFNE fact sheet 6). The yearly costs of training were calculated assuming a 10-year lifespan and a depreciation rate of 3.5%.

A breakdown of the costs of training staff to deliver psychological interventions is presented in *Table 69*.

Q5 – Is a band 8 clinical psychologist an appropriate grade for the average person likely to deliver training sessions for psychological interventions?

Q6 – Is DAFNE an appropriate source for the duration of training effect and the number of trainees per session?

Q7 – If not, what data/values should be used instead to estimate the training costs of delivering psychological interventions?

Resource use specific to the different psychological interventions

The resource use specific to the different psychological interventions are presented in *Table 70*. The mean number of sessions, the mean time spent delivering sessions and the average number of people receiving an intervention in each session were obtained from a sample size-weighted average of the data reported in the studies in the systematic review.

TABLE 69 The staff member who delivered psychological interventions to adults with T1DM in the systematic review and the associated costs per hour of staff time in the UK

Breakdown of training costs per recipient of psychological interventions	Course cost	
	Individual	Group
a) Trainer	£1860	£2480
b) Cost per trainee (a / 15.3)	£121.30	£161.74
c) Cost of trainee time	£1590	£2120
d) Cost for three trainees [(b + c) × 3]	£5133.91	£6845.22
e) Annuity factor[a]	8.32	8.32
f) Cost per year (d / e)	£617.31	£823.08
g) Cost per recipient of psychological intervention (f / 48)	£12.86	£17.15

a 3.5% depreciation and a 10-year duration.

TABLE 70 The cost of delivering CBT and counselling to adults with T1DM

Breakdown of training costs per recipient of psychological interventions	CBT	Counselling
a) Proportion of the intervention that is delivered to a group	71.1%	27.8%
Mean number of sessions		
b.1) Individual	9.2	7
b.2) Group	7	9.6
Mean time spent delivering sessions (hours)		
c.1) Individual	0.9	0.9
c.2) Group	2.2	2.3
Average number of people receiving an intervention per session		
d.1) Individual	1	1
d.2) Group	6.6	6.2
Direct costs		
e.1) Direct cost of an individual session [(b.1 × c.1 × £53) / d.1]	£433	£336
e.2) Direct cost of a group session [(b.2 × c.2 × £53) / d.2]	£133	£186
Average cost of the intervention [a*e.1 +(1-a)*e.2]	£219.86	£294.01
Indirect cost of nurse time for the session	£65.96	£55.90
Transcription of the sessions	£21.74	£27.64
Supervision costs		
Direct	£279.00	£85.31
Indirect	£52.34	£115.87
Training cost per participant	£18.26	£16.15
Capital costs of running the course (tape recorder)	£0.07	£0.07
Total cost	£657	£580

The cost of delivering a CBT intervention is £657 per participant and the cost of delivering a counselling intervention is £580 per participant.

Usual care

Whenever data on usual care were presented in the studies included in the systematic review, it was either an enhancement to usual care or the contacts were related to protocol requirements (e.g. collection of blood samples at baseline). Therefore, it was assumed that there were no additional costs associated with usual care.

Type 2 diabetes mellitus

Resources that are the same across the different psychological interventions

This section highlights the different components of intervention resource use and cost associated with the different types of interventions. These are broadly split into two categories: those types of resource use/cost that are assumed to be the same across interventions and those that are different. The following categories are assumed to be the same across interventions: the interventionists, the session-related non-contact time (either as a ratio of contact time or an absolute value), the cost of consumables and the training costs. The following categories are assumed to be different: the split between individual and group sessions, the average number of people in a group session, the number of sessions and the duration of each session. These are all dealt with in turn in the following sections.

