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Group-based self-management education for people with type 2 diabetes mellitus (Protocol)

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TABLE OF CONTENTS

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[Intervention Protocol]

Group-based self-management education for people with type 2 diabetes mellitus

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effects of group-based self-management education for adults diagnosed with T2DM on clinical, lifestyle, and psychosocial outcomes in the short (six months to 10 months), medium (> 10 months up to 18 months), and long (> 18 months) term.

To explore the intervention characteristics and processes that are aligned with effective group-based self-management education for people with T2DM.

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BACKGROUND

Description of the condition

Diabetes mellitus and its complications

Diabetes mellitus is a serious chronic condition of persistent hyperglycaemia due to defects in pancreatic insulin secretion or insulin resistance in target organs (IDF 2021). It was estimated that in 2021, 537 million adults, or 10.5% of the global population, were living with diabetes (IDF 2021). This number is predicted to rise to 643 million, or 11.3% of the global population, by 2030 (IDF 2021). Type 2 diabetes mellitus (T2DM) is the most common form of diabetes, accounting for between 90% and 95% of all diabetes cases globally (WHO 2019).

The majority of the burden of T2DM can be attributed to comorbidities and complications associated with long-term, suboptimal blood glucose control, such as retinopathy, nephropathy, neuropathy, and increased risk of cardiovascular, peripheral vascular, and cerebrovascular diseases (WHO 2019). A diagnosis of T2DM has various other implications for individuals, including the potential stigma of diabetes, possible effects on their employment, health and life insurance, ability to drive, social opportunities, and other cultural, ethical, and human rights consequences (WHO 2019). Additionally, diabetes and its complications can lead to direct economic impacts such as costs of medications, healthcare, and hospitalisations for diabetes complications, as well as indirect costs due to premature mortality, disability and absenteeism, affecting individuals, families, communities, and the broader health system (IDF 2019). An estimated 6.7 million deaths worldwide in 2021 resulted from diabetes and its complications (IDF 2021).

Diabetes management

T2DM is a complex, heterogeneous disease with its prognosis influenced by age at diagnosis, race or ethnicity, genetic, immunological, histopathological, metabolic or clinical course characteristics, and socioeconomic factors (Redondo 2020). Management of T2DM, therefore, requires individualised treatment with adaptations as the disease progresses over time (Elksnis 2019). People diagnosed with T2DM require access to immediate and ongoing care due to the long-term nature of the disease (IDF 2012). The primary goal of diabetes management is to prevent complications by maintaining blood glucose control with a general blood glycated haemoglobin (HbA1c) target of less than 7% (53 mmol/mol), whilst the subsequent goal is to identify and treat any complications as early as possible (ADA 2021; IDF 2017).

A vital aspect of T2DM management is the active involvement of individuals in their own care (Adolfsson 2008), with the diagnosis of T2DM imposing lifelong, multiple daily demands on the individual, their spouse, and family (Boothroyd 2010; WHO 2008). People with diabetes make most of their health-related decisions without input from formal health services, making them the predominant managers of their condition (Adolfsson 2007; Mensing 2003; Skinner 2006; WHO 2008). Self-management comprises three distinct sets of activities: medical management, behavioural management, and emotional management (Corbin 1988). A fundamental component of T2DM management is lifestyle change, which includes diabetes self-management education and support, medical nutrition therapy, physical activity, smoking cessation counselling, and psychosocial care (ADA 2022). If lifestyle management is not sufficient to control blood glucose levels, oral medications, combination therapy, or insulin therapy are required (IDF 2021).

Successful self-management of T2DM requires individuals to have sufficient knowledge of the condition, the skills and abilities necessary for diabetes self-care, and support to implement and sustain coping skills and behaviours to adequately undertake ongoing self-management activities (Powers 2015; Van Smoorenburg 2019). Patient education and support are essential aspects of self-management and are crucial to achieving improved outcomes for people with T2DM (Chaudry 2019). The aims are to optimise metabolic control, improve long-term diabetes control and an individual's subjective perception of physical, emotional, and social well-being, or quality of life (QOL), prevent acute and chronic complications, and reduce morbidity and mortality, all whilst remaining cost-efficient by promoting, supporting, and empowering positive self-management behaviours (ADA 2022; Campbell 1976). Additionally, it is important to consider the necessity for individuals with T2DM to maintain effective self-management behaviours. Effectively educating and supporting individuals with T2DM to self-manage their condition could vastly reduce the economic burden, disease burden, and risk of complications.

Description of the intervention

A key recommendation from the 2018 consensus report on the management of hyperglycaemia in T2DM is to offer access to ongoing diabetes self-management education and support, delivered in group or individual settings with trained educators, to all people diagnosed with T2DM (Davies 2018). This recommendation is supported by the American Diabetes Association's (ADA) Standards of Medical Care in Diabetes, which describes the importance of diabetes self-management education to facilitate the knowledge, skills, and ability needed for diabetes self-care (ADA 2022). Group-based education brings together small groups of people with T2DM to learn about self-management, and can incorporate other people within participants' social support networks, such as family members or friends (Mensing 2003). Group-based education typically focuses on topics such as blood glucose monitoring, nutrition, physical activity, medication, foot care, and smoking cessation, and are facilitated by health professionals (single disciplines or multidisciplinary teams), health professionals with peer supporters, or by peers (Odgers-Jewell 2017b). Small group education can promote health, well-being, and personal change by positively influencing group members' perceptions, beliefs, expectations, and behaviours (Borek 2018).

Group-based education interventions are complex interventions. The effectiveness of group-based education interventions is likely dependent on more than one characteristic related to the intervention (e.g. group size, the number and length of group sessions, the educational content, the use of theoretical frameworks), its implementation (e.g. face-to-face delivery, inclusion or exclusion of family and/or friends, intervention adherence, and the group facilitator's qualifications, training, level of experience, and delivery style), and the context in which it is delivered (e.g. primary care, community setting). It is likely that a range of different intervention characteristics influence effectiveness, and any combination of these intervention characteristics could be effective.

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A systematic review of group-based self-management education interventions for T2DM published in 2017 included 47 studies (Odgers-Jewell 2017b). It found that interventions were predominantly in primary care settings (34/47) and were facilitated by multidisciplinary teams of health professionals (20/47), single disciplines (17/47), health professionals with peer supporters (5/47), or by peers (5/47) (Odgers-Jewell 2017b). Furthermore, the length of interventions varied from one day to five years, the number of sessions and contact time with intervention participants ranged from one session to 36 sessions and three to 200 hours, and the group sizes varied from four to 32 participants (Odgers-Jewell 2017b).

