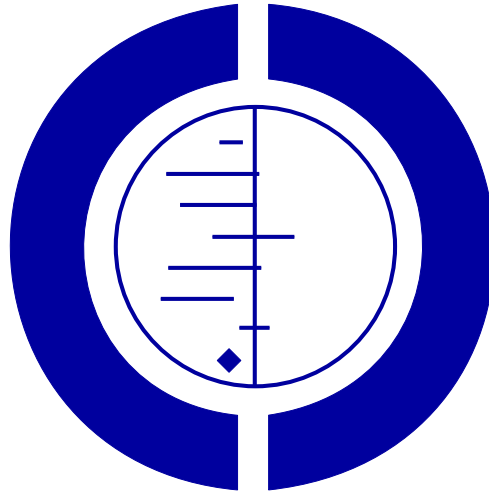


Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

Deakin T, McShane CE, Cade JE, Williams RDRR



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ABSTRACT

Background

It has been recognised that adoption of self-management skills by the person with diabetes is necessary in order to manage their diabetes. However, the most effective method for delivering education and teaching self-management skills is unclear.

Objectives

To assess the effects of group-based, patient-centred training on clinical, lifestyle and psychosocial outcomes in people with type 2 diabetes.

Search strategy

Studies were obtained from computerised searches of multiple electronic bibliographic databases, supplemented by hand searches of reference lists of articles, conference proceedings and consultation with experts in the field. Date of last search was February 2003.

Selection criteria

Randomised controlled and controlled clinical trials which evaluated group-based education programmes for adults with type 2 diabetes compared with routine treatment, waiting list control or no intervention. Studies were only included if the length of follow-up was six months or more and the intervention was at least one session with the minimum of six participants.

Data collection and analysis

Two reviewers independently extracted data and assessed study quality. A meta-analysis was performed if there were enough homogeneous studies reporting an outcome at either four to six months, 12-14 months, or two years, otherwise the studies were summarised in a descriptive manner.

Main results

Fourteen publications describing 11 studies were included involving 1532 participants. The results of the meta-analyses in favour of group-based diabetes education programmes were reduced glycated haemoglobin at four to six months (1.4%; 95% confidence interval (CI) 0.8 to 1.9; $P < 0.00001$), at 12-14 months (0.8%; 95% CI 0.7 to 1.0; $P < 0.00001$) and two years (1.0%; 95% CI 0.5 to 1.4; $P < 0.00001$); reduced fasting blood glucose levels at 12 months (1.2 mmol/L; 95% CI 0.7 to 1.6; $P < 0.00001$); reduced body weight at 12-14 months (1.6 Kg; 95% CI 0.3 to 3.0; $P = 0.02$); improved diabetes knowledge at 12-14 months (SMD 1.0; 95% CI 0.7 to 1.2; $P < 0.00001$) and reduced systolic blood pressure at four to six months (5 mmHg; 95% CI 1 to 10; $P = 0.01$). There was also a reduced need for diabetes medication (odds ratio 11.8, 95% CI 5.2 to 26.9; $P < 0.00001$; RD = 0.2; NNT = 5). Therefore, for every five patients attending a group-based education programme we could expect one patient to reduce diabetes medication.

Authors' conclusions

Group-based training for self-management strategies in people with type 2 diabetes is effective by improving fasting blood glucose levels, glycated haemoglobin and diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication.

SYNOPSIS

Group-based training for self-management strategies in people with type 2 diabetes results in better diabetes management

Adults with type 2 diabetes who have participated in group-based training programmes show improved diabetes control (fasting blood glucose and glycated haemoglobin) and knowledge of diabetes in the short (four to six months) and longer-term (12 to 14 months) whilst also having a reduced need for diabetes medication. There is also some evidence that group-based education programmes may reduce blood pressure and body weight, and increase self-empowerment, quality of life, self-management skills and treatment satisfaction. However, as only a small number of studies evaluated those outcomes, more research is required to confirm those findings.

BACKGROUND

Diabetes mellitus and its complications

Diabetes mellitus is one of the most common chronic disorders in the western world. Type 2 diabetes affects large numbers of people from a wide range of ethnic groups and at all social and economic levels. It is estimated that 194 million people worldwide, or 5.1% of the adult population currently have diabetes and that this will increase to 333 million (6.3% of the adult population by 2025) (Sicree 2003). It is felt that lifestyle, with diets high in saturated fat and decreased physical activity, together with an increased longevity, are the main factors in the dramatic increase of type 2 diabetes. Type 2 diabetes, previously referred to as non insulin dependent diabetes mellitus (NIDDM) or mature onset diabetes is more commonly diagnosed over the age of 40. It affects 75-90% of all those with diabetes (Keen 1995). An economic study 'type 2 diabetes: Accounting for a major Resource Demand in Society in the UK' (Diabetes UK 2000) has shown that microvascular and macrovascular complications increase UK National Health Service (NHS) costs more than five fold and diabetes presently consumes 9% of NHS inpatient resources. The annual direct healthcare costs of diabetes worldwide for people aged between 20 and 79, is estimated to be at least 153 billion international dollars. If predictions for diabetes prevalence are correct, total direct healthcare expenditure on diabetes worldwide will be between 213 and 396 billion international dollars in 2025, which will be between 7% and 13% (Williams 2003) of total healthcare expenditure.

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. A consequence of this is a chronic hyperglycaemia (i.e. elevated levels of plasma glucose) with disturbances of carbohydrate, fat and protein metabolism. Although the onset of type 2 diabetes is usually less dramatic than that of type 1, both types of diabetes carry a risk of multiple, disabling, yet potentially preventable complications (DCCT 1993; UKPDS-33 1998). Diabetes greatly increases the risk of coronary heart disease and stroke. Cardiovascular disease is the primary cause of death in industrialized countries. It is also set to overtake infectious diseases as the most common cause of death in many parts of the less developed world. People with diabetes are two to four times more likely to develop cardiovascular disease than people without diabetes, making it the most common complication of

diabetes (IDF 2001). Between 70 and 80% of people with diabetes dying from cardiovascular disease (Tapp 2003). Other long-term consequences of diabetes mellitus include retinopathy, nephropathy and neuropathy; it is a leading cause of blindness, end-stage renal failure and limb amputation. For a detailed overview of diabetes mellitus, please see 'Additional information' in the information about the Metabolic and Endocrine Disorders Group on the Cochrane Library (see 'About the Cochrane Collaboration', 'Collaboration Review Groups (CRGs)'). For an explanation of the methodological terms, see the main Glossary on the Cochrane Library.

It is now clear that type 2 diabetes is a progressive condition and ought never to be considered the 'mild' form of diabetes. It should always be taken seriously and the objective of treatment should be to achieve and maintain long-term near-normal blood glucose and blood pressure levels. The United Kingdom Prospective Diabetes Study (UKPDS-33 1998), the largest clinical research study of diabetes ever conducted, has provided evidence that the life threatening complications of type 2 diabetes can be reduced by a combination of optimal blood glucose and blood pressure levels. More recent epidemiological studies have shown that each 1% reduction in glycated haemoglobin was associated with the reductions in relative risk of 21% for any end point related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarction and 37% for microvascular complications (UKPDS-35 2000). Each 10 mmHg decrease in systolic blood pressure was associated with reductions in relative risk of 12% for any complication related to diabetes, 15% for deaths related to diabetes, 11% for myocardial infarction and 13% for microvascular complications (UKPDS-36 2000). Therefore, any reduction in glycated haemoglobin and blood pressure is likely to reduce the risk of complications with the lowest risk probably being in those with HbA1c values in the normal range (less than 6.0%) and systolic blood pressure values less than 120 mmHg (UKPDS-36 2000).

Self-management skills

It has been recognised that adoption of self-management skills (i.e. the learned ability to perform an act competently) by the person with diabetes is necessary to enable them to manage their diabetes (WHO 1998). Nutritional intake and modification of lifestyle are the cornerstone for treating type 2 diabetes. Although

the provision of effective ongoing education and support is necessary to equip people with the knowledge, skills, attitudes and motivation required to manage their diabetes care effectively (St Vincent Joint Task Force for Diabetes, DoH/Diabetes UK 1995), the most effective method for delivering education and teaching self-management skills is unclear.

Effective management lies almost entirely in the hands of the patient who lives with the condition. However, a health professional-centred approach based on the medical model is still traditionally used. This model of care may neglect the psychosocial and emotional aspects of the disease and could be one of the main reasons why only 7% of adults with diabetes manage to follow all the steps deemed by practitioners to be necessary for optimal management and good glycaemic control, including dietary modification, physical activity regime, compliance with medication and monitoring diabetes control (Griffin 1998).

Standards

Individual countries have developed their own standards, for example the United States of America has developed 'National Standards for Diabetes Self-Management Education' (Mensing 2003). The American standards define structure (organisation, needs assessment, programme management, programme staff, curriculum and participant access), process (assessment, plan and implementation, follow-up) and outcomes (programme outcome evaluation, participant outcome evaluation) as the core components to diabetes education programmes, along with skilled and experienced health care professionals with recent education in diabetes, educational principles, and behaviour change strategies. The German model, intensified insulin treatment as routine treatment for type 1 diabetes, has been developed by Michael Berger in Düsseldorf and is based on the Assal model of therapeutic education (Mühlhauser 1983). It is a five-day structured in-patient training programme in intensive insulin therapy and self-management. This has since been adapted and is delivered as an out-patient course (Kronsbein 1988) and as the DAFNE (Dose Adjustment For Normal Eating) project in the UK. Although the model was originally developed for people with type 1 diabetes, there are now papers evaluating its effects for people with type 2 diabetes (Gruesser 1993; Domenech 1995; Pieber 1995b).

The International Diabetes Federation has published 'International Curriculum for Diabetes Health Professional Education' (DECS 2002). A curriculum is a detailed plan for the education programme that describes the overall aims and evaluation process of the course. The mission of the Diabetes Education Consultative Section (DECS) is to provide access to expertise in diabetes education, both for people with diabetes and for health professionals. The DECS publication provides a collection of modules designed to train health professionals to the appropriate level so that they feel competent to deliver the education required by people with diabetes. Diabetes experts developed these modules with input from educators around the world. The DECS has more recently pub-

lished 'International Standards for Diabetes Education' (DECS 2003) which has been organised into structure standards, process standards and outcome standards. The standards serve to assist in the planning of health services, to prioritise resource allocation, to lend support to the lobby for the funding and recognition of diabetes education, to identify competencies required by those who deliver diabetes education, to provide a benchmark against which the quality of care can be evaluated and improved, to provide a basis for accrediting organisations and to assist individual diabetes educators to acquire the necessary credentials.

In the UK, a report with recommendations and examples of good practice (Diabetes UK 2002) was followed shortly afterwards by guidance on the use of patient education models for diabetes (NICE 2003). The guidelines recommended that educational interventions should reflect established principles of adult and active learning, be provided through an appropriately trained multidisciplinary team to groups of people with diabetes (unless group work was considered unsuitable for an individual) and take into account culture, ethnicity, disability and geographical issues. The UK public health document 'Saving Lives: Our Healthier Nation' (DoH 1999) acknowledged that in the past, too little has been done to help people with chronic disease play a part in managing their own condition. The Chief Medical Officer set up a task force to design an 'Expert Patients Programme' which was designed to address the needs of one in three of the total population who will suffer from a chronic disease or disability in their lifetime (DOH 2001). The term 'expert patient programme' suggests that the patient will have an opportunity to become an 'expert' in self-managing their condition. Based on the work of Lorig in the United States (Lorig 1999) and the UK Challenging Arthritis programme (Barlow 2000), there is increasing evidence that people have improved self-efficacy and general health and reduced incapacity upon becoming empowered to take the lead themselves in managing their chronic disease. People are empowered when they have knowledge, skills, attitudes and self-awareness necessary to influence their own behaviour and that of others in order to improve the quality of their lives (Funnell 1991). The World Health Organisation alluded to empowerment in its paper on health promotion as "the process of enabling people to increase control over, and to improve, their health" (WHO 1978); Self-efficacy is a belief. People who have self-efficacy expectations believe that they are capable of performing a given activity.

The World Health Organisation Report (WHO 1998) on therapeutic patient education also recognises the importance of patient-centred education in the effective management of chronic disease. Therapeutic patient education is education designed to help a patient (or a group of patients and their families) to manage their treatment and prevent avoidable complications, while keeping or improving their quality of life. What is specific about it is that it produces a therapeutic effect additional to that produced by all other interventions. Patient-centred education is the close involvement of patients and carers in the planning of the education

such as soliciting the patient's opinions, concepts, ideas, feelings and questions, offering support, and allowing the patient to be involved in decision making. In contrast, traditional education is didactic in nature and tends to be delivered in lecture format. The report makes recommendations about the ideal content of a specific education programme for health care providers in the field of prevention of chronic diseases and therapeutic patient education.

Systemat reviews and other evidence

Diabetes UK (formerly the British Diabetic Association) commissioned a review of the educational and psychosocial interventions for adults with diabetes (Griffin 1998). It reviewed seven meta-analyses (Brown 1988; Brown 1990; Brown 1992; Posavac 1980; Mazzuca 1982; Mullen 1985; Padgett 1988; Posavac 1980), one review (Wing 1993b) and 57 published controlled trials. More than 3000 papers were identified by a more general search unconstrained by search terms relating to study design. The three reviews by Brown underlined the volume of work in this area and have shown that education is beneficial but that the size of the effect depends on the outcome, the nature of the measure, the length of the study and the age of the participants. The degree to which the approach to educational intervention affects the outcome was not addressed. It was concluded that evaluations of education have been of variable, but frequently, poor quality and prone to selection and measurement bias, there has also been inadequate description of each intervention. Attrition rates were reported in about half of the studies and only 8% performed an intention to treat analysis. These omissions lead to bias, misunderstanding and poor generalisability of findings. Self-reported measures were shown to overestimate effects and important health outcomes, such as quality of life and cardiovascular disease risk. Cost seems rarely to have been assessed. In the meta-analysis there was a large degree of heterogeneity as broad classes of patient variables were grouped together to produce effect sizes. Posavac undertook a meta-analysis of education programmes for patients with chronic disease (not restricted to diabetes). The search strategy was less rigorous than that undertaken by Brown and studies were included if the title suggested that 'an empirical evaluation', including a control or comparison group, had been carried out. As with the Brown reviews, patient education emerged as beneficial but the effect varied according to the outcome measure. As a consequence of the limited search strategy and the small number of identified trials, publication bias was a worry and reduced the quality of the review.

Mazzuca made more effort to differentiate the educational interventions and assess relative as well as absolute effect sizes. This report added further weight to the notion that education is beneficial and supported the belief that some forms of education (behavioural) are more effective than others (didactic). However, there were several limitations with the search strategy missing many studies identified by Brown. Mullen also reviewed different interventions for all people with chronic disease. Studies were included if they had a control group or pre-test/post-test design and measured knowledge and/or adherence. Seventy studies were identified

and a scoring system divided the studies into seven educational principles. The underlying message was that education is beneficial, particularly if based on sound educational principles. As with the other reviews, interventions were poorly described in the individual trials and educational, psychological, or behavioural science theory was rarely discussed. The final meta-analysis was that of Padgett and colleagues. They estimated the overall effectiveness of educational and psychosocial interventions for people with diabetes. One hundred and ten studies met the inclusion criteria and these were scored for methodological quality. Effect sizes were calculated for 94 studies of which 14% were randomised trials. The finding that education was beneficial was confirmed once more. Dietary instruction produced the largest effects, but tended to be evaluated in the short term with physical measures such as weight and metabolic control. Although the review by Wing was not a meta-analysis, it described the lessons learnt from 15 years of trial work, looking at behaviour modification for obesity with type 2 diabetes. Wing concluded that behavioural approaches were required, rather than simple education, and that health professionals may need training in behaviour modification techniques.

In conclusion, an increasing number of trials have been undertaken, mainly in secondary care in the United States. There were important differences in culture, social structure and health care delivery. This could threaten generalisability of the results to other parts of the world. The studies tended to be small and short-term; the education programmes were more likely to be based on a lecture format, and the studies had many methodological weaknesses. However, trials that appeared to incorporate a social cognition model or involved patient activation tended to produce more positive results. The meta-analyses have many limitations with poor descriptions of the sample characteristics, the interventions and the underpinning theoretical model. Publication bias was almost certainly present in some of the reports, but it has not been formally assessed with techniques such as a funnel plot. The quality of the design and measurement used in each study was associated with the size of the outcome, yet none of the meta-analyses attempted a sensitivity analysis to gain a clearer idea of the true effect of the interventions. Although the age of participants, the type of diabetes and so on was associated with effect size, authors continued to review heterogeneous studies. Consistent conclusions run through the seven reports but this may be because the authors were all subject to similar biases (Griffin 1998).

The NHS Centre for Reviews and Dissemination, University of York reviewed the evidence for the effectiveness of self-management interventions for type 2 diabetes. The *Effective Health Care* bulletin is divided into two sections, the first dealing with renal complications and the second half, with the promotion of self-management (CRD 2000). The interventions considered in the bulletin were generally provided in addition to the information sharing that should be an integral part of routine patient care. The interventions included in the review were assigned to three broad categories: information and skills, cognitive-behavioural ap-

proaches, and patient empowerment. Both individual and group methods were included. It was concluded that further research is necessary to determine whether interventions to promote self-management had positive significant long-term effects.

More recent reviews have evaluated the effects of self-management training in type 2 diabetes (Norris 2001; Norris 2002b; Steed 2003; Van Dam 2003). Norris 2001 evaluated 72 studies and found short-term (less than six months) positive effects of self-management on knowledge, frequency and accuracy of self-monitoring blood glucose, self-reported dietary habits and glycaemic control. With longer follow-up, interventions that used regular reinforcement were sometimes effective in improving glycaemic control with patient collaboration possibly being more effective than didactic prescription. No studies demonstrated the effectiveness of self-management training on cardiovascular disease-related events or mortality and no economic analyses included indirect costs. Performance, selection, attrition, and detection bias were common in studies reviewed, limiting external generalisability. Norris 2002b performed a meta-analysis of the effect of self-management training on glycaemic control. On average, glycated haemoglobin decreased by 0.8% (95% CI 0.3 to 1.2) more than the control group at immediate follow-up and by 0.3% (95% CI 0.1 to 0.5) at four months or longer follow-up. Metabolic control improved in line with additional contact time between participant and educator; there was a decrease in glycated haemoglobin of 1% for every 23.6 hours (95% CI 13.3 to 105.4) of contact. Norris 2002b concluded that although self-management training improved diabetes control at immediate follow-up, the benefit declined between one and three months after the intervention ceased, suggesting that learned behaviours can change overtime. Steed 2003 reviewed 36 self-management and psychosocial interventions on psychosocial outcomes and found that depression seemed to be particularly improved following psychosocial interventions, whereas quality of life showed greater improvement following self-management interventions. There is no convincing evidence to further support the use of didactic education programmes. Van Dam 2003 reviewed eight publications evaluating the effects of the modification of provider-patient interaction and consulting style on diabetes self-care and diabetes outcomes. Patient behaviour-focused interventions, the enhancement of patient participation by assistant-guided patient preparation for visits to doctors, empowering group education and automated telephone management were found to be more effective than focusing on provider behaviour to change health professional consulting style into a more patient-centred one. However, although there is evidence that self-management training is effective, all four recent reviews called for further research by way of well-designed and long-term studies.

Educational programmes are frequently defined as complex interventions where it is often difficult to define the 'active ingredient'. If a programme is shown to be effective, that may be due to any combining theoretical model used, the skills of the educator, the

venue, the rapport between the participants and so on. If it is clear to those who read the results of a trial how the intervention can be transported and put into operation in other contexts, then it may not be essential to discover the precise mechanisms of action (MRC 2000). However, if sufficiently homogeneous good quality complex interventions are systematically reviewed, the active ingredient is more likely to become apparent.

Aims

As a result of the increasing prevalence of diabetes and increasing pressure on staff resources, more patients are receiving diabetes education by attending group-based programmes. None of the above reviews have evaluated the effectiveness of self-management training delivered in a group format. This systematic review aims to evaluate previous research into group-based, patient-centred educational programmes for people with type 2 diabetes. Particular attention will be placed on programmes that attempted to increase self-management skills, self-efficacy or self-empowerment and measure their impact on metabolic control, patient satisfaction and quality of life. Information gained will be used to further develop expert patient programmes for people with type 2 diabetes.

OBJECTIVES

To assess the effects of group-based (six or more people), patient-centred diabetes training on clinical, lifestyle and psychosocial outcomes both in the short (four to six months) and longer-term (more than 12 months) compared with routine care delivered on a one-to-one basis, or a combination of the two.

To observe whether the setting (primary / secondary care), the educator (physician, nurse, dietitian, other health professional, peer educator), the type of educational model or the duration/intensity of the group-based education programme affects the outcomes.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

The Cochrane Effective Practice and Organisation of Care (EPOC) review group guidelines were used for study type and amended by the Cochrane Metabolic and Endocrine Disorders Group. Studies were included if they were a randomised controlled trial (RCT) or a controlled clinical trial (CCT) and then only if they fulfilled the inclusion criteria.

Interventions involved a single or series of group sessions. Only studies that assessed outcome measures six months or more from baseline were included in this study.