TABLE 71 Detailed parameters for final costing of psychological interventions for T1DM

Item	Value	Notes	Source
Cost per hour of interventionist time	£53	Band 7 nurse	*Unit Costs of Health and Social Care 2016*[333]
Cost per hour of trainer time	£62	Band 8a clinical psychologist	*Unit Costs of Health and Social Care 2016*[333]
Cost per hour of supervisor time	£62	Band 8a clinical psychologist	*Unit Costs of Health and Social Care 2016*[333]
HCHS pay and prices 2011/12	282.5		*Unit Costs of Health and Social Care 2016*[333]
HCHS pay and prices 2015/16	297		*Unit Costs of Health and Social Care 2016*[333]
Transcription costs	£0.80	2011/12 prices	Ismail *et al.*[300]
Number of people delivered to per year	48		DAFNE[334]
CBT			
Proportion of the interventions that are delivered to a group	71.1%		Systematic review of this study
Individual sessions			
Number of sessions	9.197452229		Systematic review of this study
Mean time spent delivering sessions	0.88761175		Systematic review of this study
Average number of people receiving an intervention	1		Definition
Group sessions			
Number of sessions	7.487046632		Systematic review of this study
Mean time spent delivering sessions	2.221631206		Systematic review of this study
Average number of people receiving an intervention	6.613475177		Systematic review of this study
Hours of non-contact time per hour of contact time	0.3		ADaPT[251]
Counselling			
Proportion of the interventions that are delivered to a group	27.8%		
Individual sessions			
Number of sessions	7		Systematic review of this study
Mean time spent delivering sessions	0.904761905		Systematic review of this study
Average number of people receiving an intervention	1		Definition
Group sessions			
Number of sessions	9.615384615		Systematic review of this study
Mean time spent delivering sessions	2.269230769		Systematic review of this study
Average number of people receiving an intervention	6.230769231		Systematic review of this study
Hours of non-contact time per hour of contact time	0.2		ADaPT[251]

continued

TABLE 71 Detailed parameters for final costing of psychological interventions for T1DM (*continued*)

Item	Value	Notes	Source
Training			
Number of people trained at once	5.5		Ismail *et al.*[300]
Depletion of staff trained per year	10%		DAFNE[334]
Depreciation rate	3.50%		NICE methods guide[335]
Capital costs			
Room hire	£3.10	per hour, 2011/12 prices	Ismail *et al.*[300]
Video camera	£19.99	2011/12 prices	
Costs per person			
Handbook	£11.94	2011/12 prices	Ismail *et al.*[300]
Slides	£7.20	2011/12 prices	Ismail *et al.*[300]
Individual sessions			
Time of training sessions	30		Systematic review of this study
Group sessions			
Time of training sessions	40		Systematic review of this study
Supervision			
Capital costs			
Audio-recorder	24.99	2011/12 prices	Ismail *et al.*[300]
Lifespan of technology	5	years	Ismail *et al.*[300]
Staff costs			
Counselling			
Supervision time per session	0.140666667	per hour of contact	ADaPT[251]
Therapist non-contact	0.25	per hour of contact	ADaPT[251]
Supervisor non-contact	0.140666667	per hour of contact	ADaPT[251]
CBT			
Supervision time per session – senior	0.033166667	per hour of contact	ADaPT[251]
Supervisor non-contact – senior	0.01153845	per hour of contact	ADaPT[251]
Supervision time per session – non-senior	0.551666667	per hour of contact	ADaPT[251]
Supervisor non-contact – non-senior	0.19196155	per hour of contact	ADaPT[251]
Therapist non-contact	0.25	per hour of contact	ADaPT[251]
Intermediate calculations			
Average contact time per person			
CBT			
Group	2.515085638		ADaPT[251]
Individual	8.163766666		ADaPT[251]
Average	4.148313854		ADaPT[251]
Counselling			
Group	2.515085638		
Individual	6.333333333		
Average	5.273463866		
Transcription costs applied to % of sessions	10%		

TABLE 72 Summary of T1DM intervention costs

Item	Individual	Group
Training costs (£)		
Trainer time	1860	2480
Room hire	93	124
Video recording	21.02	21.02
Sum	1974	2625
Per participant	359	477
Cost of participant time	1590	2120
Cost of handbooks	13	13
Cost of slide printouts	8	8
Cost for number of trainees	5907.10	7852.19
Annuity factor	8.32	8.32
Cost per annum	710.28	944.16
Cost per recipient of a psychological intervention	14.80	19.67
Capital costs		
Tape recorder	£26.27	
Assumed lifespan (years)	5	
Depreciation rate	3.50%	
Annuity factor	8.32	
Cost per year	£3.16	
Cost per psychological intervention recipient	£0.07	
Intervention costs *CBT (£)*		
Direct costs of staff time to deliver the session		
Individual	432.68	
Group	133.30	
Average	219.86	
Indirect cost of nurse time for the session	65.96	
Transcription of the sessions	21.74	
Supervision costs		
Direct	279.00	
Indirect	52.34	
Training cost per participant	18.26	
Capital costs of running the course (tape recorder)	0.07	
Total cost	657	
Cost per session for comparison with Ismail *et al.*[252]	82.34	

continued

TABLE 72 Summary of T1DM intervention costs (*continued*)