Group-based education interventions for T2DM are generally poorly reported, with a recent study finding that only 32% of studies adequately described the intervention procedures in the original publication (Odgers-Jewell 2020). Poorly-reported interventions make it difficult to compare, synthesise, and evaluate the effectiveness of interventions, to define the 'active ingredients' of a successful group-based education intervention, and impede intervention replication and research translation (Odgers-Jewell 2020).

Adverse effects of the intervention

The potential adverse effects of group-based education programmes include exacerbating the possible shame and stigma of the T2DM diagnosis (Van Brakel 2006; Winkley 2015), potential insecurity resulting from comparison with others in the group who may be perceived as being better off than them (Rygg 2010), or feeling confronted through meeting people worse off than themselves (Van der Zee 1998). Additionally, previous research has indicated that barriers to attendance for group-education programmes include access issues, problems with timing due to work or family commitments, and a preference for one-to-one education (Winkley 2015).

How the intervention might work

Individuals with T2DM managed in one-to-one settings may experience deteriorating metabolic control despite intensive medical glycaemic intervention and health professionals' adherence to practice guidelines; this deterioration may be ameliorated by group education interventions (Trento 2004). Several systematic reviews, including one Cochrane Review, have evaluated the effectiveness of group-based education for people with T2DM compared to individual education, usual care, and waiting-list control, finding that group-based education had positive effects on various clinical, lifestyle, and psychosocial outcomes (Deakin 2005; Odgers-Jewell 2017b; Steinsbekk 2012). For example, the Cochrane Review (11 trials, 1532 participants) by Deakin and colleagues found that people receiving group-based education had significant improvements in HbA1c, body weight and systolic blood pressure, fasting blood glucose (FBG), a decreased need for diabetes medication, and increased diabetes knowledge compared to those receiving usual care, waiting-list control, or no intervention (Deakin 2005). These findings were confirmed by two subsequent reviews. The first (21 trials, 2833 participants), by Steinsbekk and colleagues, found group-based T2DM self-management education led to significant reductions in HbA1c, FBG levels, body weight, and improvements in diabetes knowledge, compared to usual care (Steinsbekk 2012). The most recent review (47 trials, 8533 participants), by Odgers-Jewell and colleagues, provided further evidence supporting the use of group-based education for the management of T2DM to significantly improve HbA1c, FBG, body weight, waist circumference, triglycerides, and diabetes knowledge (Odgers-Jewell 2017b).

Previous systematic reviews of the effectiveness of group-based self-management education programmes for people with T2DM suggest that the type of educator, use of insulin therapy, number of participants, intervention length, number of sessions, contact time and other factors can all impact intervention effectiveness (Deakin 2005; Odgers-Jewell 2017b; Steinsbekk 2012). However, no consensus as to which characteristics are most important for effective programmes has yet emerged from this research. This may be due to the large variation in interventions, poor intervention reporting, the limited number of studies examining the various intervention characteristics, and the interaction between, and within, the intervention characteristics. Therefore, when assessing and appraising complex interventions, it can be difficult to distinguish which intervention characteristics are most important, which are responsible for the effects, and how these multiple characteristics might interact in an additive way (Thomas 2021). Active characteristics should be described and assessed; however, they should only be examined separately if they are independent (Lenz 2007).

Research suggests that group dynamics or characteristics – such as a common purpose, pro-group perceptions, shared values and norms, the group structure, interdependence, group cohesion and climate, and opportunities for disclosure and feedback – are capable of changing group members' behaviours (Borek 2018). Findings from qualitative research suggest that characteristics specifically fostered in group-based education programmes are likely to influence intervention effectiveness. These include group interactions, peer learning, social support, normalisation through comparison with others in the same situation, and opportunities for people with T2DM to feel as though they have helped others, which may improve their self-esteem, self-perception, self-efficacy, motivation, attitudes towards diabetes, and health behaviours (Odgers-Jewell 2017a; Trento 2004). Social support provided by others has been linked to improvements in self-management, psychological functioning, and biomedical outcomes (Van Dam 2005). Peers in a group situation can offer knowledge, practical skills, personal competence, emotional support, and encouragement beyond the capacity of many health professionals (Wientjens 2008). Furthermore, people with T2DM are motivated to maintain changes following an education intervention as a result of four key factors: getting support from others, experiencing the positive effects of the changes, fearing complications, and making the changes a habit (Malpass 2009; Rise 2013). Finally, previous research has identified the important role of the facilitator in setting the tone and guiding the direction of the group, which could significantly influence the participant outcomes (Costello 2013).

Why it is important to do this review

Health professionals may eschew group-based education because the essential attributes for a successful group-based education intervention are unknown. Furthermore, no specific, evidence-based, practice guidelines for group-based education for T2DM have been identified internationally, inevitably resulting in wide

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variations in the programmes offered, and creating difficulty in the interpretation of evidence and its translation to a practice setting.

The three systematic reviews described above had limitations. The Cochrane Review was conducted in 2005 and included only 11 studies. As a result, meta-analyses for several of the main outcomes of the review were not possible, heterogeneity of the studies was high, and there were variations in follow-up analyses (Deakin 2005). The review conducted by Steinsbekk and colleagues included a greater number of studies, but only those published up to 2008, and conducted follow-up analyses of the primary outcome up to 12 months from baseline, whilst the Cochrane Review assessed follow-up two years or more from baseline (Deakin 2005; Steinsbekk 2012).The Steinsbekk 2012 review relied on the searches and assessments of the previous Cochrane Review, only searching five electronic databases from 2003 to the second week of 2008, which may have resulted in the exclusion, or omission, of some studies. The most recent systematic review was conducted in 2015 and included 47 trials (Odgers-Jewell 2017b). The results were complex, with most outcomes improving at time points proximal to the intervention, but others improving at more distal time points. The review's findings should be interpreted with caution due to the high degree of heterogeneity present in some of the meta-analyses and the moderate or high risk of bias present in most of the included studies. Finally, the conclusion from all three reviews was that, despite statistically significant improvements in the investigated outcomes, researchers could not pinpoint the exact mechanism or 'active ingredient(s)' of these complex interventions (Deakin 2005; Odgers-Jewell 2017b; Steinsbekk 2012).

This Cochrane Review builds upon the three previous reviews to update the evidence for the effectiveness of group-based interventions for T2DM management and seeks to overcome the limitations of the previous reviews. We will address intervention complexity through identifying the intervention characteristics and processes that are aligned with effective group-based self-management education interventions, presenting the characteristics of each intervention in a summary table, and extracting data using the template for intervention description and replication (TIDieR) checklist to enable a clear and detailed comparison of interventions (Hoffmann 2014). Additionally, we will attempt to determine possible reasons for heterogeneity by examining individual trial and subgroup characteristics, and by assessing whether any variations in effect size can be attributed to study design and intervention characteristics through subgroup and sensitivity analysis. Finally, the inclusion in this review of intervention studies published since the introduction of the TIDieR checklist in 2014 may assist in developing an improved understanding of the intervention characteristics associated with greater effectiveness. This review will support informed decision-making for individuals with T2DM, policymakers, and clinicians.