Types of participants

Adults with diagnosed type 2 diabetes regardless of gender or ethnicity. Ideally, the diagnostic criteria for type 2 diabetes should have been described in the trial. In order to be consistent with changes in classification and diagnostic criteria of the disease through the years, the diagnosis should have been established using the standard criteria that were valid at the beginning of the trial (ADA 1997; NDAG 1979; WHO 1980; WHO 1985; WHO 1999b).

The review excluded interventions that were specific for maturity onset diabetes of the young (MODY) or for pregnant women.

Types of intervention

Group-based educational programmes which met the following criteria:

- specific for people with type 2 diabetes;
- delivered in primary or secondary care;
- based on learner/patient-centred education;
- included or excluded family and friends;
- had a minimum of six participants in each group;
- was a minimum of one session lasting for one hour.

Comparison Group

The intervention group was compared with those participants either:

- undergoing routine treatment (receiving the standard of care recommended in that country e.g. regular follow-up with the required health professionals and a full diabetes annual review);
- remaining on a waiting list;
- experiencing no intervention i.e. the present healthcare was continued.

Types of outcome measures

Main outcome measures

Clinical:

- Metabolic control: Glycated haemoglobin (%) and fasting blood glucose (mmol/L).

Lifestyle:

- Diabetes knowledge*.

Psychosocial:

- Quality of life*;
- Empowerment/self-efficacy*.

Additional outcome measures

Clinical:

- Body weight (Kg)/body mass index (BMI)(Kg/m²);

- Blood pressure (systolic/diastolic) (mmHg);
- Lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides) (mmol/L);
- Diabetes complications (myocardial infarction, angina, heart failure, stroke, renal failure, neuropathy, retinopathy, peripheral vascular disease);
- Diabetes-related mortality (death from myocardial infarction, stroke, peripheral vascular disease, renal disease, hyper- or hypoglycaemia or sudden death);
- Adverse effects e.g. increased hypoglycaemia.

Lifestyle:

- Self-management skills (including dietary habits and physical activity levels)*.

Psychosocial:

- Patient treatment satisfaction*.

(Diabetes education studies are generally too short-term to assess incidence of diabetes complications and mortality. Therefore, the main outcome will be glycated haemoglobin. It has been shown (UKPDS-35 2000) that a 1% reduction in glycated haemoglobin reduces the risk of developing diabetes complications by 21%).

* Ideally measured using standard (validated) questionnaires.

Effect modifiers specific to the intervention or disorder

- Attendance rate;
- Number of hours of education received;
- The educator;
- The venue;
- Delivered in primary or secondary care.

Timing of outcome assessment

Short term: four to six months;

Medium term: six to 12 months;

Long term: 12 months or more.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: Metabolic and Endocrine Disorders Group search strategy

Electronic searches

The following electronic databases were searched from the date on which records began, up until January/February 2003: *The Cochrane Library*; MEDLINE; CINAHL; ERIC; ASSIA; AMED; PsycINFO; EMBASE; LILACS; NHS Economic Evaluation Database (NHS EED); British Education Index (BEI); British Nursing Index (BNI); Web of Science (WOS); Index of Scientific

& Technical Proceedings; National Research Register; Digital Dissertation Abstracts. Conference proceedings and reference lists of articles were also searched and contact was made with experts in the field. For a detailed search strategy please see under 'Additional tables' (Table 01).

Handsearching

Attempts were made to identify additional studies by searching the reference lists of relevant trials and reviews.

Other search strategies

Some of the authors of relevant identified studies and other experts (authors of reviews and well known diabetes educators) were contacted in order to obtain additional references, unpublished trials, or ongoing trials.

Additional key words of relevance could have been identified during any of the electronic or other searches. If this had been the case, electronic search strategies would have been modified to incorporate these terms. Studies published in any language were included.

METHODS OF THE REVIEW

Trial selection

Two independent reviewers (TD, CM) scanned the titles, abstract sections and keywords of every record retrieved. Full articles were retrieved for further assessment if the information suggested that the study:

1. included patients with type 2 diabetes mellitus,
2. evaluated a patient-centred group-based education programme.

Wherever there was any doubt regarding the existence of these criteria the complete article was retrieved for clarification. Interrater agreement for study selection was measured using the kappa statistic (Cohen 1960). Any differences in opinion were discussed and, if necessary, resolved by a third party (JC). There were no instances where it was necessary to contact the authors or the review group editorial base.

Quality assessment of trials

The quality of reporting of each randomised trial was assessed largely on the quality criteria specified by Schulz and by Jadad (Jadad 1996; Schulz 1995). In particular, the following factors were studied:

1. Minimisation of selection bias - a) was the randomisation procedure adequate? b) was the allocation concealment adequate?
2. Minimisation of attrition bias - a) were withdrawals and dropouts completely described? b) was analysis by intention-to-treat?
3. Minimisation of detection bias - were outcome assessors blind to the intervention?

Based on these criteria, studies were broadly subdivided into the following three categories (see Cochrane Handbook):

A - all quality criteria met: low risk of bias.

B - one or more of the quality criteria only partly met: moderate risk of bias.

C - one or more criteria not met: high risk of bias.

This classification will be used as the basis of a sensitivity analysis. Additionally, we will explore the influence of individual quality criteria in a sensitivity analysis.

Data extraction

1. General information: published/unpublished, title, authors, reference/source, contact address, country, urban/rural etc., language of publication, year of publication, duplicate publications, sponsoring, setting.
2. Trial characteristics: design, duration, randomisation (and method), validated questionnaires, allocation concealment (and method), blinding (patients, outcome assessors), check of blinding.
3. Intervention(s): Comparison group included (routine treatment, waiting list, no intervention), intervention(s) (theoretical model, duration, timing),
4. Participants: sampling (random/convenience), exclusion criteria, total number and number in comparison groups, sex, age, ethnicity, Body Mass Index, pre-existing medical conditions, educational history, standards of diabetes care, intervention delivered by primary or secondary care, diagnostic criteria, duration of diabetes, similarity of groups at baseline (including any co-morbidity), assessment of compliance, withdrawals/losses to follow-up (reasons/description), subgroups.
5. Outcomes: outcomes specified above (also: what was the main outcome assessed in the study?), any other outcomes assessed, other events, length of follow-up, quality of reporting of outcomes.
6. Results: for outcomes and times of assessment (including a measure of variation), if necessary converted to measures of effect specified below; intention-to-treat analysis.

A template data extraction form was developed and tested for suitability. Minor amendments were made before use. Before final data extraction, the data extraction form was sent to the Metabolic and Endocrine Disorders Group Editorial Base for approval. Data extraction and data entry was performed independently in duplicate by two evaluators (TD, CM). Differences in data extraction were discussed and if necessary resolved by consensus by way of the third reviewer (JC) referring back to the original article. If data were missing in a published report (see data extraction list), the reviewers tried to contact the first author.

Data analysis

Data were summarised statistically only if it was available, sufficiently similar (homogeneous), and of sufficient quality. Mean outcome data at four to six months and 12-14 months were compared rather than comparing mean change from baseline. The usual analysis in a clinical trial is comparison of the observed mean and all the individual trials had used this method. Assessment of the consistency of effects across studies is an essential part of a

meta-analysis without which the generalisability of the findings of the meta-analysis cannot be determined. Heterogeneity can be caused by the variability or differences between studies in key characteristics (clinical heterogeneity) quality (methodological heterogeneity) and effects (heterogeneity of results). Outcomes that were not significantly homogeneous for meta-analysis due to variations in measurement design, baseline characteristics, validated questionnaires, length of follow-up or missing data were summarised in a descriptive nature.

A popular test for heterogeneity (Cochran's Q) examines the null hypothesis that all studies are evaluating the same effect. The test is known to be poor at detecting true heterogeneity among studies as significant, especially when there is only a small number of studies included in the meta-analysis. In this instance, heterogeneity for tested for using a new quantity, I^2 , which described the percentage of total variation across studies that was due to heterogeneity rather than chance. It was a better measure of consistency between trials in the meta-analysis (Higgins 2003). Higgins classifies I^2 values of 25%, 50% and 75% were classified as low, moderate, and high heterogeneity respectively, whereas the Cochrane handbook assigns values greater than 50% to "substantial" heterogeneity.

The dichotomous data (e.g. mortality, medication reduction) used a random effect approach (it is unreasonable to assume that there is one 'true' effect underlying the data that is constant across different populations) and the odds ratio (O-E) summary statistic with the DerSimonian and Laird method. The meta-analytical model for the continuous data (e.g. weight, blood pressure, glycated haemoglobin) used a random effect approach with the weighted mean difference by the DerSimonian and Laird method. However, if the results across studies are conceptually the same but measured in a different way (e.g. scores on depression can be reported as means or as the percentage of patients who were depressed at some point after an intervention), standardised mean differences were used.

Subgroup analyses

Ideally a subgroup analysis would have been performed for the following:

1. Ethnicity e.g. Strategies for South Asian compared to those for white Caucasian people.
2. Theoretical model underpinning the education programme e.g. empowerment versus didactic model.
3. Duration of education programme e.g. single session compared to series of sessions.
4. Age e.g. 30 to 60 year olds compared with those aged above 60 years.
5. Gender e.g. single sex versus mixed sex sessions.
6. Education delivered within primary or secondary care.

In fact, subgroup analyses were performed only if, in the meta-analysis, there were sufficient studies and the results for one or more of the main outcome were significant.

Sensitivity analyses

Sensitivity analyses were performed (if appropriate and if a sufficient number of studies were included in the meta-analysis) in order to explore the influence of the following factors on effect size:

Repeating the analysis:

1. excluding unpublished studies;
2. taking account of study quality, as specified above;
3. excluding any very long or large studies to establish how much they dominate the results;
4. excluding studies which had been published in a foreign language and then translated;
5. excluding studies with less than 100 participants and length of follow-up less than 12 months.

A funnel plot was also performed in order to assess small study or publication bias for glycated haemoglobin at 12 to 14 months follow-up.

DESCRIPTION OF STUDIES

Trials identified

Electronic searches undertaken in January and February 2003 identified 5497 citations of which 899 were duplicates. Duplicates were identified by collating all citations into one Reference Manager database. A duplicate search was then carried out and each citation checked to ensure that it was a duplicate and not an additional paper. The titles and abstracts of 4598 citations were independently reviewed by TD and CM and 183 citations either met the inclusion criteria or required sight of full paper before a decision could be made. Thirteen abstracts required translation, of which eight were written in Spanish, three in Portuguese and two in German. A further 10 papers were identified by hand searching and by contacting experts in the field, which gave a total of 193 papers required for data extraction. Of these, three foreign language papers were unobtainable through the British Library or through inter-library loans. Two of those were written in Spanish (Luna Arriola 1994; Saenz Hernaiz 1992) and one in Chinese (Fan 1999). Twelve papers required translation: five were written in Spanish (Bundo 1993; Cabrera-Pivaral 2000; Lozano 1996; Llamas 2002; Lozano 1999), six in German (Haisch 1996; Haisch 2000; Hanefeld 1996; Hardinghaus 1996; Jungmann 1997; Rebell 2002) and one in French (Girard 1986). Of the 190 full papers obtained, 19 were duplicates reporting either the same data or follow-up data (Arauz 1997; Arauz 2001; Domenech 1994; Domenech 1995; Hanefeld 1991; Hanefeld 1996; Hansen 2002; Jungmann 1997; Jungmann 1997b; Keyserling 2000; Keyserling 2002; Miller 2002; Miller 2002c; Norris 2001; Renders 2000; Trento 1998; Trento 2001; Trento 2002).

Interrater agreement

Agreement was high between the two reviewers (TD and CM) with a Kappa statistic of 0.85 (95% CI 0.75 to 0.95). Some data were

unclear and discussion and differences of opinion were resolved via discussion without the need to obtain a third independent assessment (JC).

Excluded studies

As stated above, three foreign language papers were unobtainable. The systematic review of the 190 full publications led to the exclusion of 177 papers. Therefore 180 publications of 177 studies were excluded. Reasons for exclusion were: lack of control group; length of follow-up being too short; absence of the prespecified outcomes; intervention group in receipt of individual appointments in addition to the group-based education programme; delivery of group-based education programme to the control group; not all participants having type 2 diabetes; narrative papers, and group-based education programme that did not focus on diabetes self-management education. Several studies were excluded on more than one ground as can be seen in the excluded studies table below.

Included studies

A total of 14 publications, reporting 11 studies, met the inclusion criteria. However, one duplicate publication was a conference proceeding written in Spanish (Domenech 1994). The abstract was translated and, as it contained the same data as the English language publications, it was deemed unnecessary to have the full publications translated. Thirteen publications were therefore analysed (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Holtrop 2002; Kronsbein 1988; Lozano 1999; Pieber 1995b; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001) in order to evaluate the 11 studies. Three trials were carried out in the United States (Brown 2002; Holtrop 2002; Rickheim 2002), two in the United Kingdom (Deakin 2003; Heller 1988), two in Austria (Pieber 1995b; Zapotoczky 2001), one in Argentina (Domenech 1995), one in West Germany (Kronsbein 1988), one in Spain (Lozano 1999) and one in Italy. The Italian trial had three published publications which reported follow-up at 12 months, two and four years (Trento 1998; Trento 2001; Trento 2002). Only one of the translated publications (Lozano 1999) met the inclusion criteria sufficiently to contribute to the review.

Study design

Eight studies included in the review were randomised controlled trials, and three studies that were controlled clinical trials (Domenech 1995; Kronsbein 1988; Pieber 1995b). The length of follow-up was six months for three of the trials (Holtrop 2002; Pieber 1995b; Rickheim 2002), 12 to 14 months for six of the trials (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Kronsbein 1988; Zapotoczky 2001), and two years for one trial (Lozano 1999). As stated above, the Trento study reported follow-up at one year (Trento 1998), at two years (Trento 2001) and at four years (Trento 2002).

Participants

A total of 1532 participants were included in the 11 trials with 742 (48%) in the intervention group. The smallest study included 36 participants (Zapotoczky 2001) and the largest study, 314 par-

ticipants (Deakin 2003). The proportion of men and women was roughly the same in each group with the exception of one trial (Holtrop 2002) that recruited only women. All trials recruited adults with type 2 diabetes and the mean age of participants was between 51 and 65 years. Seven papers (Brown 2002; Deakin 2003; Heller 1988; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002) providing information on five trials reported age range. The age ranges were similar with the lower age bracket being 30-35 years and the highest age bracket being 71-85 years. One trial recruited Mexican Americans (Brown 2002); another recruited 25% South Asians and 75% white Caucasians (Deakin 2003). Two other trials (Holtrop 2002; Rickheim 2002) reported that 95% of participants were Caucasian but report ethnicity of the other 5% of participants. Duration of diabetes was reported in nine trials; in seven of those, it was between six and nine years (Brown 2002; Deakin 2003; Domenech 1994; Kronsbein 1988; Lozano 1999; Pieber 1995b; Trento 1998), in one trial it was less than a year (Rickheim 2002) and in another trial (Heller 1988) participants were newly diagnosed. Inclusion criteria for entry into individual trials is outlined in the 'characteristics of included studies' table below.

Interventions

All trials evaluated a group-based diabetes education programme. Programmes varied in duration with the least intensive being three hours per year for two years (Lozano 1999) and three or four hours per year for four years (Trento 1998; Trento 2001; Trento 2002). Eight trials described programmes that ranged from six to fifteen hours of group-based education over a period of between four weeks and 10 months (Deakin 2003; Domenech 1995; Heller 1988; Holtrop 2002; Kronsbein 1988; Pieber 1995b; Rickheim 2002; Zapotoczky 2001) with the most intense education programme being 52 hours over one year (Brown 2002). Seven of the 11 group education programmes were held in primary care (Brown 2002; Deakin 2003; Domenech 1995; Holtrop 2002; Kronsbein 1988; Lozano 1999; Pieber 1995b) with the remaining four being delivered in hospital diabetes centres (Heller 1988; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001). The educators were all health professionals, with the exception of one study where the educators were lay health advisors (Holtrop 2002). Three of the group education programmes were delivered by physicians (Domenech 1995; Pieber 1995b; Trento 1998; Trento 2001; Trento 2002) with Pieber 1995b securing additional help from office staff and Trento 1998; Trento 2001; Trento 2002 incorporating two physicians and an educationalist. Three group education programmes were delivered by a dietitian and a nurse (Brown 2002; Heller 1988; Rickheim 2002) with Brown 2002 also involving community workers. Two programmes were delivered by dietitians working alone (Deakin 2003; Zapotoczky 2001), one by a nurse working alone (Lozano 1999) and one by paramedical staff (physician assistants) (Kronsbein 1988). Five studies reported that a family member or friend was also invited to attend the programme (Brown 2002; Deakin 2003;

Domenech 1995; Heller 1988; Trento 1998; Trento 2001; Trento 2002), one study stated that the programme was for patients only (Pieber 1995b) and in the remaining five studies participation of family or friends was unclear.

The theoretical model that was used to plan the group-based education programme was only reported in five studies. Three of these (Domenech 1995; Kronsbein 1988; Pieber 1995b) had adapted the Diabetes Treatment and Teaching Programme (DTTP) which was originally developed in Germany for adults with type 1 diabetes (Mühlhauser 1983) and is based on therapeutic patient education (WHO 1998). One study was based on patient-centred education and used an empowerment model developed by Anderson 2000. Another study based the education on four different models: an adult learning model, a public health model, a health belief model and a trans theoretical model (Rickheim 2002). Lozano 1999 stated that the group education programme was 'participatory' and Trento 1998 described their programme as 'structured'. Eight studies (Deakin 2003; Domenech 1995; Heller 1988; Kronsbein 1988; Pieber 1995b; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001) provided information about the number of patients invited to attend the group education programme. The smallest groups comprised four to six participants (Heller 1988; Kronsbein 1988) and the largest groups comprised 16 to 18 patients (Zapotoczky 2001) and (Deakin 2003).

In seven studies, the comparison group received routine treatment (Deakin 2003; Domenech 1995; Heller 1988; Holtrop 2002; Lozano 1999; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001). In one study, the control group was placed on a waiting list to receive the group education programme after the study (Brown 2002), two studies stated that the control group received routine treatment and were placed on a waiting list for the education programme (Kronsbein 1988; Pieber 1995b), and in one study (Rickheim 2002) the comparison group received five hours of individual appointments. Routine treatment was defined as separate individual appointments with a dietitian, practice nurse and general practitioner (Deakin 2003), 15 to 20 minutes with a multidisciplinary diabetes team every three months (Trento 1998; Trento 2001; Trento 2002) or an individual appointment with a dietitian every three months (Zapotoczky 2001).

Outcome measures

All trials included in the review assessed the primary outcome which was glycated haemoglobin (HbA1c). These assessments were made at either four to six months (Brown 2002; Deakin 2003; Heller 1988; Holtrop 2002; Pieber 1995b; Rickheim 2002), 12-14 months (Brown 2002; Deakin 2003; Domenech 1994; Heller 1988; Kronsbein 1988; Lozano 1999; Trento 1998), two years (Lozano 1999; Trento 2001) and 4 years (Trento 2002). Eight studies stated that the HbA1c measurement was standardised (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Kronsbein 1988; Pieber 1995b; Rickheim 2002; Trento 1998;

Trento 2001; Trento 2002) and in three studies it was unclear whether HbA1c was standardised or not (Holtrop 2002; Lozano 1999; Zapotoczky 2001). Only one study identified HbA1c in the inclusion criteria, with participants requiring a HbA1c reading of more than 7% to participate in the study. Only two trials assessed fasting blood glucose at six months (Heller 1988; Brown 2002); four trials assessed it at 12 months (Brown 2002; Heller 1988; Lozano 1999; Trento 1998), two trials at two years (Lozano 1999; Trento 2001) and one trial at four years (Trento 2002). For the other main outcomes, four trials assessed diabetes knowledge at four to six months (Brown 2002; Deakin 2003; Pieber 1995b; Rickheim 2002), six at 12-14 months (Brown 2002; Deakin 2003; Heller 1988; Kronsbein 1988; Lozano 1999; Trento 1998), two at two years (Lozano 1999; Trento 2001) and one at four years (Trento 2002). Domenech 1995 assessed diabetes knowledge only in the intervention group. All knowledge questionnaires were validated except for two studies, where it was unclear whether the questionnaire was validated or not (Brown 2002; Domenech 1995). The level of participant empowerment/psychosocial self-efficacy was assessed in only two studies (Deakin 2003; Rickheim 2002) and different measurement tools were used. Quality of life was assessed in three studies (Deakin 2003; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002) again using different validated measures.

With regard to additional outcomes, five studies assessed body mass index (BMI) at four to six months (Brown 2002; Deakin 2003; Holtrop 2002; Pieber 1995b; Rickheim 2002), four studies at 12-14 months (Brown 2002; Deakin 2003; Lozano 1999; Trento 1998), two studies at two years (Lozano 1999; Trento 2001) and one study at four years (Trento 2002). Four studies assessed body weight at four to six months (Deakin 2003; Heller 1988; Pieber 1995b; Rickheim 2002), five at 12-14 months (Deakin 2003; Heller 1988; Kronsbein 1988; Trento 1998; Zapotoczky 2001) and the long-term follow-up studies of Trento assessed body weight at two years (Trento 2001) and four years (Trento 2002). Systolic and diastolic blood pressure were assessed in only two studies; at four to six months (Deakin 2003; Pieber 1995b) and 12-14 months (Deakin 2003; Zapotoczky 2001). Lipid profile was assessed between four to six months in three studies (Brown 2002; Deakin 2003; Pieber 1995b) and between 12-14 months in three studies (Brown 2002; Deakin 2003; Zapotoczky 2001) with one study assessing triglyceride level only (Kronsbein 1988).