Item	Individual	Group
Counselling (£)		
Direct costs of staff time to deliver the session		
Individual	335.67	
Group	133.29	
Average	279.49	
Indirect cost of nurse time for the session	55.90	
Transcription of the sessions	27.64	
Supervision costs		
Direct	85.31	
Indirect	115.87	
Training cost per participant	16.15	
Capital costs of running the course (tape recorder)	0.07	
Total cost	580	
Cost per session for comparison with Ismail *et al.*[252]	72.72	

Interventionists

Assume that the interventionist is a band 7 (regardless of type). We will cost this as £53 per hour worked, as most studies used nurses for psychological interventions for people with T2DM.

TABLE 73 The staff members who delivered psychological interventions to people with T2DM in the systematic review and the associated costs per hour of staff time in the UK

Interventionist	Number of studies	Typical NHS band (PSSRU)	Cost per hour (PSSRU)
Nurse/dietitian/educator	23	Band 6 (nurse specialist)	£44 (excluding standard non-patient contact)
		Band 7 (nurse advanced)	£53 (excluding standard non-patient contact)
		Band 8a (modern matron)	£62
Psychologist/psychotherapist	12	Band 7 (clinical psychologist)	£52
		Band 8a–b (clinical psychologist principle)	£62
		Band 8d–9 (clinical psychologist consultant)	Not stated
Counsellor	1	Band 5 counsellor (entry level)	£32
		Band 6 counsellor	£42
		Band 7 counsellor (specialist)	£52
		Band 8a–c counsellor consultant	£62–74
Music therapists	1	Band 6	£42
Pharmacist	1	Band 6 pharmacist	£42
		Band 7 pharmacist specialist	£52
		Band 8a–b pharmacist advanced	£62–74
		Band 8b–d pharmacist consultant	Not stated
General practitioner/ community doctor	2		£3.90 per minute (direct staff care costs and with qualifications)

Q8 – Is a band 7 interventionist (either a nurse or clinical psychologist) appropriate, if a psychological intervention were to be implemented in the UK for people with T2DM?

Session-related non-contact time

The number of hours spent on course administration was reported in only one study (Walker[336]); it was 10 minutes per 1- hour session. As this is only one study and it has been conducted in the US health-care setting, there are some concerns of the applicability of this, more generally, to psychological interventions in a UK setting. The proportion of non-contact time to contact time will be based on the ratio of direct to indirect contacts reported for band 7 hospital nurses in the PSSRU. This is for every hour of face-to-face contact; there are 1.44 hours of indirect time.

Q9 – Are you aware of any other information that gives the session-related non-contact time for health-care professionals in the field of diabetes?

Q10 – Does the ratio of 1.44 non-contact hours per hour of contact capture all non-contact time spent delivering the session (e.g. administration, rearranging session times)?

Consumable cost per session

Only one study reported the cost of consumables per session (Walker[336]), this was US$650 across 154 sessions (US$4.22 per session) in 2010–11 prices. This gives a cost of £3.18 per session after converting the cost to Great British pounds using the Organisation for Economic Co-operation and Development (OECD) purchasing power parity rates and inflating to 2015–16 prices using the HCHS pay and prices index.

Q11 – Are you aware of any other studies that give a cost of consumables spent delivering psychological interventions for people with T2DM?

Training duration

The mean duration of training for individual sessions was 30.63 hours of contact time. No studies that used a group session reported the training duration, so it was assumed that the time taken to train health-care professionals to deliver a psychological intervention was also 30.63 hours.

We will assume that both sessions were delivered by a band 8 clinical psychologist (£62 per hour) to band 7 nurses. Based on the economic analysis of the DESMOND (Diabetes Education and Self Management for Ongoing and Newly Diagnosed) structured education course for people with T2DM (Gillett *et al.*[337]), it was assumed that:

- the training session is delivered to, on average, 13 interventionists at the same time
- three interventionists per site will be trained for the course
- training will be valid for 3 years
- Each trained educator will conduct, on average, 18.7 (56/3) interventions per year.