OBJECTIVES

To assess the effects of group-based self-management education for adults diagnosed with T2DM on clinical, lifestyle, and psychosocial outcomes in the short (six months to 10 months), medium (> 10 months up to 18 months), and long (> 18 months) term.

To explore the intervention characteristics and processes that are aligned with effective group-based self-management education for people with T2DM.

METHODS

Criteria for considering studies for this review

Types of studies

We will include original studies that report randomised controlled trials (RCTs) (parallel or cross-over trials) and cluster-RCTs.

Types of participants

We will include original studies with participants aged 18 years and older and diagnosed with T2DM. We will consider including studies involving children or adolescents if data are reported separately for participants aged 18 years and older. We will only include studies reporting on group education interventions for individuals with type 1 and T2DM if data are reported separately for T2DM.

Diagnostic criteria for type 2 diabetes mellitus

In order to be consistent with changes in the classification of, and diagnostic criteria for, diabetes mellitus over the years, the diagnosis should be established using the standard criteria valid at the time of the trial commencing (for example, ADA 2003; ADA 2017; WHO 1999). Ideally, the diagnostic criteria should have been described. We will use the trial authors' definition of diabetes mellitus if necessary.

Changes in diagnostic criteria may have produced significant variability in the clinical characteristics of the participants included, as well as in the results obtained (which we will investigate through sensitivity analysis).

Types of interventions

This review will explore interventions which bring together groups of four or more people diagnosed with T2DM to learn about self-management of the condition. Education topics will likely include, but are not limited to, blood glucose monitoring, nutrition, physical activity, medication, foot care, and smoking cessation.

We plan to investigate the following comparisons of intervention versus control/comparator.

Intervention

- Group-based education intervention
- Group-based education intervention plus usual care

Group-based education interventions can be delivered face-to-face, online, or through telehealth, and can be delivered using a combination of both face-to-face and online or telehealth delivery. Furthermore, to be eligible as group-based education interventions, a minimum of four participants are required per intervention group after dropouts. Previous research has indicated that groups of four to eight participants are manageable without diminishing the opportunity for individualisation within each group (Rickheim 2002). Including interventions with a minimum of four participants will allow the inclusion of interventions experiencing attrition in the groups.

We will include interventions conducted in primary or secondary care (including community-based interventions), and facilitated by trained or untrained multidisciplinary teams of health professionals, single disciplines, health professionals with peer supporters, or by peers. We will include interventions regardless

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of whether participants' family, friends, or both are included. We acknowledge a potential minor overlap with the Cochrane Review protocol on family-based interventions for adults with type 2 diabetes mellitus (Matrook 2018). However, we note that the Matrook 2018 review will not focus exclusively on group-based interventions, or interventions which include other people diagnosed with diabetes outside the family unit (Matrook 2018).

Comparators

- Usual care (also known as routine care) only
- Waiting-list control
- Individual education

As there will be differences in what constitutes usual care, we will describe this for all trials included in the review. We will classify comparison groups as 'individual education' only if the educational curriculum is the same as the group-based education intervention, but the intervention is delivered to one individual.

To establish fair comparisons, concomitant interventions must be the same in both the intervention and comparator groups.

If a trial includes multiple arms, we will include any arm that meets the review inclusion criteria.

Minimum duration of intervention

The minimum duration of the intervention will be one session lasting one hour. The clinically meaningful minimum duration of group-based education interventions is unclear from the literature.

Minimum duration of follow-up

The minimal duration of follow-up will be six months from baseline. This is to allow time for the intervention's effects to become evident and to reflect that monitoring of diabetes control via HbA1c should occur at six-monthly intervals to reflect the rate of turnover of red blood cells in the body (Nano 2020).

Summary of specific exclusion criteria

We will exclude trials in:

- pregnant women diagnosed with T2DM or gestational diabetes;
- adults diagnosed with type 1 diabetes
- children and adolescents only.

We will exclude studies of interventions:

- providing education in individual consultations only;
- which utilise telephone calls or text messages as a complement to group-based self-management education;
- including exercise only;
- providing peer or social support only (with no self-management education); or
- where the focus of the intervention is a group-based exercise programme which may include some education.

Types of outcome measures

We will not exclude a study if it fails to report one or several of our primary or secondary outcome measures. We will only exclude studies if they measure none of the outcomes relevant to this review, provided that there is supporting evidence for this (e.g. contact with trial authors, access to the original protocol, etc.).

Primary outcomes

- Glycaemic control
- Patient-reported outcome measures
- Adverse events

Secondary outcomes

- Blood pressure
- Blood lipid profiles
- Anthropometric measures
- Morbidity/complications
- All-cause mortality

Method of outcome measurement

- Glycaemic control: HbA1c level evaluated through laboratory tests as defined by the primary article, or achieving target values or treatment targets, noting that targets for older people with diabetes mellitus are often higher than for younger people.
- Patient-reported outcome measures:
  - health-related quality of life: evaluated by a validated instrument, such as the diabetes-related quality of life measure, the 36-item Short Form survey (SF-36), or the audit of the diabetes-dependent quality of life;
  - psychological well-being: evaluated by a validated instrument, such as the World Health Organization Well-Being Index (WHO-5);
  - diabetes distress: evaluated by a validated instrument, such as Problem Areas In Diabetes (PAID);
  - patient empowerment: evaluated by a validated instrument, such as the diabetes-empowerment scale (DES-SF); or
  - depression: evaluated by a validated instrument, such as the depression module of the Patient Health Questionnaire (PHQ-9).
- Blood pressure: (systolic (mmHg) and diastolic (mmHg)) blood pressure or achieving target values or treatment targets if reported.
- Blood lipid profiles: total cholesterol (mmol/L), triglycerides (mmol/L), high-density lipoprotein (HDL) cholesterol (mmol/L) and low-density lipoprotein (LDL) cholesterol (mmol/L) or achieving target values or treatment targets.
- Anthropometric measures: body mass index (BMI), body weight and waist circumference or achieving target values or treatment targets.
- Adverse events: as defined and reported by the primary study. This may include, but is not limited to, hospitalisations, hypoglycaemic and hyperglycaemic episodes.
- Morbidity/complications: complications of diabetes, such as retinopathy, nephropathy, and neuropathy.
- All-cause mortality: defined as death from any cause.

Timing of outcome measurement

- For all-cause mortality and adverse events: any time after participants were randomised to the intervention/comparator groups.

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- For all other outcome measures: short term (six months to 10 months), medium term (> 10 months up to 18 months), long term (> 18 months) post-baseline.