Diabetes self-management skills were assessed in six studies as follows:

1. self-care activities questionnaire (validated) and dietary intake using a validated food frequency questionnaire (Deakin 2003);
2. a validated health behaviour conduct questionnaire (Trento 1998; Trento 2001; Trento 2002);
3. self-reported activity levels (frequency and duration) (Rickheim 2002);
4. self-monitoring of blood glucose levels (Lozano 1999);
5. self-monitoring of urinalysis (Kronsbein 1988);

6. a stages of change questionnaire (Holtrop 2002) assessed confidence to make changes in diet and activity. Outcomes were however presented as a pre-test/post-test comparison within the intervention group and no data were shown for the control group.

Satisfaction with treatment was assessed in only one study (Deakin 2003) and change in diabetes medication was assessed in five studies (Deakin 2003; Domenech 1995; Kronsbein 1988; Pieber 1995b; Rickheim 2002). A cost-effectiveness analysis was performed at a four year follow-up (Trento 2002) and the cost of delivering the programme was estimated in Brown 2002.

Three studies recorded the number of deaths (Deakin 2003; Kronsbein 1988; Trento 1998; Trento 2001; Trento 2002) but did not identify whether the deaths were diabetes related. Only one study recorded diabetes complications (creatinine, albuminuria, diabetic retinopathy, foot ulcers) at two years (Trento 2001) and four years (Trento 2002).

METHODOLOGICAL QUALITY

Based on the quality criteria described in the methods section above, two studies were classified as having a moderate risk of bias (Deakin 2003; Zapotoczky 2001), seven studies as having a high risk of bias (Brown 2002; Heller 1988; Holtrop 2002; Kronsbein 1988; Lozano 1999; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002) and both clinical controlled trials were identified as being at risk of having one or more of the quality criteria not met (Domenech 1995; Pieber 1995b). Interrater agreement of trial quality was 0.63 (95% CI 0.50% to 0.76%) and agreement was reached following discussion between the two reviewers (TD and CM).

Method of randomisation

Only three of eight randomised controlled trials described the method of randomisation. Two used random permuted blocks (Deakin 2003; Rickheim 2002) and one used random table numbers (Trento 1998; Trento 2001; Trento 2002).

Allocation concealment

Allocation concealment was only noted in one study (Deakin 2003). The remaining eight randomised controlled trials made no reference to allocation concealment (Brown 2002; Heller 1988; Holtrop 2002; Kronsbein 1988; Lozano 1999; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001).

Intention-to-treat analysis

Three studies reported analysis to be by intention to treat (Deakin 2003; Heller 1988; Trento 2002). The Trento study however, only reported the intention to treat analysis at the four year assessment and not in the two earlier papers (Trento 1998; Trento 2001). An intention to treat analysis was not needed for one study since there were the drop-out rate was nil and all participants were re-assessed at follow-up (Zapotoczky 2001). Intention to treat analysis was not

performed in six studies (Brown 2002; Domenech 1995; Holtrop 2002; Kronsbein 1988; Lozano 1999; Pieber 1995b) and it was unclear whether such analysis had been undertaken by Rickheim 2002.

Losses to follow-up

Losses to follow-up were described in all studies except one (Brown 2002). Losses to follow-up ranged from 0% in one study (Zapotoczky 2001); to 25% in the intervention group and 45% in the control group in another study (Domenech 1995).

Blindness of treatment

It was not possible to blind participants as to their allocation to the respective groups. However, two studies attempted to blind the control group to the fact that they were the controls by presenting 'routine treatment' as an individual appointment intervention (Deakin 2003; Rickheim 2002).

Outcome assessment

Details of blinding the outcome assessors were not described in any of the trials.

Number of participants in the study

Only three studies presented a power calculation and based recruitment numbers on the calculation (Deakin 2003; Kronsbein 1988; Lozano 1999). A further two studies referred to a power calculation but the data were not provided (Holtrop 2002; Trento 2002). The number of participants recruited in each study ranged from 36 (Zapotoczky 2001) to 314 (Deakin 2003).

Other comments on quality

One study reported different outcomes at baseline than at follow-up. For example, body mass index was assessed at baseline but weight assessed at the one year follow-up (Domenech 1995). Another study compared knowledge score and fasting blood glucose levels between the intervention and control group at follow-up but did not present baseline data for these (Heller 1988). Holtrop 2002 presented some outcomes without standard deviations and reported P-values without presenting the actual data. Although baseline data were presented by Zapotoczky 2001, statistical tests were not performed to detect if the two groups were similar at baseline.

RESULTS

Heterogeneity

A test for heterogeneity, I^2 value (Higgins 2003) was performed for each outcome. Outcomes that had substantial heterogeneity (>50%) were subject to a sensitivity analysis to detect, if possible, the source of heterogeneity. Outcomes that could not be analysed statistically were summarised in a descriptive manner.

Data analysis

Mean outcome data at four to six months and 12-14 months were compared rather than comparing mean change from baseline. The

usual analysis in a clinical trial is comparison of the observed mean and all the individual trials had used this method.

Effect of the intervention

Mortality

At the 12-14 month outcome assessment there had been a total of 15 deaths reported from three studies with a combined total of 525 participants. There was low heterogeneity ($I^2 = 36.3\%$). One study reported more deaths in the control group (Deakin 2003), whereas two studies reported more deaths in the intervention group (Kronsbein 1988; Trento 1998). Overall there were eight deaths in the intervention group and seven deaths in the control group. Participation in a group-based diabetes education programme, therefore, was not shown to affect mortality rate (odds ratio 1.2, 95% CI 0.3 to 5.6, $Z = 0.29$, $P = 0.77$).

Reduction in diabetes medication

Five studies (Deakin 2003; Domenech 1995; Kronsbein 1988; Pieber 1995b; Rickheim 2002) with a combined total of 654 participants reported outcomes on diabetes medication with no heterogeneity between the studies ($I^2 = 0\%$). Group-based diabetes education programmes led to a significant reduction in diabetes medication (odds ratio 11.8, 95% CI 5.2 to 26.9; $Z = 5.87$; $P < 0.00001$). The likelihood of group education participants reducing diabetes medication was 73/328 = 0.22 (P1) and the likelihood of control participants reducing diabetes medication was 7/326 = 0.02 (P2). The risk difference (RD) is $P1 - (P1) = 0.2$. Group education participants were, therefore, 20 absolute percentage points more likely to reduce diabetes medication compared with control participants. The number needed to treat (NNT) is $1/RD = 1/0.2 = 5$ patients. Therefore, for every five patients attending a group-based education programme we could expect one patient to reduce diabetes medication by 12-14 months.

Glycated haemoglobin

Six studies assessed glycated haemoglobin at four to six months and involving 924 participants but there was substantial heterogeneity ($I^2 = 83.7\%$) between the studies that was investigated via a sensitivity analysis. Holtrop 2002 had not included standard deviations with the glycated haemoglobin data and also had a 0.3% difference in baseline values between the intervention and control group. The mean *change* in glycated haemoglobin from baseline to six months did not differ significantly between the intervention and control group (0.4% and 0.0% respectively; $P = 0.7$). The Rickheim 2002 publication found no difference between the intervention and control group six month HbA1c means but the intervention group had a significantly higher glycated haemoglobin at baseline (Difference 0.9%; 95% CI 0.2 to 1.6; $Z = 2.38$; $P = 0.02$). The mean *change* from baseline to six months for participants in the control programme was a 1.7% (SD 1.9%) reduction in HbA1c whereas participants assigned to the group programme had a 2.5% (SD 1.8) reduction in HbA1c. The difference in HbA1c improvement was significantly greater in subjects assigned to group versus individual education (Difference 0.8%; 95% CI 0.0 to 1.6; $Z = 2.07$;

$P = 0.04$). Deakin 2003 had reported a significant reduction in glycated haemoglobin of 0.4% at four months whereas the other five studies had reported significant reductions at six months (between 0.9% and 2.0%). When the Holtrop 2002, Rickheim 2002 and Deakin 2003 studies were removed from the meta-analysis, heterogeneity reduced significantly ($I^2 = 36.7\%$). A meta-analysis was carried out with the three remaining studies Brown 2002; Heller 1988 and Pieber 1995b involving 395 participants. The overall reduction in glycated haemoglobin in the group education participants was 1.4% (95% CI 0.8 to 1.9; $Z = 4.60$; $P < 0.00001$).

At the 12-14 months' follow-up, eight studies monitored glycated haemoglobin but there was substantial heterogeneity ($I^2 = 69.6\%$). Heterogeneity was due to the Kronsbein 1988 publication which had baseline differences in glycated haemoglobin in the intervention group (7.1%, SD 1.6) versus the control group (6.5%, SD 1.6) (Difference -0.6%; 95% CI -1.2 to 0.0; $Z = 1.93$; $P = 0.05$) and similar differences at 12 months reflecting the baseline data (-0.4%; 95% CI -1.0 to 0.21; $Z = 1.28$; $P = 0.2$). A meta-analysis of the seven remaining studies (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988; Lozano 1999; Trento 1998; Zapotoczky 2001) involving a total of 1044 participants was carried out with low heterogeneity between the studies ($I^2 = 18\%$). There was an overall significant reduction in glycated haemoglobin of 0.8% (95% CI 0.7 to 1.0; $Z = 9.63$; $P < 0.00001$).

Two studies involving 333 patients assessed glycated haemoglobin at two years (Lozano 1999; Trento 2001) with no heterogeneity between the studies ($I^2 = 0\%$). There was a significant reduction in HbA1c for the patients allocated the group-based diabetes education programme as compared to the control group (1.0%; 95% CI 0.5 to 1.4; $Z = 4.44$; $P < 0.00001$). At four years' follow-up, one study involving 90 patients assessed glycated haemoglobin (Trento 2002) and found a significant reduction in the group education group compared to the control group (1.6%; 95% CI 0.9 to 2.3; $Z = 4.53$; $P < 0.00001$).

Fasting blood glucose

One study (Brown 2002) with 229 participants reported lower fasting blood glucose levels at six months in the group education programme participants compared with the control group (difference 1.7 mmol/L; 95% CI 0.7 to 2.6; $Z = 3.53$; $P = 0.0004$). Four studies assessed fasting blood glucose at 12 months (Brown 2002; Heller 1988; Lozano 1999; Trento 1998) with no heterogeneity between studies ($I^2 = 0\%$). There was an overall significant improvement in patients allocated to the group education programme compared with those in the control group (difference 1.2 mmol/L; 95% CI 0.7 to 1.6; $Z = 5.06$; $P < 0.00001$). Two studies assessed fasting blood glucose at two years (Lozano 1999; Trento 2001) and as there was substantial heterogeneity between the two studies ($I^2 = 63.6\%$) a meta-analysis was not performed. The larger of the two studies (Lozano 1999) involving 243 participants showed a significant improvement of fasting blood glucose in favour of the group education programme (difference 1.8

mmol/L; 95% CI 1.2 to 2.4, $Z = 5.99$, $P < 0.00001$) but the other study (Trento 2001) involving 80 participants did not (difference 0.7 mmol/L; 95% CI -0.4 to 1.9; $Z = 1.18$; $P = 0.24$). However, Trento 2002 reported a significant difference between groups at the four years' follow-up in favour of the group programme (difference 1.7 mmol/L; 95% CI 0.2 to 3.2; $Z = 2.16$; $P = 0.03$).

Body weight / body mass index

At four to six months there was no evidence that group-based diabetes education programmes had an impact on body weight or body mass index (BMI). Four studies, having a combined total of 566 participants, assessed body weight (Deakin 2003; Heller 1988; Pieber 1995b; Rickheim 2002). There was low heterogeneity ($I^2 = 31.3\%$). Overall reduction in body weight was 2.1 kg more than in the control group but that difference was not statistically significant (95% CI -0.5 to 4.7; $Z = 1.62$; $P = 0.11$). Four studies involving 718 participants assessed BMI (Brown 2002; Pieber 1995b; Rickheim 2002) with no heterogeneity between studies ($I^2 = 0\%$). There was a difference between groups of 0.2 kg/m² in favour of group education but, as in the case of body weight, that difference was not statistically significant (95%CI -0.7 to 1.0; $Z = 0.37$; $P = 0.71$).

At 12-14 months there was a small amount of evidence in favour of the group education programme improving body weight but not BMI. Five studies, involving 591 patients, assessed body weight (Deakin 2003; Heller 1988; Kronsbein 1988; Trento 1998; Zapotoczky 2001) with no heterogeneity between studies ($I^2 = 0\%$) and a difference between the group education and control group of 1.6 kg (95% CI 0.3 to 3.0; $Z = 2.32$; $P = 0.02$). Four studies (with a total of 751 participants) assessed BMI at 12-14 months and were included in a meta-analysis (Brown 2002; Deakin 2003; Lozano 1999; Trento 1998) with no heterogeneity ($I^2 = 0\%$) and no effect (difference 0.45 kg/m²; 95% CI -0.2 to 1.2; $Z = 1.15$; $P = 0.25$).

One study (Deakin 2003) measured waist circumference at both four and 14 months. There was no significant difference between the two groups at four months (difference 1.3 cm; 95% CI -1.8 to 4.1; $P = 0.44$) but there was a trend in favour of the group education programme at 14 months (difference 2.8 cm; 95% CI -0.3 to 5.6; $P = 0.06$).

Diabetes knowledge score

Four studies with a combined total of 708 participants measured diabetes knowledge at four to six months (Brown 2002; Deakin 2003; Pieber 1995b; Rickheim 2002). As the studies had used different validated questionnaires to measure knowledge, the statistical method used was the standardised mean difference. However, there was high heterogeneity between studies ($I^2 = 88.6\%$) presumably due to the use of different validated questionnaires. A sensitivity analysis was performed by removing each study, one-by-one, from the meta-analysis but heterogeneity remained high ($I^2 = 80-90\%$) and a meta-analysis was not performed. Three of the four studies showed statistically significant greater knowledge

scores in the intervention group (Brown 2002: SMD 0.4; 95% CI 0.2 to 0.7; $Z = 3.12$; $P = 0.002$ / Deakin 2003: SMD 0.9; 95% CI 0.7 to 1.2; $Z = 7.56$; $P < 0.00001$ / Pieber 1995b: SMD 1.4; 95% CI 1.0 to 1.9; $Z = 6.19$; $P < 0.00001$). Rickheim 2002 did not show a statistical difference in knowledge score (SMD 0.1; 95% CI -0.4 to 0.5; $Z = 0.3$; $P = 0.76$).

Six studies measured diabetes knowledge at 12-14 months (Brown 2002; Deakin 2003; Heller 1988; Kronsbein 1988; Lozano 1999; Trento 1998). However, as a result of significant heterogeneity ($I^2 = 81.2\%$), a sensitivity analysis was performed. When the data from Brown 2002 and Deakin 2003, were removed, those being the least positive studies for this aspect of the analysis, heterogeneity was reduced but was still classed as substantial ($I^2 = 57.8\%$). When Heller 1988 was also removed, on the ground that it had a slightly more positive score than the other studies, heterogeneity reduced to a very low level ($I^2 = 18.7\%$) and the meta-analysis was carried out with the remaining three studies (Kronsbein 1988; Lozano 1999; Trento 1998) with a combined total of 432 participants. Diabetes knowledge was significantly greater for the participants in the group education programme (SMD 1.0; 95% CI 0.7 to 1.2; $Z = 8.18$; $P < 0.00001$). There may be several reasons why the removal of the three studies reduced heterogeneity, for example, different scores for the validated questionnaires or different standard deviations, but each of those individual studies showed a significant increase in diabetes knowledge in the intervention group compared to the control group (Brown 2002: SMD 0.4; 95% CI 0.1 to 0.7; $Z = 3.0$; $P = 0.003$ / Deakin 2003: SMD 0.5; 95% CI 0.3 to 0.8; $Z = 4.31$; $P < 0.0001$ / Heller 1988: SMD 1.6; 95% CI 1.1 to 2.1; $Z = 5.93$; $P < 0.00001$).

Two studies measured diabetes knowledge at two years. There was, however, once again significant heterogeneity ($I^2 = 96.4\%$) and a meta-analysis was not performed. Both studies showed significant better knowledge for the intervention group (Lozano 1999: SMD 2.3; 95% CI 2.0 to 2.6; $Z = 13.85$; $P < 0.00001$; Trento 2001: SMD 0.85; 95% CI 0.4 to 1.3; $Z = 3.85$; $P = 0.0001$). At four years Trento 2002 measured diabetes knowledge and found that increased diabetes knowledge remained in the patients allocated to the group programme (SMD 1.27; 95% CI 0.82 to 1.73; $Z = 5.48$; $P < 0.00001$).

Blood pressure

Two studies measured systolic and diastolic blood pressure at four to six months (Deakin 2003; Pieber 1995b) and a meta-analysis was performed including 399 participants. There was no heterogeneity between the studies for systolic blood pressure ($I^2 = 0\%$) and low heterogeneity for diastolic blood pressure ($I^2 = 28.3\%$). Systolic blood pressure significantly reduced in patients allocated to the group education programme (5 mmHg; 95% CI 1. to 10; $Z = 2.53$; $P = 0.01$). There was a trend towards reduced diastolic blood pressure (3 mmHg; 95% CI -6 to 0; $Z = 0.38$; $P = 0.08$).

At 12-14 months, two studies measured blood pressure (Deakin 2003; Zapotoczky 2001). There was no heterogeneity between

the studies for systolic blood pressure ($I^2 = 0\%$). Although there was a small reduction in respect of systolic blood pressure, it was not statistically significant (3 mmHg; 95% CI -7 to 2; $Z = 1.24$; $P = 0.22$). A meta-analysis could not be performed for diastolic BP due to substantial heterogeneity between the two studies ($I^2 = 67.9\%$). However, neither of the two studies reported a significant difference between the intervention group and control group for diastolic blood pressure. No studies reported blood pressure measurements beyond 14 months.

Lipid profile

There were no significant differences between the two groups in respect of total cholesterol. At four to six months, three studies (Brown 2002; Deakin 2003; Pieber 1995b) including 629 participants showed substantial heterogeneity ($I^2 = 55.7\%$) and a meta-analysis was not performed. At 12-14 months, three studies (Brown 2002; Deakin 2003; Zapotoczky 2001) involving 552 patients displayed no heterogeneity ($I^2 = 0\%$) with no statistically significant differences between groups (0.09 mmol/L, 95% CI -0.09 to 0.26; $Z = 0.95$; $P = 0.34$).

With regard to triglyceride levels at four to six months, three studies (Brown 2002; Deakin 2003; Pieber 1995b) with a total of 628 patients and low heterogeneity ($I^2 = 10.5\%$) were included in the meta-analysis with a trend towards reduced triglyceride levels in favour of the group education programme (0.24 mmol/L; 95% CI -0.04 to 0.52; $Z = 1.68$; $P = 0.09$). Four studies measured triglycerides at 12-14 months (Brown 2002; Deakin 2003; Kronsbein 1988; Zapotoczky 2001) with low heterogeneity between studies ($I^2 = 15.1\%$) and including 652 participants with no statistically significant differences between groups (-0.14 mmol/L; 95% CI -0.41 to 0.13; $Z = 1.01$; $P = 0.31$).

Empowerment / self-efficacy

Deakin 2003 assessed the level of empowerment and psychosocial self-efficacy experienced by the participants using a validated questionnaire (Anderson 2000b). At four months there was a significant difference in total empowerment score between the two groups in favour of the group education programme (difference 0.3; 95% CI 0 to 0.6; $P < 0.001$). That was also the case for the three sub scales: psychosocial adjustment to diabetes (difference 0.3; 95% CI 0 to 0.6; $P = 0.002$); readiness to change (difference 0.4; 95% CI 0.2 to 0.5; $P < 0.001$); and setting and achieving goals (difference 0.3; 95% CI 0.2 to 0.5; $P < 0.001$). At 14 months empowerment scores were still significantly higher amongst patients allocated the group education programme: the total empowerment score 3.5 for the group education programme participants as opposed to 3.2 for the control group (difference 0.3; 95% CI 0.04 to 0.6; $P = 0.006$); psychosocial adjustment to diabetes (difference 0.3; 95% CI 0.02 to 0.7; $P = 0.005$); readiness to change (difference 0.3; 95% CI 0.1 to 0.5; $P = 0.001$); and setting and achieving goals (difference 0.2; 95% CI 0.05 to 0.4; $P = 0.02$).

Rickheim 2002 (a study involving 92 patients) measured psychosocial adjustment to diabetes with a validated questionnaire

and evaluated at six months. Both the intervention and control group significantly improved their psychological adjustment to diabetes ($P < 0.01$) but there was no statistical significance between the two groups ($P = 0.64$).