Q12 – Is a band 8 clinical psychologist an appropriate grade for the average person likely to deliver training sessions for psychological interventions?

Q13 – Is DESMOND an appropriate source for the duration of training effect and the number of trainees per session?

Q14 – Would DAFNE be a more appropriate source of evidence for the duration of training effect and the number of trainees per session? (10-year effect of training, three trainees per site, trainees would see 48 people per annum.)

Q15 – If neither of these data sources are appropriate, what data/values should be used instead?

TABLE 74 The staff member who delivered psychological interventions to people with T2DM in the systematic review and the associated costs per hour of staff time in the UK

Course cost	Individual	Group
a) Trainer	£2065.32	£2065.32
b) Cost per trainee (a / 13)	£158.87	£158.87
c) Cost of trainee time	£1765.51	£1765.51
d) Cost for three trainees [(b + c) × 3]	£5296.53	£5296.53
e) Annuity factor[a]	2.80	2.80
f) Cost per year (d / e)	£1890.51	£1890.51
g) Cost per recipient of psychological intervention (f / 18.7)	£101.28	£101.28

a 3.5% depreciation and a 3-year duration.

Interventions

The cost of the staff time for delivering the intervention (both direct and indirect) was recalculated for the studies based on the classification in the NMA. The three categories of intervention for people with T2DM were CBT, counselling and psychotherapy. Only weighted averages between individual and group interventions were used to estimate the cost of each of the intervention categories. The results of these analyses are presented in *Table 75*.

TABLE 75 The cost of delivering CBT, counselling and psychotherapy to people with T2DM

	CBT	Counselling
a) Proportion of the interventions that is delivered to a group	72.0%	5.5%
Mean number of sessions		
b.1) Individual	14.9	11.0
b.2) Group	7.3	5.9
Mean time spent delivering sessions (hours)		
c.1) Individual	0.6	0.8
c.2) Group	1.6	2.2
Average number of people receiving an intervention per session		
d.1) Individual	1	1
d.2) Group	7.1	8.5
Direct costs		
e.1) Direct cost of an individual session [(b.1*c.1*£53)/d.1]	£444.07	£466.17
e.2) Direct cost of an group session [(b.2*c.2*£53)/d.2]	£87.66	£80.74
Average cost of the intervention [a × e.1 + (1 – a) × e.2]	£187.29	£444.79
Other costs		
Indirect cost of nurse time for the session	£56.19	£88.96
Transcription of the sessions	£18.52	£43.98
Supervision costs		
Direct	£237.66	£136
Indirect	£91.41	£184
Training cost per participant	£42.07	£42.07
Capital costs of running the course (tape recorder)	£0.07	£0.07
Total cost	£633	£940

The cost of delivering a CBT intervention is £633 per participant; the cost of delivering a counselling intervention is £940 per participant.

Usual care

Whenever data on usual care were presented in the studies included in the systematic review, they were either an enhancement to usual care or the contacts were related to protocol requirements (e.g. collection of blood samples at baseline). Therefore, it was assumed that there were no additional costs associated with usual care.

TABLE 76 Detailed parameters for final costing of psychological interventions for T2DM

Item	Value	Notes	Source
Cost per hour of interventionist time	£53	Band 7 nurse	*Unit Costs of Health and Social Care 2016*[333]
Cost per hour of trainer time	£62	Band 8a clinical psychologist	*Unit Costs of Health and Social Care 2016*[333]
Cost per hour of supervisor time	£62	Band 8a clinical psychologist	*Unit Costs of Health and Social Care 2016*[333]
HCHS Pay and prices 2011/12	£282.5		*Unit Costs of Health and Social Care 2016*[333]
HCHS Pay and prices 2015/16	£297		*Unit Costs of Health and Social Care 2016*[333]
Transcription costs	£0.80	2011/12 prices	Ismail *et al.*[300]
Number of people delivered to per year	48		DAFNE[334]
CBT			
Proportion of the interventions that are delivered to a group	72.0%		SR
Individual sessions			
Number of sessions	14.94		Systematic review of this study
Mean time spent delivering sessions (hours)	0.561		Systematic review of this study
Average number of people receiving an intervention	1		Definition
Group sessions			
Number of sessions	7.35		Systematic review of this study
Mean time spent delivering sessions (hours)	1.591		Systematic review of this study
Average number of people receiving an intervention	7.071		Definition
Hours of non-contact time per hour of contact time	0.3		ADaPT[251]
Counselling			
Proportion of the interventions that are delivered to a group	5.5%		Systematic review of this study
Individual sessions			
Number of sessions	10.99		Systematic review of this study
Mean time spent delivering sessions (hours)	0.8		Systematic review of this study
Average number of people receiving an intervention	1		Definition