If studies report more than one set of data within a specified time point, we will select the later measure for each category. Additional time points may be added if several studies report outcomes at later time points.

Search methods for identification of studies

The full search strategies for each database are detailed in Appendix 1.

Electronic searches

An experienced information specialist designed the original search string in Ovid MEDLINE using a combination of subject terms and synonyms. This search string was then translated for use in the other databases using the Polyglot Search Translator (https://pubmed.ncbi.nlm.nih.gov/32256231/). We will search the following sources with no language restriction:

- Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Register of Studies Online (CRSO);
- MEDLINE (Ovid MEDLINE ALL 1946 to Daily Update);
- Embase (Elsevier 1947 to present);
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature);
- PsycINFO (Ovid PsycINFO 1806 to present).

Additionally, we will search the following trial registries:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/trialsearch/).

For detailed search strategies, see Appendix 1.

Searching other resources

We will try to identify other potentially eligible trials or ancillary publications by searching the reference lists of included trials, systematic reviews, meta-analyses, and health technology assessment reports. We will supplement the reference checks with a forward (citing) citation search. We will conduct these searches using the Systematic Review Accelerators SpiderCite tool (https://www.ncbi.nlm.nih.gov/pubmed/32004673). In addition, we will contact the authors of included trials to obtain additional information on the retrieved trials and establish whether we may have missed further trials.

We will not use abstracts or conference proceedings for data extraction unless full data are available from trial authors because abstracts and conference proceedings do not fulfil the CONSORT requirements, which consist of "an evidence-based, minimum set of recommendations for reporting randomised trials" (CONSORT 2018; Scherer 2007). We will present information on abstracts or conference proceedings in the 'Characteristics of studies awaiting classification' table. We define grey literature as records detected in ClinicalTrials.gov or the WHO ICTRP, which may also identify potentially eligible trials.

Data collection and analysis

Selection of studies

Two pairs of review authors (KOJ, ZAM, DPR, JTK) will independently screen the abstract, title, or both of every record retrieved by the literature searches to determine which trials we should assess further. We will obtain the full text of all potentially relevant records. We will resolve disagreements through consensus or recourse to a third review author (LEB). If we cannot resolve a disagreement, we will categorise the trial as a 'Study awaiting classification' and contact the trial authors for clarification. We will present an adapted PRISMA flow diagram to show the trial selection process (Page 2021). We will list all articles excluded after full-text assessment in a 'Characteristics of excluded studies' table and provide the reasons for exclusion. We will use the web-based screening and data extraction tool, Covidence (www.covidence.org), the primary screening and data extraction tool for Cochrane authors conducting standard intervention reviews when screening abstracts and full-text study reports, extracting data, and conducting the risk of bias assessments.

Data extraction and management

Two pairs of review authors (KOJ, ZAM, DPR, JTK) will independently extract key participant and intervention characteristics for trials that fulfil our inclusion criteria. We will resolve disagreements by discussion or, if required, by consultation with a third review author (LEB). We will describe interventions according to the 'template for intervention description and replication' (TIDieR) checklist (Hoffmann 2014; Hoffmann 2017). We will extract the following data from reports.

- Methods
  - Study design
- Participants
  - Inclusion and exclusion criteria
  - Participant details, baseline demographics (gender, age, ethnicity, years since diagnosis, and baseline HbA1c, if reported)
  - The number of participants by study and by study arm
- Interventions and comparisons according to the 'template for intervention description and replication' (TIDieR) checklist (Hoffmann 2014; Hoffmann 2017)
  - **Name of the intervention**.
  - **Why**: rationale, theory, or goal of the elements essential to the intervention.
  - **What**: physical or informational materials used in the intervention/procedures, activities, or processes used in the intervention.
  - **Who provided**: expertise, background, and specific training given.
  - **How**: describe modes of delivery.
  - **Where**: describe the location where the intervention occurred, including infrastructure and features.
  - **When/how much:** the number of times the intervention was delivered over a period of time.
  - **Tailoring**: describe if personalisation or adaptations were planned.
  - **Modifications:** during the course of the study.
  - **How well**: measurements of adherence or fidelity.

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- Outcomes
  - Definitions of relevant outcomes, method and timing of outcome measurement, as well as any subgroups relevant to the review.
- Study dates (start date and end date. If dates are not available, then this will be reported as such.)
- Study settings and country, language of publication, and study identifier
- Study funding sources
- Primary investigators' declarations of interest

We will contact authors of all included studies to enquire whether they would be willing to answer questions regarding their studies. We will document these communications. If required, we will seek relevant missing information on the study, including intervention protocols, from the primary study author(s).

Dealing with duplicate and companion publications

In the event of duplicate publications, companion documents, or multiple reports of a primary trial, we will maximise the information yield by collating all available data and using the most complete data set aggregated across all known publications. We will list duplicate publications, companion documents, multiple reports of a primary trial, and trial documents of included trials (such as trial registry information) as secondary references under the study ID of the included trial. Furthermore, we will list duplicate publications, companion documents, multiple reports of a trial, and trial documents of excluded trials (such as trial registry information) as secondary references under the study ID of the excluded trial.

Data from clinical trial registers

If data from included trials are available as study results in clinical trial registers, such as ClinicalTrials.gov or similar sources, we will make full use of this information and extract the data. If there is also a full publication of the trial, we will collate and critically appraise all available data. If a trial is marked as a completed study in a clinical trial register, but no additional information (study results, publication, or both) is available, we will add this trial to the 'Characteristics of studies awaiting classification' table.

Assessment of risk of bias in included studies

We will assess the risk of bias for all predefined primary and secondary outcomes, using the earliest timing of outcome measurement. Two review authors (KOJ, DPR) will independently assess the risk of bias for each included trial. We will resolve disagreements by consensus or by consulting a third review author (LEB). In the case of disagreement, we will consult the remainder of the review author team and make a judgement based on consensus. If there is insufficient information in the study publications, study protocols, or other sources, we will contact study authors to request missing data on risk of bias items.

We will use RoB 2, the Cochrane risk of bias tool, to evaluate individual bias items as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions*, according to the criteria and associated categorisations contained therein (Higgins 2022). The RoB 2 tool evaluates the following domains:

- bias arising from the randomisation process;
- bias due to deviations from intended interventions;
- bias due to missing outcome data;
- bias in measurement of the outcome;
- bias in selection of the reported result.

For cluster-randomised trials, we will add another domain to address a potential identification or recruitment bias as described in Chapter 23 of the *Cochrane Handbook* (Higgins 2022). Within each domain, signalling questions provide information about features of the study that are relevant to the risk of bias. We are mainly interested in the effect of assignment to the interventions at baseline, regardless of whether the interventions are received as intended (the 'intention-to-treat effect'). Possible answers to the signalling questions are 'yes', 'probably yes', 'probably no', 'no', and 'no information'. After answering the signalling questions and following the domain-specific algorithms, we will make a judgement about the risk of bias, assigning one of three levels to each domain ('low risk of bias', 'some concerns', 'high risk of bias'). Based on these results, we will make summary assessments of the risk of bias for each predefined outcome (across domains), within and across studies (Higgins 2022).