Quality of life

Two studies measured quality of life at 4-6 months (Deakin 2003; Rickheim 2002) using different validated questionnaires (Bradley 1999; Ware 1994 respectively). It was not possible to synthesise and summarise those statistically, as the scales were too dissimilar. Deakin 2003 found no overall improvement in overall quality of life but in respect to the sub-scales there were highly significant improvement in participants allocated to the group education programme: freedom to eat (difference 1.7; 95% CI 0.8 to 2.5; $P < 0.001$); enjoyment of food (difference 1.2; 95% CI 0.2 to 2.1; $P = 0.046$); and freedom to drink (difference 1.5; 95% CI 0.4 to 2.5; $P = 0.005$). Rickheim 2002 found that participants in both the intervention and control groups significantly improved their score on the SF-36 mental scale (group allocated to group education, $P < 0.01$; control group, $P = 0.04$), but there was no significant difference between the groups ($P = 0.82$). Neither group had a higher score for the SF-36 physical score at six months (Intervention group $P = 0.63$, control group $P = 0.93$) and there was no significant difference between the groups ($P = 0.69$).

At 12-14 months two studies measured quality of life, Deakin 2003 used the same validated questionnaire as that used at six months Bradley 1999 and Trento 1998 used a translated and revalidated diabetes quality of life questionnaire from the diabetes control and complications trial (DCCT 1988). It was not possible to synthesise and summarise those statistically because the scales were ranked in opposite directions. At 14 months Deakin 2003 reported similar results to those at four months, namely no significant improvement in overall quality of life, but significant improvements for the sub-scales: freedom to eat (difference 1.1; 95% CI 0.2 to 2.1; $P = 0.04$); enjoyment of food (difference 1.1; 95% CI 0.1 to 2.0; $P = 0.05$); and freedom to drink (difference 1.5; 95% CI 0.5 to 2.6; $P = 0.01$). Trento 1998 did not find a significant difference in quality of life at 12 months but reported a significant improvement in quality of life at two years (Trento 2001, $P < 0.001$) and at four years (Trento 2002, $P < 0.009$).

Self-management

Six studies measured some aspect of self-management (Deakin 2003; Holtrop 2002; Kronsbein 1988; Lozano 1999; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002). However, the variety of self-management tasks and measures resulted in a descriptive summary of the findings.

Deakin 2003 measured self-care activities using a validated questionnaire (Toobert 1994) and reported that at four months participants allocated to the group education programme had significantly increased their self-management scores for exercise ($P < 0.001$), foot care ($P = 0.008$) and self monitoring of blood glucose levels ($P = 0.009$). At 14 months, self-management scores had re-

mained significant in respect of exercise ($P = 0.02$) and foot care ($P = 0.003$) but there was no significant difference between the groups for self-monitoring of blood glucose levels ($P = 0.17$). Food intake was measured with a validated food frequency questionnaire (Little 1999) and, at four months reported that the participants allocated to group education had increased energy intake from carbohydrate (difference 4.1%; 95% CI 0.4 to 7.9; $P = 0.03$), total sugars (difference 5.1%; 95% CI 2.4 to 7.9; $P < 0.001$) and more fruit and vegetable portions per day (difference 1 portion; 95% CI 0.2 to 1.8; $P = 0.01$) when compared with the control group. At 14 months there were trends suggesting that the participants invited to the group intervention compared to those in the control group were consuming more percentage energy from carbohydrate (difference 3.3%; 95% CI 0.3 to 6.9; $P = 0.07$), more energy from total sugars (difference 6.6%; 95% CI 3.4 to 9.9; $P < 0.001$), less energy from total fat (difference 2.7%; 95% CI 0.3 to 5.6; $P = 0.08$), less energy from saturated fat (difference 1.1%; 95% CI 0.0 to 2.3; $P = 0.05$) and an extra two portions of fruit and vegetables per day (difference 2.2 portions; 95% CI 1.1 to 3.2; $P < 0.001$).

Rickheim 2002 measured self-reported physical activity and found no statistically significant difference within groups (intervention group, $P = 0.38$; control group, $P = 0.39$) or between the two groups ($P = 0.83$). Lozano 1999 measured the percentage of participants who carried out self-monitoring of blood glucose levels and found a significant difference between the two groups in favour of the group education programme at both one and two years ($P < 0.005$). Kronsbein 1988 measured the percentage of participants who were carrying out urinalysis at 12 months and reported a significant difference between participants allocated to the group programme and those in the control group (72% versus 2%; 95% CI 57% to 83%; $P < 0.0001$). Holtrop 2002 reported that the group programme participants made positive movement in stages of change for five behaviours: physical activity ($P = 0.003$); reduction of high fat foods ($P = 0.008$); consumption of five portions of fruit and vegetables ($P < 0.0001$); consumption of three meals daily ($P = 0.9$); limitation of refined sugar intake to one product per day or less ($P = 0.001$). However, the statistical analysis was preformed on pre-test means versus post-test means for the intervention group and no data were provided for the control group. Trento developed and validated a health behaviours questionnaire and reported that the score at was significantly greater for the group education participants than for the controls at one year (Trento 1998, $P < 0.005$), two years (Trento 2001, $P < 0.001$) and four years (Trento 2002, $P < 0.001$).

Treatment satisfaction

One study (Deakin 2003), using a validated questionnaire, measured change in treatment satisfaction and found that participants in both the group education programme and the control group were more satisfied with their treatment than they were at baseline. However, the group education participants were significantly more satisfied with treatment at four months (difference in score

4.4; 95% CI 2.6 to 6.1; $P < 0.001$) and 14 months (difference in score 3.7; 95% CI 1.5 to 6.0; $P = 0.002$).

Cost effectiveness

Brown 2002 reported that the cost of providing the intervention (52 contact hours over 12 months) was US \$ 384 per person assuming that costs of monitoring supplies were eligible for third-party reimbursement. However, a cost effectiveness analysis was not carried out. Trento 2002 calculated that over the study period group care required 196 minutes and US \$ 756.54 per patient, compared with 150 minutes and US \$ 665.77 for the control patients. That finding indicated that an additional US \$ 2.12 was spent per point gained in the quality of life score.

Complications

Only one study monitored the presence of diabetes complications and it reported no significant differences between the group education participants and controls in respect of diabetic retinopathy and foot ulcers at two years (Trento 2001) but found that at four years, diabetic retinopathy had progressed more slowly amongst participants that had attended the group education programme ($P < 0.009$).

Adverse effects

No adverse effects were reported for the group education participants or the controls.

Subgroup analyses

Ethnicity

Seven studies did not provide data about the ethnic background of the participants (Domenech 1995; Heller 1988; Kronsbein 1988; Lozano 1999; Pieber 1995b; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001). Although two studies (Domenech 1995; Rickheim 2002) stated the percentage of white Caucasian participants, no information was provided about the ethnic background of the other participants. Deakin 2003 reported that 80 out of 314 (25.5%) participants were from a South Asian background, the remaining 234 participants being white Caucasian. A subgroup analysis had been reported for the primary outcome, glycated haemoglobin at both four and 14 months, and showed significant differences between the intervention and control group in favour of the group-based education programme (four month difference 1.0%; 95% CI 0.3% to 1.7%; $P = 0.004$; 14 month difference 0.8%; 95% CI 0.1% to 1.5%; $P = 0.02$). All 226 participants recruited in the Brown 2002 study were Mexican Americans and significant differences in respect of glycated haemoglobin were shown at both six and 12 months in favour of the group-based education programme (six month difference: 1.4%; 95% CI 0.7 to 2.2; $P < 0.001$; 12 month difference: 0.8%; 95% CI 0.0 to 1.5; $P = 0.04$). A meta-analysis was performed for ethnic group other than white Caucasian using data from the Brown 2002 and Deakin 2003 studies and showed significant differences in respect of glycated haemoglobin at both four to six months (BN = 302 participants, $I^2 = 0\%$, difference 1.2%; 95% CI 0.7 to 1.7; $Z =$

4.55; $P < 0.00001$) and 12-14 months ($N = 299$ participants, $I^2 = 0\%$, difference 0.8%; 95% CI 0.3 to 1.3; $Z = 3.07$; $P = 0.002$) in favour of group-based education programmes.

Theoretical model

Only five studies identified the theoretical model underpinning the group education programme and those were based around therapeutic patient education, patient activation and empowerment (Deakin 2003; Domenech 1995; Kronsbein 1988; Pieber 1995b; Rickheim 2002). A subgroup analysis was performed with two studies that had been included in the meta-analysis for glycated haemoglobin at four to six months (Deakin 2003; Pieber 1995b) and a significant reduction in glycated haemoglobin was present in favour of the group education participants (Heterogeneity, $I^2 = 45.8\%$) (0.5%; 95% CI 0.2 to 0.8; $Z = 3.32$; $P = 0.0009$). A subgroup analysis could not be performed for glycated haemoglobin at 12-14 months because there was substantial heterogeneity ($I^2 = 61.9\%$) between the two studies (Domenech 1995; Deakin 2003). However, both studies had shown a significant improvement in favour of the group-based education programme in line to those in the main meta-analysis (Domenech 1995, difference 1.0%; 95% CI 0.8 to 1.2; $P < 0.00001$; Deakin 2003, difference 0.7%; 95% CI 0.4 to 1.0; $P < 0.0001$).

Duration of education programme

The least intensive group education programmes delivered by Trento 1998 and Lozano 1999, both of which incorporated only three to four hours of education during the first year had similar results in respect of glycated haemoglobin as those resulting from the most intensive programme that delivered 52 hours of education and support in the same time period.

Gender

All group-based education programmes included an relatively even mix of males and females (range 35% - 55% males) except for Holtrop 2002 that recruited females only. That study was not included in the main meta-analysis for glycated haemoglobin due to substantial heterogeneity. None of the publications had differentiated between males and females when presenting the results data and therefore a subgroup analysis for gender could not be performed.

Primary / secondary care

Three of the four studies included in the glycated haemoglobin meta-analysis at four to six months were delivered in primary care (Brown 2002; Deakin 2003; Pieber 1995b). One was delivered at a hospital diabetes unit (Heller 1988). When a subgroup analysis was performed on the primary care studies that had been included in the original meta-analysis (Brown 2002; Pieber 1995b), the significant reduction in glycated haemoglobin remained for group education participants (1.1%; 95% CI 0.6 to 1.6; $Z = 4.43$; $P < 0.00001$). When the studies based at a hospital diabetes unit (secondary care) were removed from the 12 - 14 month meta-analysis on glycated haemoglobin (Heller 1988; Trento 1998; Zapotoczky 2001) and a subgroup analysis was carried out on the

four studies delivered in primary care (Brown 2002; Deakin 2003; Domenech 1995; Lozano 1999), there was very low heterogeneity between studies ($I^2 = 8.8\%$) and the significant reduction in glycated haemoglobin remained (0.9%; 95% CI 0.8 to 1.0; $Z = 12.89$; $P < 0.00001$).

Number of participants in the group education programme

Two of the studies (Deakin 2003; Zapotoczky 2001) had larger groups comprising between 16 and 18 patients (and some carers) in each diabetes education programme. A subgroup analysis was performed to detect whether large groups reduced the effectiveness of the intervention and this was shown not to be the case. There was no heterogeneity between the two studies ($I^2 = 0\%$) and glycated haemoglobin at 12-14 months remained significantly reduced in respect of the group education participants (0.7%; 95% CI 0.4 to 1.0; $Z = 4.54$; $P < 0.00001$).

Educator

Three of the group-based education programmes were delivered by physicians trained in adult education principles (Domenech 1995; Pieber 1995b; Trento 1998; Trento 2001; Trento 2002). Two studies including 175 participants evaluated glycated haemoglobin at 12 months (Domenech 1995; Trento 1998). A sub-group analysis excluding those studies resulted in there being no heterogeneity ($I^2 = 0\%$) between the remaining five studies including 869 participants: delivered by a nurse (Lozano 1999); a dietitian (Deakin 2003; Zapotoczky 2001); a combination of the two (Brown 2002; Heller 1988). The effect size for nurses and/or dietitians delivering the group education programme was shown to same as that of the full meta-analysis; 0.8% reduction (95% CI 0.5 to 1.0; $Z = 7.04$; $P < 0.00001$) compared to 0.8% reduction (95% CI 0.7 to 1.0; $Z = 9.63$; $P < 0.00001$). The study that had not been included in the 12-14 month meta-analysis for glycated haemoglobin because of substantial heterogeneity (Kronsbein 1988) was the publication in which physician assistants had delivered the programme (Kronsbein 1988).

Sensitivity analysis

Sensitivity analyses have been performed as required to detect and explain the source of heterogeneity between studies. All studies were published papers with the exception of one (Deakin 2003) which was, at the time of the review, published as three conference abstracts and submitted as a full paper for publication. The study by Deakin 2003 was excluded from the meta-analysis at four to six months due to substantial heterogeneity possibly due to outcomes being collected at four months instead of six months and the smaller reported effect size. However, at 12-14 months the Deakin 2003 was included in the meta-analysis and the effect size and percentage of heterogeneity remained was similar when the study was excluded, 0.9% reduction ($I^2 = 17.9\%$; 95% CI 0.8 to 1.0; $Z = 12.24$; $P < 0.00001$) compared with the 0.8% reduction ($I^2 = 18\%$; 95% CI 0.7 to 1.0; $Z = 9.63$; $P < 0.00001$) calculated in the main meta-analysis.

None of the studies were graded 'A' for quality and only two studies graded 'B' (Deakin 2003; Zapotoczky 2001) (see quality assessment of trials in the methods section). When the meta-analysis was repeated including only those studies assessed as being better quality (Deakin 2003; Zapotoczky 2001) the effect size (reduction in glycosylated haemoglobin for the group education participants) at 12-14 months remained similar to the calculated effect size in the main meta-analysis, 0.7% reduction ($I^2 = 0\%$; 95% CI 0.4 to 1.0; $Z = 4.54$; $P < 0.00001$) compared with the 0.8% reduction ($I^2 = 18\%$; 95% CI 0.7 to 1.0; $Z = 9.63$; $P < 0.00001$) seen in the main meta-analysis. None of the studies included were large multi-centre trials and therefore a sensitivity analysis was not carried out in respect of trial size. One of the studies was written in Spanish and was translated before being included in the review (Lozano 1999). Removal of that study from the 12-14 month meta-analysis for glycosylated haemoglobin resulted in a similar effect size (0.9% reduction; 95% CI 0.7 to 1.0; $Z = 12.02$; $P < 0.00001$) compared to the 0.8% reduction (95% CI 0.7 to 1.0; $Z = 9.63$; $P < 0.00001$) calculated in the main meta-analysis. Removal of all studies having less than 100 participants from the 12-14 month meta-analysis on glycosylated haemoglobin left three studies to be re-analysed with no heterogeneity ($I^2 = 0\%$) (Brown 2002; Deakin 2003; Lozano 1999). The effect size for reduction in glycosylated haemoglobin in the group education participants remained constant, 0.8% reduction (95% CI 0.5 to 1.0; $Z = 6.77$; $P < 0.00001$) compared to the 0.8% reduction (95% CI 0.7 to 1.0; $Z = 9.63$; $P < 0.00001$) calculated in the main meta-analysis.

DISCUSSION

Summary

This review systematically reviewed 11 studies of group-based, patient-centred educational programmes for people with type 2 diabetes and found that these programmes resulted in clinically and statistically significant health outcomes. Three studies (Brown 2002; Heller 1988; Pieber 1995b) were included in a meta-analysis for glycosylated haemoglobin at four to six months and showed that patients attending group education programmes had reduced glycosylated haemoglobin of 1.4% (95% CI 0.8 to 1.9; $P < 0.00001$). Three studies could not be included in the meta-analysis due to substantial heterogeneity: Deakin 2003 reported a smaller effect size at four months than the other studies reported at six months and that may be due to the fact that glycosylated haemoglobin is a measure of diabetes control over a period of approximately three months, therefore, the four month assessment may have been too close to baseline for improvements in diabetes control to be apparent; Holtrop 2002 had not included standard deviations but still reported a reduced glycosylated haemoglobin in favour of group-based education; Rickheim 2002 showed statistically significant differences between the intervention and control group at baseline that negatively impacted on the six-month post-intervention comparisons. However change data (from baseline to six months) re-

vealed statistically significant differences in glycosylated haemoglobin in favour of the group-based education programme. At 12-14 months seven studies involving 1044 participants were included in the meta-analysis and showed a reduced glycosylated haemoglobin in favour of group-based education (difference 0.8%; 95% CI 0.7 to 1.0; $P < 0.00001$). The study not included in the meta-analysis at 12-14 months (Kronsbein 1988) due to substantial heterogeneity had a significant difference for glycosylated haemoglobin at baseline (0.6%, $P = 0.05$) in favour of the control group and a very small effect size of 0.2% at 12 months in favour of the group programme. However, that study had been published in 1988 before the benefits of optimal glycaemic control had been established. The mean baseline glycosylated haemoglobin level in that study was good (7.1%) and participants were encouraged to reduce diabetes medication rather than to improve their diabetes control. Two of the studies assessed outcomes at two years and the results indicated that the improved metabolic control was still apparent (1.0%; 95% CI 0.5 to 1.4; $P < 0.00001$). One study showed continued benefit at four years (1.6%; 95% CI 0.9 to 2.3; $P < 0.00001$). There was also a significant reduction in fasting blood glucose levels amongst group programme participants at four to six months (1.7 mmol/L; 95% CI 0.7 to 2.6; $P = 0.00004$), 12-14 months (1.2 mmol/L; 95% CI 0.7 to 1.6; $P < 0.00001$) and four years (1.7 mmol/L; 95% CI 0.2 to 3.2; $P = 0.03$). At two years (Lozano 1999) involving 243 participants showed a significant improvement of fasting blood glucose in favour of the group education programme (difference 1.8 mmol/L; 95% CI 1.2 to 2.4; $Z = 5.99$; $P < 0.00001$) but the other study (Trento 1998) involving 80 participants did not (difference 0.7 mmol/L; 95% CI -0.4 to 1.9; $Z = 1.18$; $P = 0.24$). Five studies showed that by attending a group education programme, patients were able to significantly reduce their diabetes medication by 12-14 months (odds ratio 11.79; 95% CI 5.17 to 26.90; $P < 0.00001$).

There was no indication that group-based diabetes education programmes impacted on body weight or body mass index at four to six months. However at 12-14 months there was some evidence that the group education programme reduced body weight (1.6 kg; 95% CI 0.3 to 3.0; $P = 0.02$). There was either insufficient weight loss to affect body mass index or, alternatively, no effect may have been seen in BMI because not enough studies reported BMI and only two studies were included in the meta-analysis whereas five studies were included for the body weight meta-analysis. One study (Deakin 2003) presented data to suggest that the programme could reduce waist circumference (2.8 cm; 95% CI -0.3 to 5.6; $P = 0.06$). Diabetes knowledge was significantly improved at four to six months in three out of four studies in the group education participants but a meta-analysis was carried out due to substantial heterogeneity. At 12-14 months, a meta-analysis was carried out with three studies and shown significant improvements for diabetes knowledge in the group education participants (SMD 0.95; 95% CI 0.7 to 1.2; $Z = 8.18$; $P < 0.00001$). The remaining three studies that could not be included in the meta-analysis due to

substantial heterogeneity also reported significant improvements in diabetes knowledge in the group education participants. Statistically significant improvements in diabetes knowledge was also reported in favour of group-based diabetes education in two studies at two years and in one study at four years. At four to six months patients allocated to the group education programme experienced a significant reduction in systolic blood pressure (5 mmHg; 95% CI 1 to 10; $P = 0.01$) and a trend towards reduced diastolic blood pressure (3 mmHg; 95% CI 0 to 6; $P = 0.08$). However, there were no clinical or statistically significant reductions in systolic or diastolic blood pressure at 12-14 months.

There was no evidence at any of the time periods that group-based diabetes education programmes positively impact on total cholesterol levels. There was a trend towards reduced triglyceride levels at four to six months (0.24 mmol/L; 95%CI -0.04 to 0.52; $P = 0.09$) but not at 12-14 months.

There was strong evidence from one study (Deakin 2003), that measured patient self-empowerment, that attending a patient-centred, group-based diabetes education programme significantly improved empowerment and psychosocial self-efficacy at both four months ($P < 0.001$) and 14 months ($P < 0.001$). Only two studies measured quality of life and there was no evidence that the group education participants experienced overall improved quality of life at four to six months or 12-14 months, although they did experience a significantly better quality of life for the food and drink variables (Deakin 2003). One study reported significantly improved quality of life at both two years (Trento 2001, $P < 0.001$) and four years (Trento 2002, $P < 0.009$). There was evidence that the group education programme improved self-management skills as a result of self-monitoring of blood glucose levels (Deakin 2003; Lozano 1999) and urinalysis (Kronsbein 1988), consumption of a healthier diet (Deakin 2003; Holtrop 2002), foot care (Deakin 2003) and improved health behaviours (Trento 1998; Trento 2001; Trento 2002). There was conflicting evidence in respect of physical activity. Deakin 2003 reported a positive effect at both four months ($P < 0.001$) and 14 months ($P = 0.02$); Rickheim 2002 reported no effect ($P = 0.83$). Treatment satisfaction was only measured in one study (Deakin 2003) but that study indicated improved satisfaction amongst group participants ($P < 0.001$). Although Brown 2002 estimated the cost per patient of attending the programme, there was only one study that reported a cost effectiveness analysis. In that study US \$2.12 per patient for every point gained on the quality of life score (Trento 2002). There was no evidence that group-based diabetes education programmes reduced the incidence of acute complications (hypoglycaemia / hyperglycaemia) but there was a small amount of evidence for a reduction in chronic complications: Trento 2002 reported a reduced progression to diabetic retinopathy at four years.