continued

TABLE 76 Detailed parameters for final costing of psychological interventions for T2DM (*continued*)

Item	Value	Notes	Source
Group sessions			
Number of sessions	5.885		Systematic review of this study
Mean time spent delivering sessions (hours)	2.191		Systematic review of this study
Average number of people receiving an intervention	8.465		Definition
Hours of non-contact time per hour of contact time	0.2		ADaPT[251]
Psychotherapy			
Proportion of the interventions that are delivered to a group	0.0%		
Individual sessions			
Number of sessions	12		
Mean time spent delivering sessions (hours)	0.5		
Average number of people receiving an intervention	1		
Group sessions			
Number of sessions	–		
Mean time spent delivering sessions (hours)	–		
Average number of people receiving an intervention	–		
Hours of non-contact time per hour of contact time	0.2	Assumed it is closer to counselling than CBT (as a result of the proportion of events that are individual sessions)	ADaPT[251]
Training			
Time spent training nurses (hours)	33.31		
Cost per hour of trainer time	£62		PSSRU
Cost per hour of interventionist time	£53		PSSRU
Duration of training (hours)	10		Assumed same as type 1
Number of people in a training session	13		Gillett *et al.*[337]
Number of nurses per centre	3		Gillett *et al.*[337]
Depreciation rate	0.035%		NICE methods guide[335]
Number of people trained at once	5.5		Ismail *et al.*[300]
Number of people receiving a psychological intervention per year	18.7		Gillett *et al.*[337]
Capital costs			
Room hire	£3.1	Per hour, 2011/12 prices	Ismail *et al.*[300]
Video camera	£19.99	2011/12 prices	
Costs per person			
Handbook	£11.94	2011/12 prices	Ismail *et al.*[300]
Slides	£7.2	2011/12 prices	Ismail *et al.*[300]

TABLE 76 Detailed parameters for final costing of psychological interventions for T2DM (*continued*)

Item	Value	Notes	Source
Intermediate calcs			
Average contact time per person (hours)			
CBT			
Group	1.654		
Individual	8.379		
Average	3.534		
Counselling			
Group	1.523		
Individual	8.796		
Average	8.392		

TABLE 77 Summary of T2DM intervention costs

Item	Cost (£)
Training costs	
Trainer time	2065
Room hire	98.22
Video-recording	21.02
Sum	2185
Per participant	397.19
Cost of participant time	1765.51
Cost of handbooks	11.36
Cost of slide print outs	6.85
Cost for number of trainees	6542.73
Annuity factor	8.32
Cost per annum	786.71
Cost per recipient of a psychological intervention	42.07
CBT	
Direct costs of staff time to deliver the session	
Average	187.29
Indirect cost of nurse time for the session	56.19
Transcription of the sessions	18.52
Supervision costs	
Direct	237.66
Indirect	91.41

continued

TABLE 77 Summary of T2DM intervention costs (*continued*)

Item	Cost (£)
Training cost per participant	42.07
Capital costs of running the course (tape recorder)	0.07
Total cost	633
Counselling	
Direct costs of staff time to deliver the session	
Average	445
Indirect cost of nurse time for the session	88.96
Transcription of the sessions	43.98
Supervision costs	
Direct	136
Indirect	184
Training cost per participant	42.07
Capital costs of running the course (tape recorder)	0.07
Total cost	940
Psychotherapy	
Direct costs of staff time to deliver the session	
Average	318
Indirect cost of nurse time for the session	63.6
Transcription of the sessions	31.44
Supervision costs	
Direct	97.06
Indirect	131.828
Training cost per participant	42.07
Capital costs of running the course (tape recorder)	0.07
Total cost	684

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