We will use the RoB 2 Excel tool to manage the data supporting the answers to the signalling questions and risk of bias judgements (available at www.riskofbias.info/). All these data will be publicly available as supplementary material in a public repository (Flemyng 2023).

Summary assessment of risk of bias

We will present a risk of bias graph and a risk of bias summary figure. We will distinguish between self-reported, investigator-assessed, and adjudicated outcome measures. We will consider the following self-reported outcomes:

- adverse events;
- patient-reported outcome measures.

We will consider the following outcomes to be investigator-assessed:

- glycaemic control (HbA1c);
- blood pressure;
- blood lipid profiles;
- anthropometric measures;
- morbidity/complications;
- all-cause mortality.

Risk of bias for an outcome within a study and across domains

We will assess the risk of bias for an outcome measure by including all entries relevant to that outcome (i.e. both study-level entries and outcome-specific entries). For each specific outcome, we will establish an overall risk of bias judgement using the following criteria.

- Low risk of bias: we judged the study to be at low risk of bias for all domains for this result.
- Some concerns: we judged the study to raise some concerns in at least one domain for this result, but not to be at high risk of bias for any domain.

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- High risk of bias: we judged the study either to be at high risk of bias in at least one domain for this result, or to raise some concerns for multiple domains in a way that substantially lowers confidence in the result.

Risk of bias for an outcome across studies and across domains

To facilitate our assessment of the certainty of evidence for key outcomes, we will assess risk of bias across studies and domains for the outcomes included in the summary of findings table. We will define the evidence as being at low risk of bias when most information comes from studies at low risk of bias, to have some concerns for risk of bias when most information comes from studies at low risk of bias or with some concerns, and high risk of bias when a sufficient proportion of information comes from studies at high risk of bias.

Measures of treatment effect

When at least two included trials are available for a comparison of a given outcome, we will try to express dichotomous data as a risk ratio (RR) with 95% confidence intervals (CIs). For continuous outcomes measured on the same scale (e.g. weight loss in kg), we will estimate the intervention effect using the mean difference (MD) with 95% CIs. For continuous outcomes that measure the same underlying concept (e.g. health-related quality of life) but use different measurement scales, we will calculate the standardised mean difference (SMD). We will express time-to-event data as a hazard ratio (HR) with 95% CIs.

Unit of analysis issues

We will take into account the level at which randomisation occurred, such as cross-over studies, cluster-randomised trials, and multiple observations for the same outcome. If more than one comparison from the same study is eligible for inclusion in the same meta-analysis, we will either combine groups to create a single pair-wise comparison, or we will appropriately reduce the sample size so that the same participants do not contribute data to the meta-analysis more than once (splitting the 'shared' group into two or more groups). Although the latter approach offers some solutions for adjusting the precision of the comparison, it does not account for correlation arising from the inclusion of the same set of participants in multiple comparisons (Higgins 2022).

We will attempt to re-analyse cluster-RCTs that have not appropriately adjusted for potential clustering of participants within clusters in their analyses. The variance of intervention effects will be inflated by a design effect. Calculation of a design effect involves the estimation of an intracluster correlation coefficient (ICC) as specified in Chapter 23 of the *Cochrane Handbook* (Higgins 2022). We will obtain estimates of ICCs by contacting study authors, or by imputing ICC values using either estimates from other included studies that report ICCs or external estimates from empirical research. We plan to examine the impact of clustering by performing sensitivity analyses.

For cross-over studies, we will include data from the first period, following the guidance in Section 23.2.6 of the *Cochrane Handbook* (Higgins 2022).

Dealing with missing data

If possible, we will obtain missing data from the authors of included studies. We will carefully evaluate important numerical data, such as screened, randomly-assigned participants, as well as intention-to-treat, as-treated, and per-protocol populations, in our risk of bias assessments. For this, we will investigate attrition rates (e.g. dropouts, losses to follow-up, and withdrawals), and critically appraise issues concerning missing data and imputation methods (e.g. last observation carried forward). For our primary analyses, we will conduct available-case analyses, considering these issues when assessing the risk of bias and the certainty of the evidence.

For studies in which the standard deviation (SD) of the outcome is not available at follow-up, or we cannot recreate it, we will standardise by the mean of the pooled baseline SD from studies that reported this information.

Assessment of heterogeneity

As group education interventions are known to be complex, we expect heterogeneity (between studies) to be high across most outcome measures. In the event of substantial clinical or methodological heterogeneity, we will not report trial results as the pooled effect estimate in a meta-analysis.

We will take into account a visual examination of the variability in point estimates and the overlap in confidence intervals. We will use the I^2 statistic to estimate the degree of heterogeneity present amongst the trials in each analysis. If we identify substantial unexplained heterogeneity, we will report it and explore possible causes by prespecified subgroup analysis. We will use the rough guide to interpretation as outlined in Chapter 10 of the *Cochrane Handbook* (Higgins 2022), as follows:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

We will avoid the use of absolute cut-off values but interpret I^2 in relation to (a) the size and direction of effects, and (b) strength of evidence for heterogeneity (e.g. P value from the Chi^2 test, or CI for I^2).

Assessment of reporting biases

If we include 10 or more trials that investigate a particular outcome, we will use funnel plots to assess small-study effects. Several explanations may account for funnel plot asymmetry, including true heterogeneity of effect with respect to trial size, poor methodological design (and hence bias of small trials), and publication bias (Sterne 2017). Therefore, we will interpret the results carefully (Sterne 2011).

Data synthesis

We plan to undertake a meta-analysis only if we judge the participants, interventions, comparisons, and outcomes to be sufficiently similar to ensure a result that is clinically meaningful. Unless good evidence shows homogeneous effects across studies of different methodological quality, we will primarily summarise data using a random-effects model (Wood 2008). We will interpret random-effects meta-analyses with due consideration for the whole distribution of effects and will present a confidence interval. We will perform statistical analyses according to the statistical guidelines presented in the *Cochrane Handbook* (Deeks 2022). When meta-analysis is not possible, we will conduct alternative

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forms of synthesis, including the summary of effect estimates, the combination of P values, and vote counting based on the direction of effects, as described in Chapter 12 of the *Cochrane Handbook* (McKenzie 2022).