The studies were carried out in various developed countries within Europe and in the United States, but there were no studies from developing countries. Although ethnicity was reported in some of

the studies, there wasn't enough information to perform a subgroup analysis for ethnicity. However, there is evidence that delivery of the programme to ethnic minority groups in a language that they are familiar with still delivers the benefits for glycated haemoglobin (Brown 2002; Deakin 2003). Although the theoretical model underpinning the programme was not always visible, there is evidence that if the programme is based on therapeutic patient education with participatory/empowering and adult-centred principles, it is likely to be effective. However, only one study measured patient empowerment and further research would be necessary to confirm those findings. Only three studies measured blood pressure and that may reflect on the year that studies were undertaken, as the benefits of optimal blood pressure for people with type 2 diabetes have only been evident since the publication of the United Kingdom Diabetes Prospective Study (UKPDS-33 1998). Two studies followed up beyond 12-14 months (Lozano 1999; Trento 2001; Trento 2002) and continued to obtain significant clinical and statistical results. Trento repeated the education programme in year two and then delivered seven sessions in years three and four. Lozano provided further education in year two. Subgroup analysis provided evidence that group-based diabetes education programmes were equally effective when delivered in primary and secondary care by any health professional who was trained to deliver the programme. There was less evidence for the delivery of the programme by trained lay health workers or physician assistants due to the general scarcity of studies in this area. There is no evidence to suggest that group education programmes are less effective when delivered to larger groups of 16 to 18 participants. It was not possible to detect if programmes were more successful if a family member or friend was also invited to participate, as four studies did not indicate whether patients were accompanied or not. Ten studies compared the group programme with a waiting list control and/or routine treatment. One study (Rickheim 2002) delivered the group education programme to the control group, except that delivery was via individual appointments rather than a group environment. It resulted in the control group having five hours of one-to-one education. However, an improvement in glycaemic control of those allocated to the group education programme was apparent when compared to those receiving the intensive individual education ($P = 0.05$). Therefore an intensive individual approach, which is probably unrealistic given the prevalence of diabetes and the projected epidemic (Sicree 2003), was shown to be less efficacious than a group education programme.

Limitations of the review

The quality of studies included in the review were assessed as either moderate or poor quality based on the criteria Schulz 1995 and Jadad 1996. The randomisation procedure was generally adequate, as were the descriptions of drop-outs. There was a lower percentage of drop-out compared to the findings from other reviews of diabetes education (Griffin 1998; Norris 2001). The three factors that impacted on quality were (1) that only one study stated

that there was allocation concealment, (2) only two studies analysed the data by intention to treat and (3) it was unclear whether outcome assessors were blind to the intervention. However, unlike a drug/placebo trial, it is very difficult to provide allocation concealment and blind the outcome assessors for a group-based educational intervention and several of the studies were delivered before analysis by intention-to-treat was recommended.

The review included only 13 papers, which reported 11 studies and involved 1532 patients. Because of variety in programme content, outcomes and length of follow-up, when it was possible to perform a meta-analysis, the number of studies included in each analysis was small. It was not possible to carry out a meta-analysis on several for several of the main outcomes of the review (such as self-management skills, empowerment/self-efficacy and quality of life) due to significant heterogeneity between studies. Educational interventions are complex interventions and it is difficult to identify the active ingredient(s) with any precision. Therefore, although the review has shown that group-based diabetes education programmes result in clinical, and statistically significant health outcomes, the exact mechanism of action can be discussed but not identified.

Generalisability and applicability of results

As with all clinical trials, it is possible that participants in the studies may not be truly representative of the local adult population with type 2 diabetes, as people who volunteer to take part in clinical trials tend to be a more committed and motivated subgroup and generally receive more attention when participating in a clinical trial. Although having motivated participants will not effect differences between the two groups as both the intervention and control group are part of the motivated subgroup, it may effect the generalisability of the results if group education programmes are provided as routine treatment. Delivering group-based diabetes education programmes to the general adult population with type 2 diabetes may result in a bigger drop out rate and smaller effect sizes. The 11 studies were carried out in different developed countries throughout Europe and the United States. Although not clearly stated, it is presumed that the majority of participants were mainly white Caucasians with others being of South Asian and Mexican American decent. There will therefore, there will have been lingual and cultural diversity as well as differences in the respective healthcare systems. The results of this review are therefore generalisable to adults with type 2 diabetes in many different developed countries and there is no evidence to suggest that group-based self-management strategies would not be suitable for developing countries as long as the group-based diabetes education programme was delivered in a familiar language and was sensitive to the culture of the population.

Routine diabetes education is still dominated by the traditional model in which doctors, nurses, dietitians and other members of the health care team interact with patients on a one-to-one basis. That style of treatment leads to active prescription of diet,

medication and advice on healthy practices but may not stimulate effective patient motivation and behaviour change (Trento 2002). However, the scarcity of time and resources have led to more diabetes teams in primary and secondary care contemplating and commencing group-based diabetes education programmes. Many national (DOH 2001b; DOH 2003; Mensing 2003; NICE 2003) and international (DECS 2003) standards now recommend group education programmes. However, this is the first systematic review to evaluate their efficacy. If the results from this review can be translated to routine care, the 1% reduction in glycated haemoglobin may reduce the relative risk of developing secondary complications of diabetes by 21% (UKPDS-35 2000).

AUTHORS' CONCLUSIONS

Implications for practice

The 11 studies included in this systematic review provide evidence that group-based diabetes education programmes for adults with type 2 diabetes result in clinically important improvements in health outcomes for glycated haemoglobin, fasting blood glucose levels and diabetes knowledge at four to six months' and 12 months' follow-ups. If additional group education sessions are provided on an annual basis, benefits in glycated haemoglobin, fasting blood glucose and diabetes knowledge may be longer-term (two to four years). Adults with type 2 diabetes attending a group education programme may also benefit from reduced blood pressure and triglyceride level at four to six months but those effects are likely to be much more short-term than, for example small reductions in body weight which were apparent at 12-14 months. There is some evidence that group education programmes can, both at four to six months and 12-14 months, reduce the requirement for diabetes medication, improve diabetes and healthy living self-management skills, increase patient self-empowerment and improve food related aspects of quality of life. At longer-term follow-up (two to four years), group education programmes may still result in improved quality of life and reduce the progression to diabetic retinopathy.

There is no evidence to suggest that programmes delivered in either primary or secondary care are more efficacious. There is also no evidence to suggest that the programme is more effective if delivered by a physician, dietitian or nurse as long as the health professional is trained to deliver a diabetes education programme. However, there is less evidence in this review to support delivery of group education programmes by trained lay health workers or physician assistants, mainly due to lack of studies. Programmes based on therapeutic patient education using the principles of empowerment, participation and adult learning have proved to be efficacious. Delivery of the group-based diabetes education programme to groups of 4-6 participants or 16-18 participants does not appear to alter the effectiveness of the education, nor does the

duration of the programme impact on effectiveness. It has however been observed that providing additional education sessions on an annual basis results in long-lasting benefits to health and psychosocial outcomes. For a more thorough analysis of educational concepts and methods for evaluation a qualitative analysis may be necessary.

Implications for research

As the review is based on only 11 studies and many outcomes resulted from the synthesis of just two or three studies, further studies are required to confirm:

- 1) The theoretical model underpinning the programme. Are group education programmes more efficacious if based on therapeutic patient education incorporating empowerment, participation and adult learning principles?
- 2) The efficacy of group education programmes on blood pressure readings. Findings concluding the benefits of optimum blood pressure are relatively new due to the relatively recent findings regarding the benefits of optimum blood pressure.
- 3) The degree of treatment satisfaction as the patients voice has become much more important in the delivery of healthcare interventions, more information is required as to whether patients find group education programmes acceptable.
- 4) The effect of group education programmes on quality of life.
- 5) The efficacy of the programme for ethnic minority groups. Further research is required before it can be confirmed that diabetes group education is appropriate for all people from all ethnic backgrounds.
- 6) The reduced risk of developing the secondary complications of diabetes.
- 7) The cost effectiveness of delivering group-based self-management strategies for people with type 2 diabetes.
- 8) The effectiveness of peer educators in delivering group based diabetes education programmes

NOTES

The wording of the objectives has changed from the published protocol because the original ones did not differentiate between

short and longer-term outcomes and did not include important outcomes such as blood pressure. Classifying objectives as clinical, lifestyle and psychosocial was thought to be clearer to the reader.

Types of interventions has been amended from the published protocol as it was necessary to identify the minimum number of patients and minimum length of time that would be classed as a group education programme.

The section on assessing the quality of case, cohort and qualitative studies has been removed from the 'Quality Assessment of Trials' as these studies were not included in the review.

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POTENTIAL CONFLICT OF INTEREST

None known.

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*Indicates the major publication for the study

T A B L E S**Characteristics of included studies**

Study	Brown 2002
Methods	Trial design: Randomised controlled trial Ethics approval obtained: Yes Patient consent obtained: Yes Randomisation method: Unclear Length of follow-up: 1 year Blinding of patient (P), educator (E), researcher (R): P = no, E = unclear, R = unclear Analysis by intention to treat: No Power calculation: Not stated
Participants	Setting: Community Country: US Number: IG = 128, CG = 128 Age+/-SD: IG = 54.7+/- 8.2, CG = 53.3+/-8.3 Sex: IG = 40% M, CG = 32% Ethnicity: Mexican Americans Duration of diabetes: IG = 7.6+/-5.8, CG = 8.1+/-6.9 Socioeconomic status: Starr county is the poorest county in Texas with high unemployment at 24.4% Education background: Not stated but language of preference = spanish with 40% reading little or no English Drop out (%): Overall 10% Inclusion criteria: Between 35-70 years/diagnosed with Type 2 diabetes after 35 years/FBG>140mg/dl or taken insulin or oral hypoglycaemic agents for >1 year/willing to participate Exclusion criteria: Pregnancy/medical condition where changes to diet or exercise levels would be contraindicated
Interventions	Intervention: Group education programme delivered by nurse, dietitian & community worker. Duration: 52 hours over 12 months (12 weekly meetings + 14 biweekly sessions) Number of participants in group programme: Unclear Including family/friends: Yes Control: Waiting list
Outcomes	Collected at 6 and 12 months. 1. HbA1c (%) 2. Fasting blood glucose (mg/dl) 3. Lipids mg/dl)

Characteristics of included studies (Continued)

	<ul style="list-style-type: none"> 4. BMI (Kg/m²) 5. Health beliefs 6. diabetes knowledge (score)
Notes	<ul style="list-style-type: none"> 1. Intervention group = IG, Control group = CG 2. Figure 1 = recruitment and retention data unclear 3. All participants received standard education before randomised
Allocation concealment	B

Study	Deakin 2003
Methods	Trial design: Randomised controlled trial Ethics approval obtained: Yes Patient consent obtained: Yes Randomisation method: random permuted blocks Length of follow-up: 12 months post-intervention Blinding of patient (P), educator (E), researcher (R): P = yes, E = no, R = no Analysis by intention to treat: Yes Power calculation: yes
Participants	Setting: Primary care Country: UK Number: IG = 157, CG = 157 Age+/-SD: IG = 61.3+/-9.7, CG = 61.8+/-11.0 Sex: IG = 48.4% M, CG = 54.8% M Ethnicity: IG = 116 white Caucasian/41 South Asian, CG = 118 white Caucasian/39 South Asian Duration of diabetes:IG = 6.6+/-6.4yr, CG = 6.7yr+/-6.7yr Socioeconomic status: Not stated Education background: Not stated Drop out (%): IG = 4.5%, CG = 10.2% Inclusion criteria: Adults with Type 2 diabetes Exclusion criteria: unable to attend programme or participate due to physical or mental reason.
Interventions	Intervention: Group education programme delivered by diabetes educator lasting for 6 consecutive weeks, each session 2 hours (total time = 12 hours) Number of patients in group programme: 16 Including family/friends: Yes Control: Routine treatment (individual appointments with dietitian and primary care team).
Outcomes	4 and 14 months <ul style="list-style-type: none"> 1. HbA1c (%) 2. Blood pressure (mmHg) 3. Weight (kg) 4. BMI (kg/m²) 5. Waist circumference (inch) 6. Lipid profile 7. Knowledge (score) 8. Self-management skills 9. Food frequency questionnaire 10. Treatment satisfaction 11. Quality of life 12. Empowerment score
Notes	1. Intervention group = IG, Control group = CG
Allocation concealment	A

Characteristics of included studies (Continued)

Study	Domenech 1994
Methods	Conference proceeding written in Spanish. English language paper Domenech 1995 (below)
Participants	
Interventions	
Outcomes	
Notes	
Allocation concealment	D

Study	Domenech 1995
Methods	<p>Trial design: Clinical controlled trial</p> <p>Ethics approval obtained: Yes</p> <p>Patient consent obtained: Yes</p> <p>Randomisation method: Not randomised - physicians trained to deliver education programme versus physicians who don't provide education programme</p> <p>Length of follow-up: One year</p> <p>Blinding of patient (P), educator (E), researcher (R): P = unclear, E = No, R = unclear</p> <p>Analysis by intention to treat: No</p> <p>Power calculation: not stated</p>
Participants	<p>Setting: Primary care</p> <p>Country: Argentina</p> <p>Number: IG = 40, CG = 39</p> <p>Age+/-SD: IG = 52.7+/- 3.1, CG = 53.1+/-1.1</p> <p>Sex: IG = 55% M, CG = 56% M</p> <p>Ethnicity: Not stated</p> <p>Duration of diabetes: IG = 6.3+/- 1.3, CG = 6.9+/-0.7</p> <p>Socioeconomic status: Reported to be the same in both groups but no data given</p> <p>Education background: Not stated</p> <p>Drop out (%): IG = 25%, CG = 45%</p> <p>Inclusion criteria: Not defined</p> <p>Exclusion criteria: newly diagnosed/age above 60 years/presence of advanced complications or other severe disease</p>
Interventions	<p>Intervention: Group based structured teaching/treatment programme provided by previously trained physicians.</p> <p>Educator: Physician Duration = 4 weekly sessions lasting 90-120 min (total 6-8 hrs)</p> <p>Number of participants in group programme: 5 - 8</p> <p>Including family/friends: yes</p> <p>Control: Routine treatment</p>
Outcomes	<p>12 months</p> <ol style="list-style-type: none"> HbA1c (%) Knowledge score (intervention group only) weight (Kg) Change in diabetes medication (no/day)
Notes	<ol style="list-style-type: none"> Intervention group = IG, Control group = CG BMI reported with baseline characteristics but just weight at follow-up Knowledge score only assessed in intervention group Oral hypoglycaemic agents - number of people taking them reported at baseline but daily average reported at follow-up
Allocation concealment	D

Characteristics of included studies (Continued)

Study	Heller 1988
Methods	<p>Trial design: Randomised controlled trial</p> <p>Ethics approval obtained: Unclear</p> <p>Patient consent obtained: Unclear</p> <p>Randomisation method: Unclear</p> <p>Length of follow-up: 1 year</p> <p>Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear</p> <p>Analysis by intention to treat: No</p> <p>Power calculation: not stated</p>
Participants	<p>Setting: Hospital diabetes clinic</p> <p>Country: UK</p> <p>Number: IG = 36, CG = 39</p> <p>Age+/-SD: IG = 56.5, CG = 56.4</p> <p>Sex: IG = 55% M, CG = 41% M</p> <p>Ethnicity: Not stated</p> <p>Duration of diabetes: New diagnosed</p> <p>Socioeconomic status: Not stated</p> <p>Education background: Not stated</p> <p>Drop out (%): IG = 10, CG = 17%</p> <p>Inclusion criteria: New diagnosed diabetes/BMI>27/age 30-75 yrs</p> <p>Exclusion criteria: Anyone with ketonuria/diagnosis made when inpatient</p>
Interventions	<p>Intervention: Group education programme, 4.5 hr for 3 consecutive weeks, 1.5 hr at both 3 & 6 months (total = 7.5 hr)</p> <p>Educator: Diabetes specialist nurse and dietitian</p> <p>Number of participants in group programme: 4-6 patients plus spouse or friend</p> <p>Including family/friends: Yes</p> <p>Control: Routine treatment - individual appointments with physician and dietitian at least at 3,6 & 12 months</p>
Outcomes	<p>6 and 12 months</p> <ol style="list-style-type: none"> 1. HbA1c (%) 2. Blood glucose (mmol/l) 3. Weight loss (Kg) 4. Diabetes knowledge
Notes	<ol style="list-style-type: none"> 1. Intervention group = IG, Control group = CG 2. Fasting blood glucose and diabetes knowledge compared at 12 months but no baseline data
Allocation concealment	B

Study	Holtrop 2002
Methods	<p>Trial design: Randomised controlled trial</p> <p>Ethics approval obtained: Unclear</p> <p>Patient consent obtained: Yes</p> <p>Randomisation method: Unclear</p> <p>Length of follow-up: 6 months</p> <p>Blinding of patient (P), educator (E), researcher (R): P = No, E = unclear, R = unclear</p> <p>Analysis by intention to treat: Yes</p> <p>Power calculation: unclear</p>
Participants	<p>Setting: Primary care</p> <p>Country: US</p> <p>Number: IG = 67, CG = 65</p> <p>Age+/-SD: IG = 58, CG = 65</p> <p>Sex: IG = 0% M, CG = 0% M</p>

Characteristics of included studies (Continued)

	<p>Ethnicity: IG = 95% Caucasian, CG = 95% Caucasian Duration of diabetes: Not stated Socioeconomic status: Not stated Education background: 86% achieved high school education Drop out (%): Unclear Inclusion criteria: >40 years/female/Type 2 diabetes/HbA1c>7% in past 6 months/BMI>27.3 Exclusion criteria: Not defined</p>
Interventions	<p>Intervention: Group programme delivered by trained lay health advisors for six weekly 1 1/2 hour sessions (total time = 9 hours) Number of participants in group programme: Not stated Including family/friends: Unclear Control: Routine treatment as required with family physician</p>
Outcomes	<p>6 months 1. HbA1c (%) 2. BMI 3. Dietary habits 4. Beliefs 5. Stages of change</p>
Notes	<p>1. Intervention group = IG, Control group = CG P-values given without data and several SD missing</p>
Allocation concealment	B

Study **Kronsbein 1988**

Methods	<p>Trial design: Controlled clinical trial Ethics approval obtained: yes Patient consent obtained: Unclear Randomisation method: No randomisation Length of follow-up: 1 year Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear Analysis by intention to treat: No Power calculation: yes</p>
Participants	<p>Setting: Primary care Country: Germany Number: IG = 50, CG = 49 Age+/-SD: IG = 65+/-9, CG = 63+/-8 Sex: IG = 42% M, CG = 39% M Ethnicity: Not stated Duration of diabetes: IG = 7+/-5, CG = 7+/-6 Socioeconomic status: Not stated Education background: Not stated Drop out (%): IG = 23%, CG = 21% Inclusion criteria: Fulfilling the WHO criteria for NIDDM (Type 2 diabetes) Exclusion criteria: Physical/mental handicaps that prevented participants from following education programme</p>
Interventions	<p>Intervention: Group structured treatment and teaching programme (DTTP) for 1 1/2 - 2 hours per week for 4 weeks (total time = 6-8 hours) Educator: Paramedical staff (physician assistants) Number of participants in group programme: 4-6 Including family/friends: Unclear Control: Routine treatment whilst on waiting list</p>
Outcomes	12 months

Characteristics of included studies (Continued)

1. HbA1c (%)
2. Weight (Kg)
3. Knowledge (score)
4. Lipids (mmol/l)
5. Glucosuria
6. No oral hypoglycaemic agents (%)

Notes 1. Intervention group = IG, Control group = CG

Allocation concealment D

Study **Lozano 1999**

Methods Trial design: Randomised controlled trial
 Ethics approval obtained: Not stated
 Patient consent obtained: Not stated
 Randomisation method: Not stated. Classified by age & sex before randomisation
 Length of follow-up: 2 yrs
 Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear
 Analysis by intention to treat: No
 Power calculation: yes

Participants Setting: Primary care
 Country: Spain
 Number: IG = 120, CG = 123
 Age+/-SD: IG = 63.8, CG = 64.7
 Sex: IG = 48% M, CG = 48% M
 Ethnicity: Not stated
 Duration of diabetes: IG = 8.1, CG = 9.1
 Socioeconomic status: Low-medium socioeconomic status
 Education background: Not stated
 Drop out (%): IG = 4%, CG = 3%
 Inclusion criteria: Not defined
 Exclusion criteria: Attended group education during the last two years/limitations which prevent attending sessions and self-management

Interventions Intervention: Health educational workshop lasting 1hr 30 min on two consecutive days and repeated in year two
 Educator: Nurses
 Number of participants in group programme: Unclear
 Including family/friends: Unclear
 Control: Routine treatment

Outcomes 1 and 2 years
 1. HbA1c (%)
 2. Blood glucose (mg/dl)
 3. BMI (Kg/m²)
 4. Knowledge
 5. Self-monitoring

Notes 1. Intervention group = IG, Control group = CG.