Subgroup analysis and investigation of heterogeneity

We aim to explore the key characteristics contributing to the effectiveness of group-based interventions (Objectives*: second objective*) by presenting the characteristics of each intervention in a summary table and extracting intervention data using the TIDieR checklist to enable a clear and detailed comparison of interventions (Hoffmann 2014; Hoffmann 2017). Additionally, we will explore potential reasons for heterogeneity by examining individual trial and subgroup characteristics and assessing whether any variations in effect size can be attributed to study design and intervention characteristics through subgroup analyses.

We expect the following characteristics to introduce clinical heterogeneity, and we plan to carry out the following subgroup analyses, including an investigation of interactions (Altman 2003).

- **Control group:** control groups receiving an individual intervention are likely to have greater improvements in glycaemic control than control groups receiving usual care.
- **Intervention delivery:** we expect interventions delivered face-to-face, those delivered online or through telehealth, and those which utilise both online and face-to-face delivery could result in differences in effect sizes.
- **Intervention length (months):** we expect longer interventions (> 18 months) to result in greater improvements in glycaemic control due to the ongoing support provided throughout the intervention period.
- **Number of sessions and contact time (hours):** we expect interventions providing more contact time (> 18 hours) and sessions (> 10 sessions) to result in greater improvements in outcomes due to increased opportunities to improve diabetes knowledge and self-management skills.
- **Type of educator(s):** we expect interventions delivered by a single health discipline (i.e. nurses, dieticians, or physicians), multidisciplinary teams of health professionals, health professionals supported by 'peers' or people diagnosed with T2DM who are not qualified health professionals, and interventions delivered exclusively by peers to have differing effects.
- **Number of participants:** we expect interventions with smaller groups (four to 10 participants after dropouts) to have greater improvements in outcomes due to increased contact time and opportunities for individualisation of learning and goals.
- **Inclusion of family, friends, or both (yes/no):** we expect the inclusion of family, friends, or both in the intervention to improve outcomes for the person with diabetes.

We recognise that appropriate interpretation of subgroup analyses requires caution (Deeks 2022), and that subgroup comparisons are observational (Higgins 2022). As such, we have prespecified subgroup analyses rather than undertaking subgroup analyses after the results of the studies have been compiled (post hoc) to avoid data dredging (Higgins 2022). We will explore whether there is indirect evidence to support the subgroup analysis findings (i.e. they are clinically plausible and supported by other external or indirect evidence); whether the magnitude of the difference is practically important; and whether there is a statistically significant difference between subgroups.

Sensitivity analysis

We plan to perform sensitivity analyses to explore the influence on effect sizes of restricting the analysis to studies at an overall low risk of bias (when applicable/possible).

Summary of findings and assessment of the certainty of the evidence

We will present the overall certainty of the evidence for each outcome specified below, according to the GRADE approach, which takes into account issues related to internal validity (overall risk of bias, inconsistency, imprecision, publication bias) and external validity (such as directness of results). Two review authors (KOJ, JTK) will independently rate the certainty of the evidence for each outcome. We will resolve any differences in assessment by discussion or by consultation with a third review author (DPR).

We will present a summary of the evidence in a summary of findings table. This will provide key information about: the best estimate of the magnitude of effect, in relative terms and as absolute differences for each relevant comparison of alternative management strategies; the numbers of participants and studies addressing each important outcome; and a rating of overall confidence in effect estimates for each outcome. We will create the summary of findings table using the methods described in the *Cochrane Handbook* (Schünemann 2022), and employing Review Manager 5 (RevMan Web 2022) and GRADEpro software (GRADEpro GDT).

If meta-analysis is not possible, we will present the results in a narrative format in the summary of findings table. We will justify all decisions to downgrade the certainty of the evidence by using informative footnotes, and we will use GRADE guidelines for these informative statements (Santesso 2016; Santesso 2020).

We will create summary of findings tables for the following comparisons and outcomes.

- Comparison(s): group-based education interventions (face-to-face, online, or telehealth; face-to-face with online or telehealth), including or excluding usual care, compared to:
  - usual care (also known as routine care) only;
  - waiting-list control;
  - individual education.
- Outcomes
  - Glycaemic control (HbA1c)
  - Patient-reported outcome measures
  - Adverse events
  - Blood pressure
  - Blood lipid profiles
  - Anthropometric measures
  - Morbidity/complications

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- Sign-off Editor (final editorial decision): Brenda Bongaerts, Institute of General Practice, Medical Faculty of the Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany;
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- Copy Editor (copy-editing and production): Faith Armitage, Cochrane Central Production Service;
- Peer-reviewers (provided comments and recommended an editorial decision): Kate Lorig, Stanford University School of Medicine, USA (Clinical reviewer); Maria-Inti Metzendorf*, Cochrane Metabolic and Endocrine Disorders Group, Institute of General Practice, Medical Faculty of the Heinrich Heine University, Düsseldorf, Germany (Information Specialist reviewer); and Virginia Hagger, School of Nursing & Midwifery, Deakin University, Burwood, VIC, Australia (Clinical Reviewer);
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APPENDICES

Appendix 1. Search strategies

We designed the initial search in Ovid MEDLINE. The search strategy was then translated to search the Cochrane Central Register of Controlled Trials (CENTRAL), Embase, CINAHL, PsycINFO using the Polyglot Search Translator (https://pubmed.ncbi.nlm.nih.gov/32256231/**). There were no language or date restrictions.**

MEDLINE (via Ovid)

(exp Patient Education as Topic/ OR exp Group Processes/ OR exp Psychotherapy, Group/ OR exp Self-Help Groups/ OR Self management.ti,ab. OR Self-management.ti,ab. OR Behavior therapy.ti,ab. OR Behaviour therapy.ti,ab. OR CLMP.ti,ab. OR Medicine wheel.ti,ab. OR Viva Bien.ti,ab. OR DART.ti,ab. OR Group-based education.ti,ab. OR Diabetes education.ti,ab. OR Group intervention.ti,ab. OR Group interventions.ti,ab. OR ((Group) adj1 (Process OR Processes OR Psychotherapy OR Lifestyle OR Visit OR Program*)).ti,ab.)

AND

(exp Diabetes Mellitus, Type 2/ OR MODY.ti,ab. OR NIDDM.ti,ab. OR T2DM.ti,ab. OR ((non insulin OR noninsulin OR Type 2 OR Type II OR Ketosis-Resistant OR Ketosis resistant OR Maturity-Onset OR Maturity onset OR Mature-onset OR Mature onset OR Adult-onset OR Adult onset OR Slow-onset OR Slow onset OR Stable) adj1 (Diabetes)).ti,ab.)

AND

(exp Body weight/ OR Body weight.ti,ab. OR Body mass.ti,ab. OR BMI.ti,ab. OR Food Score.ti,ab. OR RFS.ti,ab. OR Glycated haemoglobin.ti,ab. OR Glycated hemoglobin.ti,ab. OR Nutrition.ti,ab. OR Blood pressure.ti,ab.OR Physical activity.ti,ab. OR Healthy eating.ti,ab. OR HbA1c.ti,ab. OR Behaviour change.ti,ab. OR Behavior change.ti,ab. OR Depression/ OR (Glycaemic control OR Glycemic control OR Blood lipids OR Quality of life OR Diabetes distress OR Depressive symptoms OR Emotional well being).ti,ab.)

AND

(Group.ti,ab. OR Groups.ti,ab.)

NOT

(exp Diabetes Insipidus/ OR Diabetes Insipidus.ti,ab.)

AND

(((randomized controlled trial OR controlled clinical trial).pt. OR randomized.ab. OR randomised.ab. OR placebo.ab. OR drug therapy.fs. OR randomly.ab. OR trial.ab. OR Control group.ab. OR groups.ab.) NOT (exp animals/ NOT humans.sh.))

CENTRAL (via Wiley)

([mh "Patient Education as Topic"] OR [mh "Group Processes"] OR [mh "Psychotherapy, Group"] OR [mh "Self-Help Groups"] OR "Self management":ti,ab OR Self-management:ti,ab OR "Behavior therapy":ti,ab OR "Behaviour therapy":ti,ab OR CLMP:ti,ab OR "Medicine wheel":ti,ab OR "Viva Bien":ti,ab OR "Group-based education":ti,ab OR "Diabetes education":ti,ab OR ((Group) NEXT (Process OR Processes OR Psychotherapy OR Lifestyle OR Intervention OR Interventions OR Visit OR Program*)):ti,ab)

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(Continued)

AND

([mh "Diabetes Mellitus, Type 2"] OR MODY:ti,ab OR NIDDM:ti,ab OR T2DM:ti,ab OR (("non insulin" OR noninsulin OR "Type 2" OR "Type II" OR Ketosis-Resistant OR "Ketosis resistant" OR Maturity-Onset OR "Maturity onset" OR Mature-onset OR "Mature onset" OR Adult-onset OR "Adult onset" OR Slow-onset OR "Slow onset" OR Stable) NEXT (Diabetes)):ti,ab)

AND

([mh "Body weight"] OR "Body weight":ti,ab OR "Body mass":ti,ab OR BMI:ti,ab OR "Food Score":ti,ab OR RFS:ti,ab OR "Glycated haemoglobin":ti,ab OR "Glycated hemoglobin":ti,ab OR Nutrition:ti,ab OR "Blood pressure" OR "Physical activity":ti,ab OR "Healthy eating":ti,ab OR HbA1c:ti,ab OR "Behaviour change":ti,ab OR "Behavior change":ti,ab OR [mh ^Depression] OR "Glycaemic control":ti,ab OR "Glycemic control":ti,ab OR "Blood lipids":ti,ab OR "Quality of life":ti,ab OR "Diabetes distress":ti,ab OR "Depressive symptoms":ti,ab OR "Emotional well being":ti,ab)

AND

(Group:ti,ab OR Groups:ti,ab)

NOT

([mh "Diabetes Insipidus"] OR "Diabetes Insipidus":ti,ab)

Embase (via Elsevier)

('patient education'/exp OR 'group process'/exp OR 'group therapy'/exp OR 'self help'/exp OR "Self management":ti,ab OR Self-management:ti,ab OR "Behavior therapy":ti,ab OR "Behaviour therapy":ti,ab OR CLMP:ti,ab OR "Medicine wheel":ti,ab OR "Viva Bien":ti,ab OR "Group-based education":ti,ab OR 'Diabetes education':ti,ab OR ((Group) NEXT/1 (Process OR Processes OR Psychotherapy OR Lifestyle OR Intervention OR Visit OR Program*)):ti,ab)

AND

('non insulin dependent diabetes mellitus'/exp OR MODY:ti,ab OR NIDDM:ti,ab OR T2DM:ti,ab OR (("non insulin" OR noninsulin OR "Type 2" OR "Type II" OR Ketosis-Resistant OR "Ketosis resistant" OR Maturity-Onset OR "Maturity onset" OR Mature-onset OR "Mature onset" OR Adult-onset OR "Adult onset" OR Slow-onset OR "Slow onset" OR Stable) NEXT/1 (Diabetes)):ti,ab)

AND

('Body weight'/exp OR "Body weight":ti,ab OR "Body mass":ti,ab OR BMI:ti,ab OR "Food Score":ti,ab OR RFS:ti,ab OR "Glycated haemoglobin":ti,ab OR "Glycated hemoglobin":ti,ab OR Nutrition:ti,ab OR "Blood pressureOR Physical activity":ti,ab OR "Healthy eating":ti,ab OR HbA1c:ti,ab OR 'Behaviour change':ti,ab OR 'Behavior change':ti,ab OR Depression/de/mj OR ('Glycaemic control' OR 'Glycemic control' OR 'Blood lipids' OR 'Quality of life' OR 'Diabetes distress' OR 'Depressive symptoms' OR 'Emotional well being'):ti,ab)

AND

(Group:ti,ab OR Groups:ti,ab)

NOT

('Diabetes Insipidus'/exp OR "Diabetes Insipidus":ti,ab)

AND

(random* OR factorial OR crossover OR placebo OR blind OR blinded OR assign OR assigned OR allocate OR allocated OR 'crossover procedure'/exp OR 'double-blind procedure'/exp OR 'randomized controlled trial'/exp OR 'single-blind procedure'/exp) NOT ('animal'/exp NOT ('animal'/exp AND 'human'/exp))

CINAHL (via EBSCO)

((MH "Patient Education+") OR (MH "Group Processes+") OR (MH "Psychotherapy, Group+") OR (MH "Support Groups+") OR (TI "Self management" OR AB "Self management") OR (TI Self-management OR AB Self-management) OR (TI "Behavior therapy" OR AB "Behavior therapy") OR (TI "Behaviour therapy" OR AB "Behaviour therapy") OR (TI CLMP OR AB CLMP) OR (TI "Medicine wheel" OR AB "Medicine wheel") OR (TI "Viva Bien" OR AB "Viva Bien") OR (TI "Group-based education" OR AB "Group-based education") OR (TI "Diabetes education" OR AB "Diabetes education") OR (((TI Group OR AB Group)) W1 ((TI Process OR AB Process) OR (TI Processes OR AB

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(Continued)

Processes) OR (TI Psychotherapy OR AB Psychotherapy) OR (TI Lifestyle OR AB Lifestyle) OR (TI Intervention OR AB Intervention) OR (TI Visit OR AB Visit) OR (TI Program* OR AB Program*))))