Allocation concealment B

Study **Pieber 1995**

Methods Trial design: Controlled clinical trial
 Ethics approval obtained: Not stated

Characteristics of included studies (Continued)

	<p>Patient consent obtained: Not stated Randomisation method: not randomised - physicians trained to deliver the programme versus physician not delivering an education programme Length of follow-up: 6 months Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear Analysis by intention to treat: No Power calculation: not stated</p>
Participants	<p>Setting: Primary care Country: Austria Number: IG = 45, CG = 49 Age+/-SD: IG = 63.9+/-8.2, CG = 65.4+/-11.2 Sex: IG = 42% M, CG = 47% M Ethnicity: Not stated Duration of diabetes: IG = 7.6+/-5.6, CG = 6.9+/-6.1 Socioeconomic status: Not stated Education background: Not stated Drop out (%): IG = 13.5%, CG = 10.9% Inclusion criteria: Non-insulin-treated Type 2 diabetes/absence of physical or mental conditions preventing patients participating in programme Exclusion criteria: Not defined</p>
Interventions	<p>Intervention: Diabetes Treatment and teaching Programme (DTTP) consisting of 4 weekly sessions (total 6-8 hr) Educator: Physician and office staff Number of participants in group programme: 4-8 Including family/friends: No Control: Routine treatment with waiting list</p>
Outcomes	<p>6 months 1. HbA1c (%) 2. Diabetes Knowledge (score) 3. BMI (Kg/m²) 4. Weight (kg) 5. Lipid profile (mmol/l) 6. Diabetes medication (no/day) 7. Blood pressure (mmHg)</p>
Notes	<p>1. Intervention group = IG, Control group = CG 2. No between group statistics for changes to diabetes medication</p>
Allocation concealment	D

Study **Rickheim 2002**

Methods	<p>Trial design: Randomised controlled trial Ethics approval obtained: Yes Patient consent obtained: Yes Randomisation method: Block randomisation Length of follow-up: 6 months Blinding of patient (P), educator (E), researcher (R): P = no, E = no, R = unclear Analysis by intention to treat: Yes Power calculation: not stated</p>
Participants	<p>Setting: Diabetes centre Country: US Number: IG = 87, CG = 83 Age+/-SD: IG = 51.6+/-9.2, CG = 52.9+/-12.8</p>

Characteristics of included studies (Continued)

	<p>Sex: IG = 35.6% M, CG = 32.5% M Ethnicity: IG = 89.5% Caucasian, CG = 96.4% Caucasian Duration of diabetes: IG = 1.1+/-4.0, CG = 0.6+/-1.7 Socioeconomic status: Not stated Education background: % high school or lower IG = 25.3%, CG = 24.1% Drop out (%): IG = 51%, CG = 41% Inclusion criteria: Newly diagnosed with Type 2 diabetes or no history of previous group diabetes education/referred to education centre Exclusion criteria: Not defined</p>
Interventions	<p>Intervention: group diabetes education programme consisting of 4 sessions (total 7 hours) Educator: Nurse and dietitian Number of participants in group programme: 4-8 Including family/friends: Unclear Control: Routine self-management education 5hours over 4 sessions (Individual appointments)</p>
Outcomes	<p>6 months 1. HbA1c (%) 2. Weight (Kg) 3. BMI (Kg/M2) 4. Diabetes Knowledge (score) 5. Adjustment to diabetes (ATT19) 6. Quality of life 7. Activity levels (freq/duration) 8. Diabetes medication (% of participants taking)</p>
Notes	<p>1. Intervention group = IG, Control group = CG 2. Large drop out rate - even with intention to treat</p>
Allocation concealment	B

Study

Trento 1998

Methods	<p>Trial design: Randomised controlled trial Ethics approval obtained: Conformed with principles stated in the Declaration of Helsinki Patient consent obtained: Yes Randomisation method: Random table numbers Length of follow-up: 1 year Blinding of patient (P), educator (E), researcher (R): P = unclear, E = blinded to which participants in control group, R = unclear Analysis by intention to treat: No Power calculation: not stated</p>
Participants	<p>Setting: Diabetes outpatient department Country: Italy Number: IG = 55, CG = 57 Age+/-SD: IG = 61.6, CG = 61.0 Sex: IG = 47% M, CG = 61% M Ethnicity: Not stated Duration of diabetes: IG = 9.1 year, CG = 9.2 year Socioeconomic status: IG/CG Housewife - 15%/8% Retired - 21%/28% White collar worker - 4%/5% Blue collar worker - 9%/8% Other - 4%/7% Education background: Despite randomisation the CG were more literate and had attended more years of schooling</p>

Characteristics of included studies (Continued)

	Drop out (%): 8 declined to participate (IG=5/CG=3) and 16% (IG) & 12% (CG) dropped out during first year Inclusion criteria: Less than 80 yrs/treated with diet or oral hypoglycaemic agents/followed in clinic >1 year Exclusion criteria: Not defined
Interventions	Intervention: Structured group education programme every 3 months for 1 year (4 x 60/70 mins) Educator: Two physicians and educationist Number of participants in group programme: 10 Including family/friends: Yes but optional Control: Routine treatment
Outcomes	1 year 1. HbA1c (%) 2. FBG (mmol/l) 3. Weight (Kg) 4. BMI (Kg/m ²) 5. Knowledge (score) 6. Conduct (score) 7. Quality of life (score) 8. Treatment
Notes	1. Intervention group = IG, Control group = CG
Allocation concealment	B

Study **Trento 2001**

Methods	Trial design: Randomised controlled trial Ethics approval obtained: Conformed with the principles stated in the Declaration of Helsinki Patient consent obtained: Yes Randomisation method: Random table numbers Length of follow-up: 2 years Blinding of patient (P), educator (E), researcher (R): P = unclear, E = blinded to who in control group, R = unclear Analysis by intention to treat: No Power calculation: not stated
Participants	Setting: Diabetes outpatient department Country: Italy Number: IG = 56, CG = 56 Age+/-SD: IG = 62, CG = 61 Sex: IG = 48% M, CG = 61% M Ethnicity: Not stated Duration of diabetes: IG = 9.4, CG = 9.8 Socioeconomic status: IG/CG Housewife - 14%/10% Retired - 24%/27% White collar worker - 4%/2% Blue collar worker - 7%/8% Other - 7%/9% Education background: Despite randomisation the CG were more educated Drop out (%): IG = 23%, CG = 16% Inclusion criteria: Type 2 diabetes treated with diet or oral hypoglycaemic agents who had attended clinic for at least one year Exclusion criteria: Not defined
Interventions	Intervention: Structured education programme every 3 months for 2 years (1 hour x 8 = 8hr/2 yr) Educator: Two physicians and educationist Number of participants in group programme: 10

Characteristics of included studies (Continued)

	Including family/friends: Yes - optional Control: Routine treatment
Outcomes	2 years 1. HbA1c (%) 2. FBG (mmol/l) 3. Weight (Kg) 4. BMI (Kg/m ²) 5. Knowledge (score) 6. Conduct (score) 7. Quality of life (score) 8. Treatment 9. Complications 10. Lipids (mmol/l)
Notes	1. Intervention group = IG, Control group = CG 2. Participant numbers at baseline reported slightly different than in 1998 paper
Allocation concealment	B

Study Trento 2002

Methods	Trial design: Randomised controlled trial Ethics approval obtained: Conformed with the principles stated in the Declaration of Helsinki Patient consent obtained: Yes Randomisation method: Random table numbers Length of follow-up: 4 years Blinding of patient (P), educator (E), researcher (R): P = unclear, E = blinded to who in control group, R = unclear Analysis by intention to treat: Yes Power calculation: mentioned but not stated
Participants	Setting: Diabetes outpatient department Country: Italy Number: IG = 56, CG = 56 Age+/-SD: IG = 62, CG = 61 Sex: IG = 48% M, CG = 61% M Ethnicity: Not stated Duration of diabetes: IG = 9.4, CG = 9.8 Socioeconomic status: IG/CG Housewife - 14%/10% Retired - 24%/27% White collar worker - 4%/2% Blue collar worker - 7%/8% Other - 7%/9% Education background: Despite randomisation the CG were more educated Drop out (%): IG = 20%, CG = 20% Inclusion criteria: Type 2 diabetes treated with diet or oral hypoglycaemic agents who had attended clinic for at least one year Exclusion criteria: Not defined
Interventions	Intervention: Structured education programme every 3 months for 2 years and 7 sessions in year 3 +4 (total 15hrs/4yrs) Educator: Two physicians and educationist Number of participants in group programme: 10 Including family/friends: Yes - optional Control: Routine treatment
Outcomes	4 years

Characteristics of included studies (Continued)

	<ol style="list-style-type: none"> 1. HbA1c (%) 2. FBG (mmol/l) 3. Weight (Kg) 4. BMI (Kg/m²) 5. Lipids (mmol/l) 6. Blood pressure (mmHg) 7. Knowledge (score) 8. Conduct (score) 9. Quality of life (score) 10. Treatment 11. Complications
Notes	1. Intervention group = IG, Control group = CG 2. Participant numbers at baseline reported slightly different than in 1998 paper
Allocation concealment	B

Study	Zapotoczky 2001
Methods	<p>Trial design: Randomised controlled trial</p> <p>Ethics approval obtained: Unclear</p> <p>Patient consent obtained: Unclear</p> <p>Randomisation method: Unclear</p> <p>Length of follow-up: 1 year</p> <p>Blinding of patient (P), educator (E), researcher (R): P = unclear, E = unclear, R = unclear</p> <p>Analysis by intention to treat: No drop-outs</p> <p>Power calculation: not stated</p>
Participants	<p>Setting: Hospital diabetes unit</p> <p>Country: Austria</p> <p>Number: IG = 18, CG = 18</p> <p>Age+/-SD: IG = 62+/-8.2, CG = 53+/-11.4</p> <p>Sex: IG = 44% M, CG = 28% M</p> <p>Ethnicity: Not stated</p> <p>Duration of diabetes: Not stated</p> <p>Socioeconomic status: Not stated</p> <p>Education background: Not stated</p> <p>Drop out (%): 0%</p> <p>Inclusion criteria: Not defined</p> <p>Exclusion criteria: Not defined</p>
Interventions	<p>Intervention: 1.5 hour monthly group education for 10 months (total time = 15 hours)</p> <p>Educator: dietitian</p> <p>Number of participants in group programme: 18</p> <p>Including family/friends: Unclear</p> <p>Control: routine treatment = 4 individual appointments</p>
Outcomes	<p>12 months</p> <ol style="list-style-type: none"> 1. HbA1c (%) 2. Blood pressure (mmHg) 3. Lipid profile (mg/dl) 4. Weight (Kg)
Notes	<p>1. Intervention group = IG, Control group = CG</p> <p>All participants attended a 4 week education programme before randomisation</p>
Allocation concealment	B

Characteristics of included studies (Continued)

Characteristics of excluded studies

ADA 2001	Not a controlled clinical trial, a descriptive paper
Agurs-Collins 1997	The control group received a group-based diabetes education programme
Araujo 1989	Not a controlled clinical trial, a descriptive paper (translated Portuguese paper)
Arauz 1997	Length of follow-up less than six months (translated Spanish paper)
Arauz 2001	No control group (translated Spanish paper)
Aráuz 2001	Duplicate paper (Arauz 2001)
Assal 1988	Not a controlled clinical trial, a descriptive paper
Barcelo 2001	Recruited participants with both Type 1 and Type 2 diabetes
Barnard 1982	1. No control group 2. No group-based diabetes education programme 3. Length of follow-up less than six months
Barnard 1992	No control group
Basa 1995	No control group
Basina 2002	Editorial reviewing effectiveness of Diabetes management with no intervention
Berger 1996	Descriptive paper of previous study with no control group
Berger 1999	No intervention, descriptive paper
Blonk 1994	Behavioural weight loss programme with exercise sessions and not a group-based diabetes education programme
Boehm 1993	Not comparing group-based diabetes education programme with routine treatment/waiting list or no intervention
Bouldin 2002	Review of clinical guidelines with no intervention
Bradshaw 1999	Not a group-based diabetes education programme
Brown 1988	This is a paper reporting a meta-analysis of educational interventions but not group education interventions. Individual studies included in the meta-analysis were assessed for suitability for inclusion in the review but no papers met the inclusion criteria.
Brown 1995	1. No control group 2. Length of follow-up less than six months
Brown 1999	Pilot study for paper included in the review. Descriptive paper with no data presented.
Bundo 1993	A letter to respond to a previous paper and not a clinical controlled trial (translation of Spanish paper)
Burden 2000	Not a controlled clinical trial, a descriptive paper
Caballero 1998	Descriptive study with no control group
Cabrera-Pivaral 2000	Both intervention and control group received group-based diabetes education programme
Cabrera-Pivaral 2001	1. The control group also received group-based diabetes education programme 2. Only outcomes LDL cholesterol/fasting blood glucose (translated Spanish paper)
Calle-Pascual 1992	1. No primary outcome (HbA1c) 2. Research design unclear 3. Control group received group-based diabetes education programme
Campbell 1988	Both intervention and control group received group-based diabetes education programme
Campbell 1990	The control group received a group-based diabetes education programme
Campbell 1996	Trial comparing four interventions with the primary intervention being individual (not group-based) behavioural programme

Characteristics of excluded studies (Continued)

Cetti 2002	Descriptive study and not a controlled clinical trial
Clark 1999	Descriptive paper not a controlled clinical trial
Clark 2001	Not a group-based diabetes education programme
Clement 1995	Review of diabetes self-management interventions and not group-based programmes
Cohen 1982	1. Involved Type 1 and Type 2 diabetes 2. Length of follow-up less than six months 3. No HbA1c outcome 4. Majority of outcomes collected from intervention group only
Cooper 2001	Descriptive paper comparing meta-analyses on chronic disease patient education
Corabian 2001	This is a paper reporting a systematic review of educational interventions but not group education interventions. Individual studies included in the Corabian review were assessed for suitability for inclusion in the Cochrane review but no papers met the inclusion criteria
Corbett 1999	1. No control group 2. No group-based diabetes education programme 3. Study recruited people with Type 1 and Type 2 diabetes
D'Eramo-Melkus 1992	Diabetes education programme included group and individual sessions.
DPP Research GP 2002	Participants have impaired glucose tolerance and not diagnosed diabetes
Dunn 1988	Not a controlled clinical trial. A descriptive chapter on diabetes education
Eakin 2002	Review of diabetes self-management interventions in disadvantaged populations but not a review comparing group interventions with individual sessions. Individual papers assessed but none met the inclusion criteria.
Elshaw 1994	1. Length of follow-up less than six months 2. Outcomes assessment only included BMI and dietary intake
Ezenwaka 2002	Survey and not a controlled clinical trial
FEND 2000	A conference overview and not a controlled clinical trial
Falkenberg 1986	Control group also received group-based diabetes education programme
Fan 1999	Chinese paper unable to obtain through the British Libuary or inter-libuary loans
Ferreira 2001	No control group
Fishbein 1993	Not a clinical trial, an observational paper
Fritsche 1999	1. No control group 2. Inpatient diabetes education programme
Fukuda 1999	1. Study recruited people with Type 2 diabetes and impaired glucose tolerance 2. Inpatient diabetes education programme
Funnell 1998	Diabetes education programme included group and individual sessions.
Gaede 2001	Diabetes education programme included group and individual sessions.
Gagliardino 2001	1. Not comparing group education with individual or routine care 2. Not a clinical controlled trial
Gamsu 2002	No control group
Garcia 1996	No control group
García 1997	Not a controlled clinical trial - no control group
Gillibrand 2001	Diabetes education programme for nursing staff, not patients
Girard 1986	No control group (translated French paper)
Glasgow 1989	1. Unclear outcomes 2. Length of follow-up less than six months

Characteristics of excluded studies (Continued)

Glasgow 1992	Immediate group had outcome assessment follow-up at six months but delayed group only received posttest follow-up at three months.
Glasgow 2002	Intervention is not a group-based diabetes education programme
Gough 1990	1. Not a controlled trial 2. Length of follow-up less than six months
Griffin 1999	Not a controlled clinical trial, an editorial paper
Haapa 1999	1. Research design unclear 2. Both groups received group-based diabetes education programme. Intervention evaluated a follow-up module
Haisch 1996	1. Not a group-based diabetes education programme 2. Length of follow-up less than six months 3. Research design not appropriate (translated German paper)
Haisch 2000	Both groups received group-based diabetes education programme (German paper)
Haisch 2002	No control group (translated German paper)
Halle 1999	1. No control group 2. No group-based diabetes education programme
Halle 1999b	1. No control group 2. Length of follow-up less than six months 3. Diabetes education programmes includes both group-based and individual sessions
Hampton 1988	An audit and not a clinical trial
Hanefeld 1991	1. Diabetes education programmes includes both group-based and individual sessions 2. No primary outcome (HbA1c)
Hanefeld 1996	1. Diabetes education programmes includes both group-based and individual sessions 2. No primary outcome (HbA1c) German paper (translated)
Hansen 2002	Danish summary of Cochrane review on health professional diabetes education (Renders 2000)
Hardinghaus 1996	No control group German paper (translated)
Hartwell 1986	The control group received a group-based diabetes education programme
Heath 1991	Weight loss competition with no control group
Henry 1997	1. Length of follow-up less than six months 2. Less than 6 participants in each diabetes education programme
Hughes 1999	Excluded - participants have type 1 and type 2 diabetes. Research design unclear. Individual appointments (control) not routine treatment.
Hunter 1999	Not a controlled clinical trial, a descriptive paper
Jaber 1996	1. No group-based diabetes education programme 2. Length of follow-up less than six months
Jacobs 2000	1. No control group 2. Length of follow-up less than six months 3. No statistical tests
Jennings 1990	1. The trial design and outcomes don't meet the systematic review criteria 2. Length of follow-up less than six months
Jiang 1999	Length of follow-up less than six months
Julius 1993	The primary outcome is work absenteeism
Jungmann 1997	No control group (translated German paper)

Characteristics of excluded studies (Continued)

Jungmann 1997b	No control group (translated German paper) (same paper as Jungmann 1997)
Jungmann 1997c	No control group (translated German paper) (same paper as Jungmann 1997)
Kaplan 1985	1. The control received a group-based diabetes education programme 2. Length of follow-up less than six months
Kaplan 1987	1. The control group received a group-based diabetes education programme 2. Outcomes not relevant
Kaplan 1987b	1. The control group received a group-based diabetes education programme 2. Research design not clear
Kendall 1987	Trial comparing two different group-based diabetes education programmes with no routine treatment group
Kendall 1990	1. Both groups received a group-based diabetes education programme 2. Only nutritional outcomes
Keyserling 2000	1. Intervention is individual behaviour counselling 2. Outcomes not appropriate
Keyserling 2002	Intervention included three group sessions and 12 monthly phone calls. Not possible to detect whether any effects are due to the group aspect or telephone calls
Krier 1999	The intervention group also received individual appointments as part of the intervention
Lacey 2000	Literature review of CHD risk management in diabetes education interventions
Laitinen 1993	The intervention group also received individual appointments as part of the intervention
Laitinen 1994	The intervention group also received individual appointments as part of the intervention
Larme 1998	Not a controlled clinical trial, a descriptive paper
Lazcano 1999	1.Length of follow-up less than six months 2. Only outcome data reported is fasting blood glucose
Levenson 2002	Both groups received group-based diabetes education programme
Ligtenberg 1998	1. Not a group-based diabetes education programme, exercise training 2. Length of follow-up less than six months
Llamas 2002	1. No control group 2. Length of follow-up unclear
Lo 1996	1. No group-based education programme 2. Length of follow-up less than six months
Lozano 1996	Length of follow-up less than six months (translated spanish paper)
Luna Arriola 1994	Spanish dissertation unable to obtain
Madjarof 2001	1. No control group 2. Less than 6 participants in education programme 3. Length of follow-up unclear
Maljanian 2002	1. No control group 2. Less than 6 participants in education programme 3. Length of follow-up unclear
Mancino 2002	No group-based diabetes education programme
Martinez 1999	Unable to obtain paper from the British Library or inter-library loans
Maxwell 1992	Unable to obtain paper from the British Library or inter-library loans
Mayer-Davis 2001	1. Both groups received 8 week education programme. Intervention is the type of evaluation. 2. Few outcomes & follow-up less than 6 months.
Mazzuca 1986	1. Study recruited people with Type 1 and Type 2 diabetes 2. Diabetes education programme included group and individual sessions.