AND

((MH "Diabetes Mellitus, Type 2+") OR (TI MODY OR AB MODY) OR (TI NIDDM OR AB NIDDM) OR (TI T2DM OR AB T2DM) OR (((TI "non insulin" OR AB "non insulin") OR (TI noninsulin OR AB noninsulin) OR (TI "Type 2" OR AB "Type 2") OR (TI "Type II" OR AB "Type II") OR (TI Ketosis-Resistant OR AB Ketosis-Resistant) OR (TI "Ketosis resistant" OR AB "Ketosis resistant") OR (TI Maturity-Onset OR AB Maturity-Onset) OR (TI "Maturity onset" OR AB "Maturity onset") OR (TI Mature-onset OR AB Mature-onset) OR (TI "Mature onset" OR AB "Mature onset") OR (TI Adult-onset OR AB Adult-onset) OR (TI "Adult onset" OR AB "Adult onset") OR (TI Slow-onset OR AB Slow-onset) OR (TI "Slow onset" OR AB "Slow onset") OR (TI Stable OR AB Stable)) W1 ((TI Diabetes OR AB Diabetes))))

AND

((MH "Body weight+") OR (TI "Body weight" OR AB "Body weight") OR (TI "Body mass" OR AB "Body mass") OR (TI BMI OR AB BMI) OR (TI "Food Score" OR AB "Food Score") OR (TI RFS OR AB RFS) OR (TI "Glycated haemoglobin" OR AB "Glycated haemoglobin") OR (TI "Glycated hemoglobin" OR AB "Glycated hemoglobin") OR (TI Nutrition OR AB Nutrition) OR (TI "Blood pressure OR Physical activity" OR AB "Blood pressure OR Physical activity") OR (TI "Healthy eating" OR AB "Healthy eating") OR (TI HbA1c OR AB HbA1c) OR (TI "Behaviour change" OR AB "Behaviour change") OR (TI "Behavior change" OR AB "Behavior change") OR (MH Depression) OR ((TI "Glycaemic control" OR AB "Glycaemic control") OR (TI "Glycemic control" OR AB "Glycemic control") OR (TI "Blood lipids" OR AB "Blood lipids") OR (TI "Quality of life" OR AB "Quality of life") OR (TI "Diabetes distress" OR AB "Diabetes distress") OR (TI "Depressive symptoms" OR AB "Depressive symptoms") OR (TI "Emotional well being" OR AB "Emotional well being")))

AND

((TI Group OR AB Group) OR (TI Groups OR AB Groups))

NOT

((MH "Diabetes Insipidus+") OR (TI "Diabetes Insipidus" OR AB "Diabetes Insipidus"))

AND

((MH "Clinical Trials+") OR (MH "Intervention Trials") OR (MH "Quantitative Studies") OR TI placebo* OR AB placebo* OR (MH "Placebos") OR (MH "Random Assignment") OR TI random* OR AB random* OR TI ((singl* or doubl* or tripl* or trebl*) W1 (blind* or mask*)) OR AB ((singl* or doubl* or tripl* or trebl*) W1 (blind* or mask*)) OR TI clinic* trial* OR AB clinic* trial* OR PT clinical trial)

PsycINFO (via Ovid)

(Self management.ti,ab. OR Self-management.ti,ab. OR Behavior therapy.ti,ab. OR Behaviour therapy.ti,ab. OR CLMP.ti,ab. OR Medicine wheel.ti,ab. OR Viva Bien.ti,ab. OR "Group-based education" OR "Diabetes education".ti,ab. OR ((Group) adj1 (Process OR Processes OR Psychotherapy OR Lifestyle OR Intervention OR Visit OR Program*)).ti,ab.)

AND

(MODY.ti,ab. OR NIDDM.ti,ab. OR T2DM.ti,ab. OR ((non insulin OR noninsulin OR Type 2 OR Type II OR Ketosis-Resistant OR Ketosis resistant OR Maturity-Onset OR Maturity onset OR Mature-onset OR Mature onset OR Adult-onset OR Adult onset OR Slow-onset OR Slow onset OR Stable) adj1 (Diabetes)).ti,ab.)

AND

(Body weight.ti,ab. OR Body mass.ti,ab. OR BMI.ti,ab. OR Food Score.ti,ab. OR RFS.ti,ab. OR Glycated haemoglobin.ti,ab. OR Glycated hemoglobin.ti,ab. OR Nutrition.ti,ab. OR Blood pressure.ti,ab.OR Physical activity.ti,ab. OR Healthy eating.ti,ab. OR HbA1c.ti,ab. OR "Behaviour change".ti,ab. OR "Behavior change".ti,ab. OR exp major depression/ OR "Glycaemic control".ti,ab. OR "Glycemic control".ti,ab. OR "Blood lipids".ti,ab. OR "Quality of life".ti,ab. OR "Diabetes distress".ti,ab. OR "Depressive symptoms".ti,ab. OR "Emotional well being".ti,ab.)

AND

(Randomized.ti,ab. OR randomised.ti,ab. OR placebo.ti,ab. OR drug therapy.mp. OR randomly.ti,ab. OR trial.ti,ab. OR groups.ti,ab.)

AND

(Group.ti,ab. OR Groups.ti,ab.)

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NOT

(Diabetes Insipidus.ti,ab.)

Trial registry searches
WHO ICTRP
Diabetes (condition line)
AND
"Group therapy" OR "Group process" OR "Group processes" OR "Group psychotherapy" OR "Behavior therapy" OR "Behaviour therapy" (intervention line)
Clinicaltrials.gov
(Diabetes)
AND
("Group therapy" OR "Group process" OR "Group processes" OR "Group psychotherapy" OR "Behavior therapy" OR "Self-Help Groups" OR "Behavior therapy" OR "Behaviour therapy")

CONTRIBUTIONS OF AUTHORS

All review authors contributed to, read, and approved the final protocol draft.

Kate Odgers-Jewell: conception and design of work, protocol draft, finalisation of protocol.

Lauren E Ball: conception and design of work, search strategy development, revised protocol.

Jaimon T Kelly: conception and design of work, revised protocol.

Zoe A Michaleff: conception and design of work, revised protocol.

Justin Clark: conception and design of work, search strategy design, revised protocol.

Mark A Jones: conception and design of work, design of review methods, revised protocol.

Dianne P Reidlinger: conception and design of work, revised protocol.

DECLARATIONS OF INTEREST

Kate Odgers-Jewell (KOJ): none known.

Dianne P Reidlinger (DPR): none known.

Lauren E Ball (LEB): none known.

Zoe A Michaleff (ZAM): none known.

Justin Clark (JC): none known.

Mark A Jones (MJ): none known.

Jaimon T Kelly (JTK): none known.

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NOTES

We have based parts of the Methods, as well as Appendix 1 of this Cochrane Protocol, on a standard template established by the Cochrane Metabolic and Endocrine Disorders Group.

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