Characteristics of excluded studies (Continued)

McMurray 2002	1. No control group 2. No group-based education programme
McNabb 1993	Trial design not appropriate and outcomes not reported for the comparison group
Miller 1999	1. Length of follow-up less than six months 2. The only outcome is knowledge
Miller 2002	Length of follow-up less than six months
Miller 2002b	Length of follow-up less than six months
Miller 2002c	Length of follow-up less than six months
Morgan 1988	Not a group-based diabetes education programme
Muhlhauser 2002	Not a clinical controlled trial, a descriptive paper
Mulrow 1987	Number of participants in each group-based education programme less than 6
Noel 1998	The control group received a group-based diabetes education programme
Norris 2001	Systematic review of diabetes self-management programmes but not reviewing group-based programmes
Norris 2002	Systematic review of diabetes self-management programmes with a meta-analysis of the effect on glycaemic control but not reviewing group-based programmes
Norris 2002b	A systematic review of disease and case management and not group-based diabetes education programmes
Norris 2002c	A systematic review of diabetes self-management education in the community but not group-based diabetes education programmes
Pacyk 2001	1. No control group 2. Length of follow-up less than six months
Padgett 1988	Meta-analysis of education/psychosocial interventions on management of diabetes but not comparing group-sessions with individual
Rabkin 1983	Length of follow-up less than six months
Rachmani 2002	Not a group-based diabetes education programme
Raji 2002	Recruited Type1 and Type 2 diabetes
Raz 1988	Diabetes education programme included group and individual sessions.
Rebell 2002	Inpatient group-based diabetes education programme German paper (translated)
Renders 2000	Systematic review on health professional diabetes education
Ridgeway 1999	Diabetes education programme included group and individual sessions.
Rivera Tejada 1996	Not a controlled clinical study, a descriptive paper
Rubin 1991	1. The study includes people with Type 1 and Type2 diabetes 2. No control group
Saenz Hernaiz 1992	Spanish paper unable to obtain via inter-library loans or the British library
Samaras 1997	The intervention was structured exercise sessions and not a group-based diabetes education programme
Sarkadi 2001	1. No control group 2. Retrospective paper
Scain 1986	1. No control group 2. Retrospective paper
Schiel 1999	1. Inpatient diabetes education programme 2. Main outcome is self-monitoring of blood glucose levels
Scott 1984	Length of follow-up less than six months
Simmons 1992	Evaluation between attenders and non-attenders

Characteristics of excluded studies (Continued)

Simmons 1996	1. Primary intervention is an exercise programme 2. Unclear research design
Steed 2003	Length of follow-up less than six months
Surwit 2002	Both the intervention and the control group received a group-based diabetes education programme
Swenson 2000	Not a controlled clinical trial and included participants with both type 1 and type 2 diabetes
Tankova 2001	1. No control group 2. Study recruited participants with both Type 1 and Type 2 diabetes
Toobert 2002	Outcome measures not relevant
Unknown 1994	Short report of diabetes education programme
Unknown 2002	Not a controlled clinical trial - a descriptive paper
Uusitupa 1993	The intervention group received individual appointments as part of the intervention
Uusitupa 1996	No group-based diabetes education programme
Vaaler 2000	A review evaluating methods of achieving optimal glycaemic control and not group-based diabetes education programmes
Van 2000	1. No primary outcome (HbA1c) 2. Four interventions with two group programmes but no routine treatment, waiting list controls
Vanninen 1992	The intervention group received individual appointments as part of the intervention
Vanninen 1993	Not a group-based diabetes education programme, intensive diet and exercise delivered on an individual basis
Vazquez 1998	1. Length of follow-up less than six months 2. Nutrition outcomes only
Veldhuizen 1995	All three groups received group-based diabetes education programme. Intervention assessed pharmaceutical care model
Wang 1998	1. No control group 2. The study recruited participants with Type 1 and Type 2 diabetes
Wheeler 2001	Not a clinical controlled trial, a descriptive paper
White 1986	The control group received a group-based diabetes education programme
Wierenga 1990	Not a controlled clinical trial, a qualitative study
Wilson 1987	Length of follow-up less than six months
Wing 1985	The control group received a group-based diabetes education programme
Wing 1988	Intervention self-monitoring blood glucose training and not a group-based diabetes education programme
Wing 1993b	Not a trial evaluating a group-based diabetes education programme
Wroe 1995	Not a controlled clinical trial, a conference report
Wroe 2000	Not a controlled clinical trial, a conference report
Wroe 2000b	Not a controlled clinical trial, a conference report
Wroe 2001	Not a controlled clinical trial, a conference report
Wroe 2001b	Not a controlled clinical trial, a conference report
Wroe 2001c	Not a controlled clinical trial, a conference report
Wroe 2002	Not a controlled clinical trial, a conference report
Wroe 2002b	Not a controlled clinical trial, a conference report
de Weerd 1991	The trial included people with both type 1 and type 2 diabetes

ADDITIONAL TABLES

Table 01. Search strategy

Electronic searches

Unless otherwise stated, search terms were free text terms; exp = exploded MeSH: Medical subject heading (Medline medical index term); the dollar sign (\$) stands for any character(s); the question mark (?) = to substitute for one or no characters; tw = text word; pt = publication type; sh = MeSH: Medical subject heading (Medline medical index term); adj = adjacency.

1. diabetes mellitus, non insulin dependent [MeSH Terms]
2. insulin resistance [MeSH Terms]
3. obesity in diabetes [MeSH Terms]
4. impaired glucose tolerance [Title/Abstract]
5. glucose intolerance [Title/Abstract]
6. insulin resistance [Title/Abstract]
7. mody [Title/Abstract]
8. dm2 [Title/Abstract]
9. niddm [Title/Abstract]
10. iddm [Title/Abstract]
11. non insulin dependent [Title/Abstract]
12. noninsulin dependent [Title/Abstract]
13. noninsulindependent [Title/Abstract]
14. type 2 diabet* [Title/Abstract]
15. type ii diabet* [Title/Abstract]
16. nonketotic diabet* [Title/Abstract]
17. non ketotic diabet*
18. adult onset diabet* [Title/Abstract]
19. late onset diabet*
20. metabolic syndrom* [Title/Abstract]
21. plurimetabolic syndrom* [Title/Abstract]
22. or/1-21
23. dermatomyositis[MeSH Terms]
24. Myotonic dystrophy[MeSH Terms]
25. Diabetes insipidus[MeSH Terms]
26. dermatomyositis[Title/Abstract]
27. myotonic dystroph*[Title/Abstract]
28. diabet* insipidus[Title/Abstract]
29. or/23-28
30. 22 not 29
31. education [MeSH Terms]
32. self care [MeSH Terms]
33. patient education [MeSH Terms]
34. self efficacy [MeSH Terms]
35. behavior therapy [MeSH Terms]
36. empowerment [Title/Abstract]
37. self care [Title/Abstract]
38. education* [Title/Abstract]
39. self efficac* [Title/Abstract]

Table 01. Search strategy (Continued)

Electronic searches

- 40. program* [Title/Abstract]
- 41. group method* [Title/Abstract]
- 42. group management [Title/Abstract]
- 43. evaluation* [Title/Abstract]
- 44. lifestyle [Title/Abstract]
- 45. behavior?r* therap* [Title/Abstract]
- 46. or/31-45
- 47. randomized controlled trial [Publication Type]
- 48. randomized controlled trials [MeSH Terms]
- 49. random allocation [MeSH Terms] random [Title/Abstract]
- 50. allocat*[Title/Abstract]
- 51. assign [Title/Abstract]
- 52. controlled clinical trial [Publication Type]
- 53. clinical trial [Publication Type]
- 54. clinical trials [MeSH Terms]
- 55. clinical trial* [Title/Abstract]
- 56. double blind method [MeSH Terms]
- 57. single blind method [MeSH Terms]
- 58. single blind*[Title/Abstract]
- 59. single mask*[Title/Abstract]
- 60. double blind* [Title/Abstract]
- 61. double mask* [Title/Abstract]
- 62. placebos [MeSH Terms]
- 63. placebo [Title/Abstract]
- 64. research design [MeSH Terms]
- 65. comparative study [MeSH Terms]
- 66. evaluation studies [MeSH Terms]
- 67. follow up studies [MeSH Terms]
- 68. prospective studies [MeSH Terms]
- 69. control stud*[Title/Abstract]
- 70. volunteer study [Title/Abstract]
- 71. intervention studies [MeSH Terms]
- 72. intervention stud*[Title/Abstract]
- 73. or/47-72
- 74. 30 and 46 and 73

Table 02. Original Outcomes Data 1

Study	Outcome	Base-line:group	Base-line:control	4-6 months: group	4-6 months: control	12-14 months: group	12-14 months: contro	2+ years: group	2+ years: control
Brown 2002	HbA1c (%)	11.8 (3.0)	11.8 (3.0)	10.8 (2.8)	12.2 (3.0)	10.9 (2.6)	11.6 (2.9)	---	---
	Fasting blood glucose	213.0 (45.5)	207.1 (71.4)	185.2 (60.9)	215.0 (66.8)	195.0 (63.2)	210.5 (66.6)	---	---

Table 02. Original Outcomes Data 1 (Continued)

Study	Outcome	Base- line:group	Base- line:controlgroup	4-6 months:	4-6 months: control	12-14 months: group	12-14 months: contro	2+ years: group	2+ years: control
	(mg/dl)								
	Systolic blood pressure (mmHg)	---	---	---	---	---	---	---	---
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total Choles- terol (mg/dl)	211.8 (45.3)	203.6 (48.8)	192.5 (40.3)	189.1 (107.9)	189.9 (36.4)	187.6 (42.7)	---	---
	Triglyc- eride (mg/dl)	215.4 (130.1)	195.6 (112.0)	185.9 (40.5)	237.7 (234.1)	214.4 (194.9)	198.7 (148.4)	---	---
	Weight (kg)	---	---	---	---	---	---	---	---
	BMI (Kg/m ²)	32.3 (6.0)	32.1 (6.4)	31.7 (5.8)	32.5 (6.8)	32.2 (6.5)	32.3 (6.5)	---	---
	Diabetes knowledge score	36.2 (6.2)	37.3 (6.3)	---	---	42.9 (4.9)	40.9 (4.9)	---	---
Deakin 2003	HbA1c (%)	7.7 (1.6)	7.7 (1.6)	7.4 (1.3)	7.8 (1.6)	7.1 (1.1)	7.8 (1.6)	---	---
	Fasting blood glucose	---	---	---	---	---	---	---	---
	Systolic blood pressure (mmHg)	148 (20)	148 (24)	143 (19)	148 (23)	141 (17)	144 (24)	---	---
	Diastolic blood pressure (mmHg)	83 (11)	82 (12)	79 (10)	81 (12)	78 (10)	80 (11)	---	---
	Total Choles- terol (mmol/l)	5.1 (1.1)	4.9 (1.0)	4.9 (1.0)	5.0 (1.0)	4.8 (1.1)	4.7 (1.0)	---	---
	Triglyc- erides	2.5 (1.4)	2.3 (1.1)	2.3 (1.2)	2.4 (1.4)	2.1 (1.1)	2.0 (1.2)	---	---

Table 02. Original Outcomes Data 1 (Continued)

Study	Outcome	Base- line:group	Base- line:controlgroup	4-6 months: group	4-6 months: control	12-14 months: group	12-14 months: contro	2+ years: group	2+ years: control
	(mmol/l)								
	Weight (kg)	83.2 (14.5)	82.8 (17.6)	82.9 (14.9)	82.6 (17.9)	82.7 (14.8)	83.9 (18.8)	---	---
	BMI (kg/m ²)	30.8 (5.3)	30.6 (5.7)	30.7 (5.4)	30.4 (5.8)	30.6 (5.5)	31.0 (6.4)	---	---
	Diabetes knowledge score	7.5 (3.5)	7.0 (3.1)	10.4 (2.8)	7.8 (2.9)	9.3 (3.1)	7.8 (2.7)	---	---
Domenech 1994/1995	HbA1c (%)	9.0 (2.6)	9.0 (2.2)	---	---	8.8 (0.4)	9.8 (0.4)	---	---
	Fasting blood glucose	---	---	---	---	---	---	---	---
	Systolic blood pressure (mmHg)	---	---	---	---	---	---	---	---
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total cholesterol	---	---	---	---	---	---	---	---
	Triglyc- erides	---	---	---	---	---	---	---	---
	Weight (kg)	---	---	---	---	-2.4 (0.5)	-0.4 (0.5)	---	---
	BMI (kg/m ²)	31.0 (7.0)	29.0 (4.0)	---	---	---	---	---	---
	Diabetes knowledge score	---	---	---	---	---	---	---	---
Heller 1988	HbA1c (%)	12.3 (2.8)	12.7 (2.5)	7.5 (1.7)	9.5 (2.7)	9.0 (2.5)	9.9 (3.2)	---	---
	Fasting blood glucose	---	---	---	---	9.1 (3.7)	10.3 (4.7)	---	---
	Systolic blood pressure	---	---	---	---	---	---	---	---

Table 02. Original Outcomes Data 1 (Continued)

Study	Outcome	Base- line:group	Base- line:control	4-6 months: group	4-6 months: control	12-14 months: group	12-14 months: contro	2+ years: group	2+ years: control
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total cholesterol	---	---	---	---	---	---	---	---
	Triglycerides	---	---	---	---	---	---	---	---
	Weight (kg)	86.9 (11.6)	86.1 (12.9)	79.9 (5.3)	84.1 (6.4)	81.4 (3.8)	83.1 (3.2)	---	---
	BMI (kg/m ²)	31.2 (3.1)	32.0 (3.8)	---	---	---	---	---	---
	Diabetes knowledge score	---	---	---	---	24.4 (3.4)	18.4 (4.1)	---	---
Holtrop 2002	HbA1c (%)	8.0 (no SD)	7.7 (no SD)	8.0 (no SD)	8.1 (no SD)	---	---	---	---
	Fasting blood glucose	---	---	---	---	---	---	---	---
	Systolic blood pressure	---	---	---	---	---	---	---	---
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total cholesterol	---	---	---	---	---	---	---	---
	Triglycerides	---	---	---	---	---	---	---	---
	Weight (kg)	---	---	---	---	---	---	---	---
	BMI (kg/m ²)	35.4 (5.8)	37.9 (8.1)	no value	no value	---	---	---	---
	Diabetes knowledge score	---	---	---	---	---	---	---	---
Kronsbein 1988	HbA1c (%)	7.1 (1.6)	6.5 (1.6)	---	---	7.1 (1.6)	6.7 (1.5)	---	---
	Fastng	---	---	---	---	---	---	---	---

Table 02. Original Outcomes Data 1 (Continued)

Study	Outcome	Base- line:group	Base- line:controlgroup	4-6 months:	4-6 months: control	12-14 months: group	12-14 months: contro	2+ years: group	2+ years: control
	blood glucose								
	Systolic blood pressure	---	---	---	---	---	---	---	---
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total cholesterol	---	---	---	---	---	---	---	---
	Triglyc- erides (mmol/l)	3.7 (2.6)	3.4 (1.9)	---	---	3.0 (2.5)	3.4 (2.3)	---	---
	Weight (kg)	76.5 (12.6)	75.1 (12.9)	---	---	73.8 (12.6)	74.8 (13.2)	---	---
	BMI (kg/m2)	---	---	---	---	---	---	---	---
	Diabetes knowledge score	9.0 (3.0)	9.0 (3.0)	---	---	13.0 (4.0)	10.0 (4.0)	---	---
Lozano 1999	HbA1c (%)	6.6 (1.4)	6.7 (1.3)	---	---	6.3 (1.3)	7.1 (1.3)	6.1 (1.0)	7.2 (3.0)
	Fasting blood glucose (mg/dl)	165.8 (45.8)	168.0 (45.4)	---	---	153.4 (41.1)	179.0 (47.4)	148.7 (34.3)	181.1 (48.9)
	Systolic blood pressure	---	---	---	---	---	---	---	---
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total cholesterol	---	---	---	---	---	---	---	---
	Triglyc- erides	---	---	---	---	---	---	---	---
	Weight (kg)	---	---	---	---	---	---	---	---
	BMI	30.2 (5.6)	29.1 (4.7)	---	---	29.9 (4.7)	29.2 (4.7)	29.9 (5.1)	28.7 (4.3)

Table 02. Original Outcomes Data 1 (Continued)

Study	Outcome	Base- line:group	Base- line:control	4-6 months: group	4-6 months: control	12-14 months: group	12-14 months: contro	2+ years: group	2+ years: control
	(kg/m2)								
	Diabetes knowledge score	7.0 (2.6)	6.3 (2.6)	---	---	10.0 (2.9)	7.0 (2.6)	11.2 (1.6)	6.4 (2.44)
Pieber 1995	HbA1c (%)	8.6 (1.8)	8.8 (2.1)	8.1 (1.6)	9.0 (1.8)	---	---	---	---
	Fasting blood glucose	---	---	---	---	---	---	---	---
	Systolic blood pressure	161 (20)	157 (21)	144 (21)	150 (24)	---	---	---	---
	Diastolic blood pressure	92 (11)	91 (13)	81 (10)	86 (14)	---	---	---	---
	Total cholesterol (mmol/l)	6.5 (1.3)	6.6 (1.7)	6.1 (1.0)	6.5 (1.8)	---	---	---	---
	Triglyc- erides (mmol/l)	3.0 (2.3)	2.6 (1.8)	2.4 (1.8)	2.8 (2.5)	---	---	---	---
	Weight (kg)	82.1 (14.5)	81.8 (13.1)	79.4 (13.9)	82.1 (13.6)	---	---	---	---
	BMI (kg/m2)	30.2 (4.7)	30.2 (4.5)	29.2 (4.5)	30.3 (4.9)	---	---	---	---
	Diabetes knowledge score	44 (19)	39 (18)	69 (21)	40 (19)	---	---	---	---

Table 03. Original Outcomes Data 2

Study	Outcome	Baseline: group	Baseline: control	4-6 months: group	4-6 months: control	12-14 months: group	12-14 month: control	2+ years: group	2+ years: control
Rickheim 2002	HbA1c (%)	8.9 (1.9)	8.0 (1.7)	6.5 (0.7)	6.5 (0.9)	---	---	---	---
	Fasting blood	---	---	---	---	---	---	---	---

Table 03. Original Outcomes Data 2 (Continued)

Study	Outcome	Baseline: group	Baseline: control	4-6 months: group	4-6 months: control	12-14 months: group	12-14 month: control	2+ years: group	2+ years: control
	glucose								
	Systolic blood pressure	---	---	---	---	---	---	---	---
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total cholesterol	---	---	---	---	---	---	---	---
	Triglyc- erides	---	---	---	---	---	---	---	---
	Weight (kg)	101.1 (17.9)	108.9 (23.1)	99.3 (15.1)	98.8 (22.3)	---	---	---	---
	BMI (kg/m ²)	33.8 (6.1)	34.9 (6.5)	33.3 (6.1)	32.1 (7.0)	---	---	---	---
	Diabetes knowledge score	8.4 (2.7)	7.6 (2.8)	12.6 (1.6)	12.5 (1.5)	---	---	---	---
Trento 1998/2001/2002	HbA1c	7.4 (1.4)	7.4 (1.4)	---	---	7.1 (1.3)	7.5 (1.5)	2yr: 7.5 (1.4) / 4yr: 7.0 (1.1)	2yr: 8.3 (1.8) / 4yr: 8.6 (2.1)
	Fasting blood glucose (mmol/l)	9.8 (2.6)	10.0 (3.1)	---	---	9.9 (2.4)	10.7 (3.1)	2yr: 9.9 (2.7) / 4yr: 9.3 (2.6)	2yr: 9.2 (2.9) / 4yr: 11.0 (4.6)
	Systolic blood pressure (mmHg)	---	---	---	---	---	---	---	---
	Diastolic blood pressure	---	---	---	---	---	---	---	---
	Total cholesterol (mmol/l)	5.8 (1.1)	5.5 (0.9)	---	---	---	---	2yr: 5.7 (1.2) / 4yr: 5.8 (1.3)	2yr: 5.6 (1.2) / 4yr: 5.8 (1.3)
	Triglyc- erides (mmol/l)	2.6 (no SD)	1.7 (no SD)	---	---	---	---	2yr: 2.1 (no SD) / 4yr: 2.11 (no SD)	2yr: 1.7 (no SD) / 4yr: 1.64 (no SD)
	Weight	77.4	78.2	---	---	76.0	77.1	2yr: 76	2yr: 77.1

Table 03. Original Outcomes Data 2 (Continued)

Study	Outcome	Baseline: group	Baseline: control	4-6 months: group	4-6 months: control	12-14 months: group	12-14 month: control	2+ years: group	2+ years: control
	(kg)	(13.1)	(14.6)			(13.4)	(14.7)	(13.4) / 4yr: 75.2 (13.0)	(14.7) / 4yr: 76.9 (16.1)
	BMI (kg/m ²)	29.7 (4.5)	27.8 (4.1)	---	---	29.0 (4.4)	27.7 (4.2)	2yr: 29.0 (4.4) / 4yr: 28.7 (4.0)	2yr: 27.6 (4.2) / 4 yr: 27.6 (4.7)
	Diabetes knowledge score	14.9 (7.9)	20.2 (7.4)	---	---	24.0 (6.6)	17.4 (8.6)	2yr: 24.0 (6.6) / 27.1 (6.6)	2yr: 17.4 (8.6) / 4 yr: 17.2 (8.7)
Zapo- toczky 2001	HbA1c (%)	8.6 (1.6)	8.0 (1.5)	---	---	7.7 (1.4)	8.3 (1.5)	---	---
	Fasting blood glucose	---	---	---	---	---	---	---	---
	Systolic blood pressure (mmHg)	137 (12)	135 (17)	---	---	136 (14)	137 (12)	---	---
	\diastolic blood pressure (mmHg)	90 (8)	87 (11)	---	---	86 (8)	83 (6)	---	---
	Total cholesterol (mg/dl)	247 (62)	230 (41)	---	---	241 (61)	235 (34)	---	---
	Triglyc- erides (mg/dl)	245 (172)	173 (66)	---	---	207 (138)	147 (56)	---	---
	Weight (kg)	88.1 (16.7)	87.9 (13.2)	---	---	82.3 (13.6)	86.0 (11.7)	---	---
	BMI (kg/m ²)	---	---	---	---	---	---	---	---
	Diabetes knowledge score	---	---	---	---	---	---	---	---

G R A P H S

Comparison 01. Group-based diabetes education programme versus individual routine treatment

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Death	3	525	Odds Ratio (Random) 95% CI	1.24 [0.28, 5.56]
02 Reduction in diabetes medication	5	654	Odds Ratio (Random) 95% CI	11.79 [5.17, 26.90]
03 Glycated haemoglobin (4-6 months)	3	395	Weighted Mean Difference (Random) 95% CI	-1.35 [-1.93, -0.78]
04 Glycated haemoglobin (12-14 months)	7	1044	Weighted Mean Difference (Random) 95% CI	-0.82 [-0.99, -0.65]
05 Glycated haemoglobin (2 years)	2	333	Weighted Mean Difference (Random) 95% CI	-0.97 [-1.40, -0.54]
06 Fasting blood glucose (12-14 months)	4	641	Weighted Mean Difference (Random) 95% CI	-1.17 [-1.63, -0.72]
07 Weight (4-6 months)	4	566	Weighted Mean Difference (Random) 95% CI	-2.13 [-4.71, 0.45]
08 Weight (12-14 months)	5	591	Weighted Mean Difference (Random) 95% CI	-1.61 [-2.97, -0.25]
09 Body Mass Index (4-6 months)	4	718	Weighted Mean Difference (Random) 95% CI	-0.16 [-1.00, 0.68]
10 Body Mass Index (12-14 months)	4	751	Weighted Mean Difference (Random) 95% CI	0.45 [-0.32, 1.23]
11 Diabetes knowledge (12-14 months)	3	432	Standardised Mean Difference (Random) 95% CI	0.95 [0.72, 1.18]
12 Systolic blood pressure (4-6 months)	2	399	Weighted Mean Difference (Random) 95% CI	-5.37 [-9.53, -1.21]
13 Diastolic blood pressure (4-6 months)	2	399	Weighted Mean Difference (Random) 95% CI	-2.65 [-5.57, 0.28]
14 Systolic blood pressure (12-14 months)	2	327	Weighted Mean Difference (Random) 95% CI	-2.61 [-6.74, 1.52]
15 Total cholesterol (12-14 months)	3	552	Weighted Mean Difference (Random) 95% CI	0.09 [-0.09, 0.26]
16 Triglycerides (4-6 months)	3	628	Weighted Mean Difference (Random) 95% CI	-0.24 [-0.52, 0.04]
17 Triglycerides (12-14 months)	4	652	Weighted Mean Difference (Random) 95% CI	0.14 [-0.13, 0.41]

Comparison 02. Sub-group analyses

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Ethnicity: glycated haemoglobin 4-6 months	2	302	Weighted Mean Difference (Fixed) 95% CI	-1.18 [-1.69, -0.67]
02 Ethnicity: glycated haemoglobin 12-14 months	2	299	Weighted Mean Difference (Fixed) 95% CI	-0.78 [-1.28, -0.27]
03 Theoretical model: glycated haemoglobin 4-6 months	2	399	Weighted Mean Difference (Fixed) 95% CI	-0.50 [-0.79, -0.20]
04 Educator: glycated haemoglobin 12-14 months	5	869	Weighted Mean Difference (Fixed) 95% CI	-0.75 [-0.96, -0.54]
05 Primary care intervention: glycated haemoglobin 4-6 months	2	320	Weighted Mean Difference (Fixed) 95% CI	-1.13 [-1.64, -0.63]

06 Primary care intervention: glycated haemoglobin 12-14 months	4	837	Weighted Mean Difference (Fixed) 95% CI	-0.90 [-1.04, -0.76]
---	---	-----	---	----------------------

Comparison 03. Sensitivity analyses

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Published studies: glycated haemoglobin 12-14 months	6	753	Weighted Mean Difference (Fixed) 95% CI	-0.90 [-1.04, -0.75]
02 Study quality:glycated haemoglobin 12-14 months	2	327	Weighted Mean Difference (Fixed) 95% CI	-0.70 [-1.00, -0.40]
03 Non-translated publications: glycated haemoglobin 12-14 months	6	801	Weighted Mean Difference (Fixed) 95% CI	-0.88 [-1.02, -0.73]
04 Studies with more than 100 participants: glycated haemoglobin 12-14 months	3	758	Weighted Mean Difference (Fixed) 95% CI	-0.75 [-0.97, -0.53]

COVER SHEET

Title	Group based training for self-management strategies in people with type 2 diabetes mellitus
Authors	Deakin T, McShane CE, Cade JE, Williams RDRR
Contribution of author(s)	TRUDI DEAKIN - protocol development, searching for trials, quality assessment of trials, data extraction, data analysis, review development. CATHERINE McSHANE - quality assessment of trials, data extraction, second reviewer. JANET CADE - protocol development, third reviewer for resolving differences, review development. RHYS WILLIAMS - protocol development, review development.
Issue protocol first published	2002/1
Review first published	2004/4
Date of most recent amendment	20 March 2005
Date of most recent SUBSTANTIVE amendment	23 February 2005
What's New	Information not supplied by author
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author
Date authors' conclusions section amended	Information not supplied by author
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Cochrane Library number CD003417
Editorial group Cochrane Metabolic and Endocrine Disorders Group
Editorial group code HM-ENDOC

GRAPHS AND OTHER TABLES

Fig. 1. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.01 Death

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 01 Death

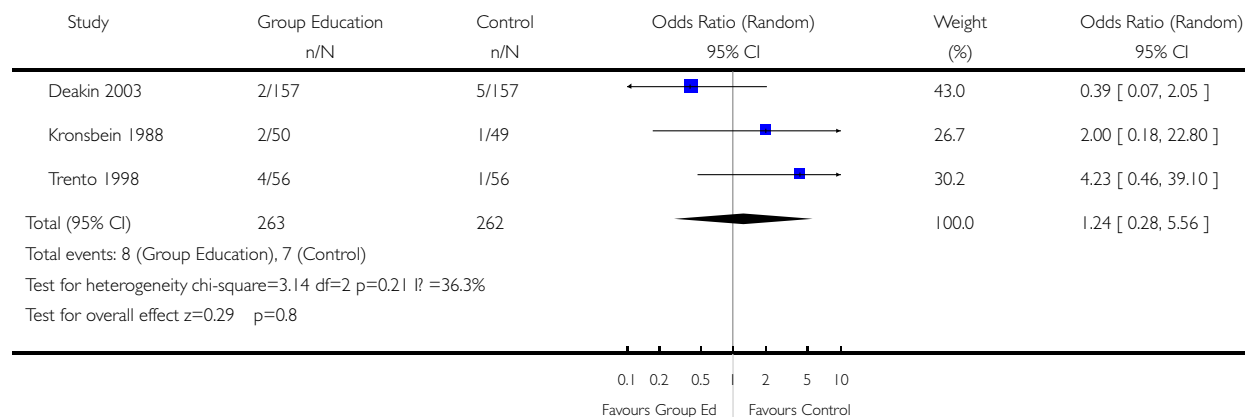


Fig. 2. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.02 Reduction in diabetes medication

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 02 Reduction in diabetes medication

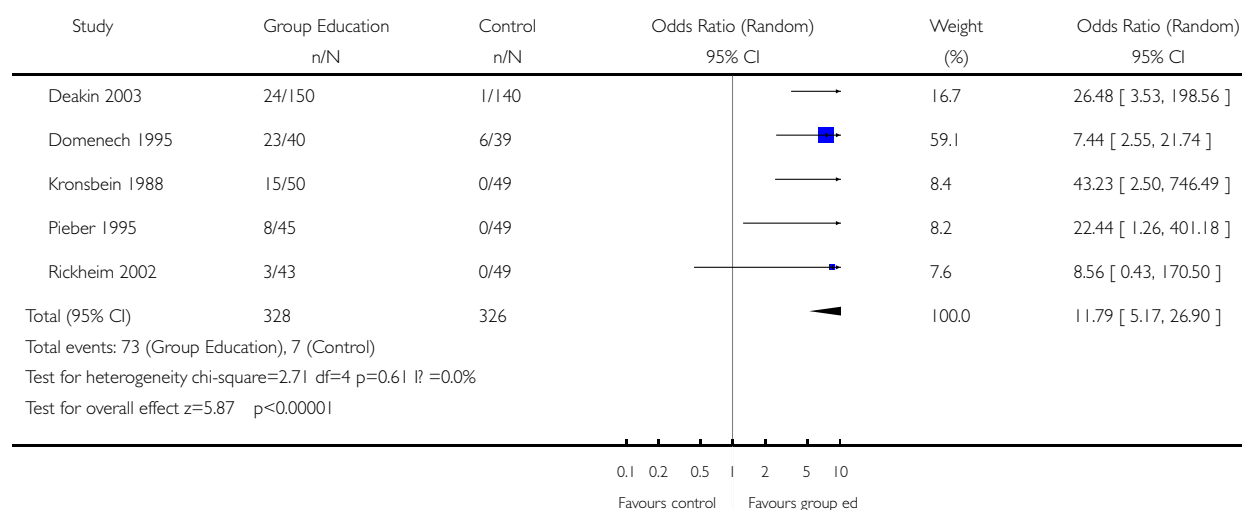


Fig. 3. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.03 Glycated haemoglobin (4-6 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 03 Glycated haemoglobin (4-6 months)

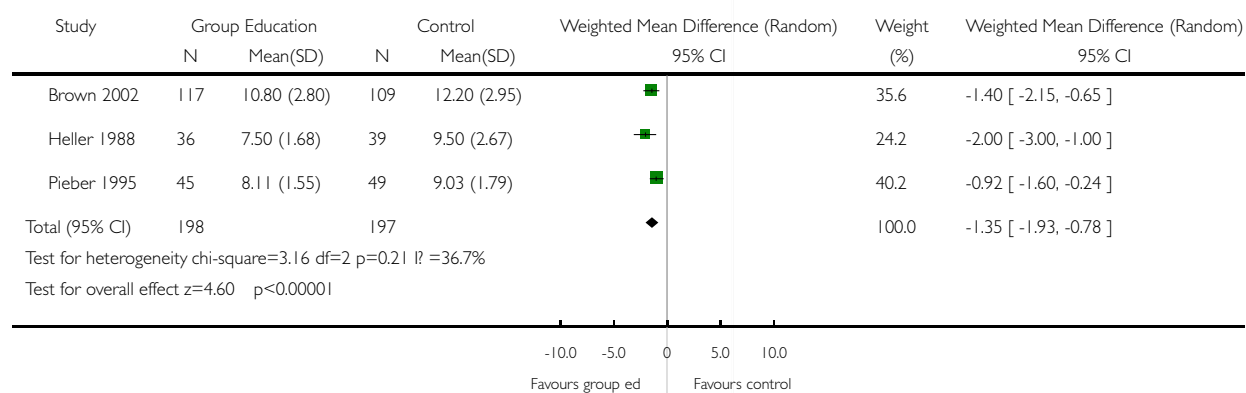


Fig. 4. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.04 Glycated haemoglobin (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 04 Glycated haemoglobin (12-14 months)

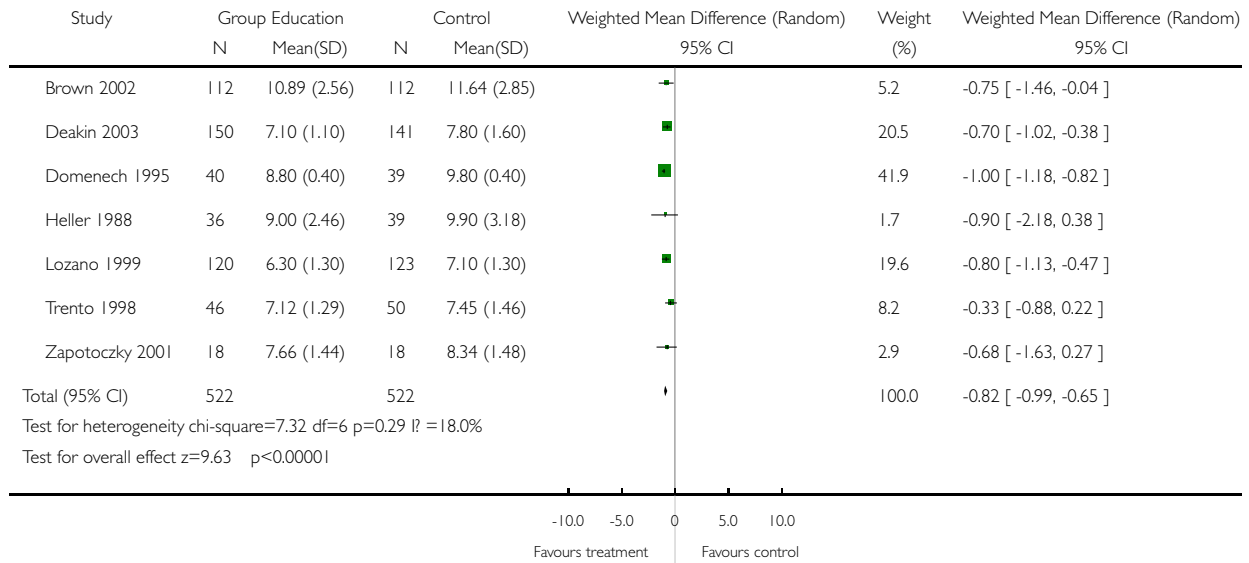


Fig. 5. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.05 Glycated haemoglobin (2 years)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 05 Glycated haemoglobin (2 years)

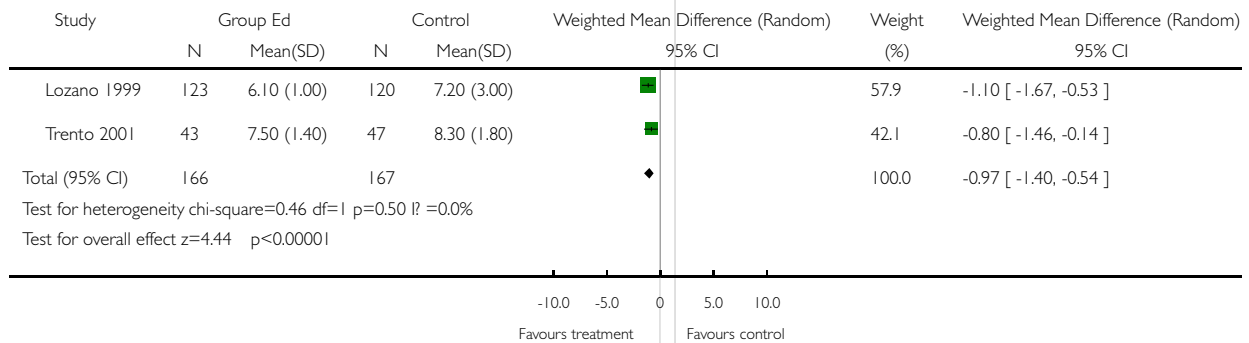


Fig. 6. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.06 Fasting blood glucose (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 06 Fasting blood glucose (12-14 months)

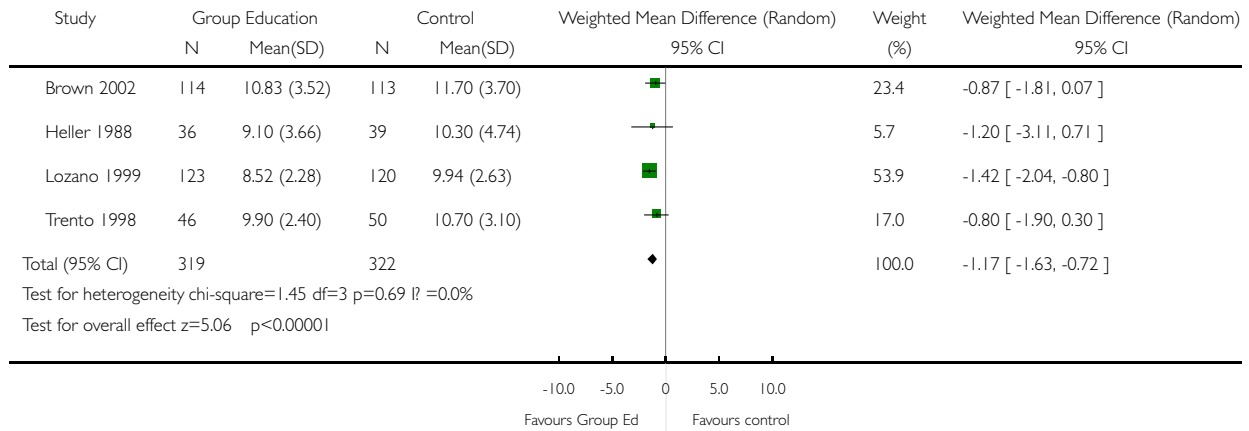


Fig. 7. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.07 Weight (4-6 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 07 Weight (4-6 months)

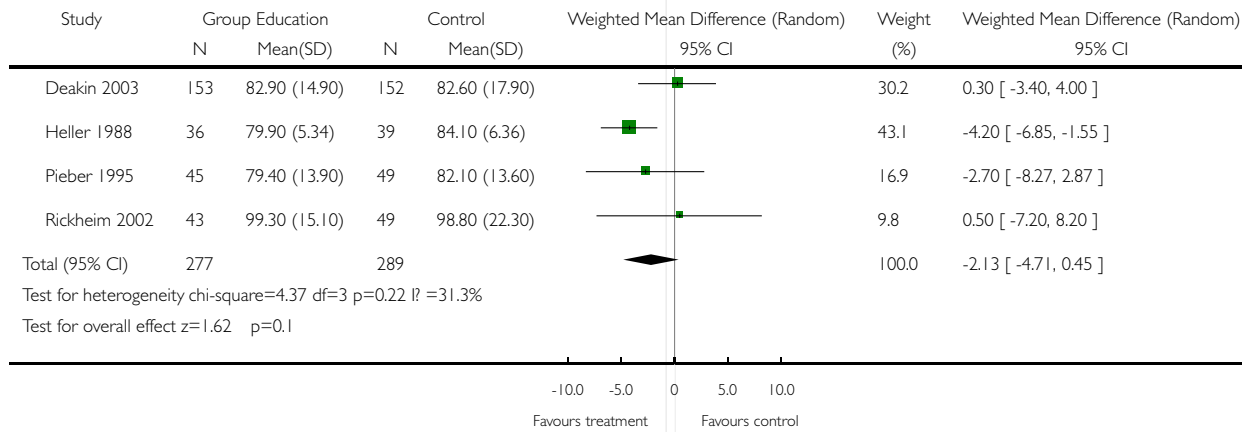


Fig. 8. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.08 Weight (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 08 Weight (12-14 months)

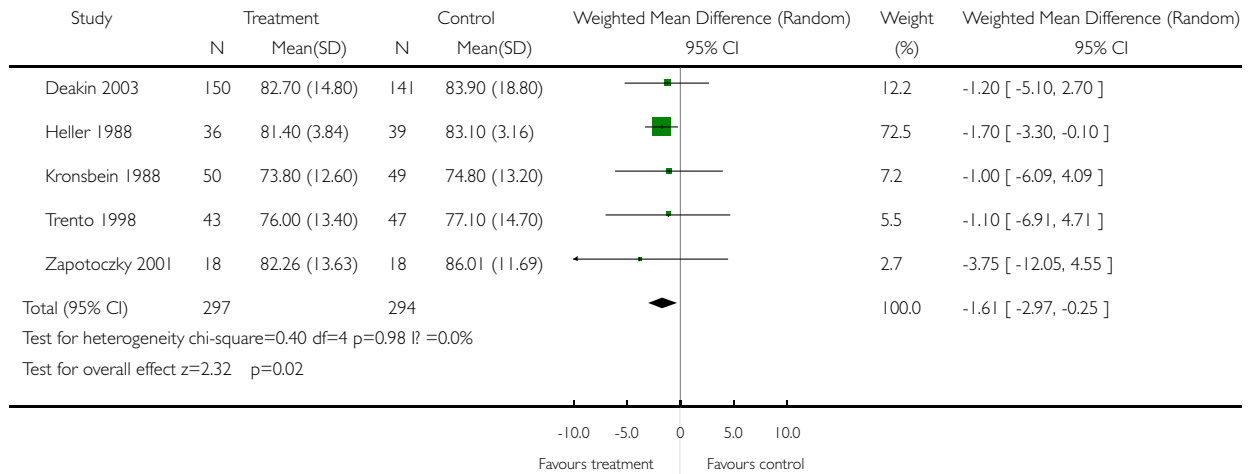


Fig. 9. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.09 Body Mass Index (4-6 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 09 Body Mass Index (4-6 months)

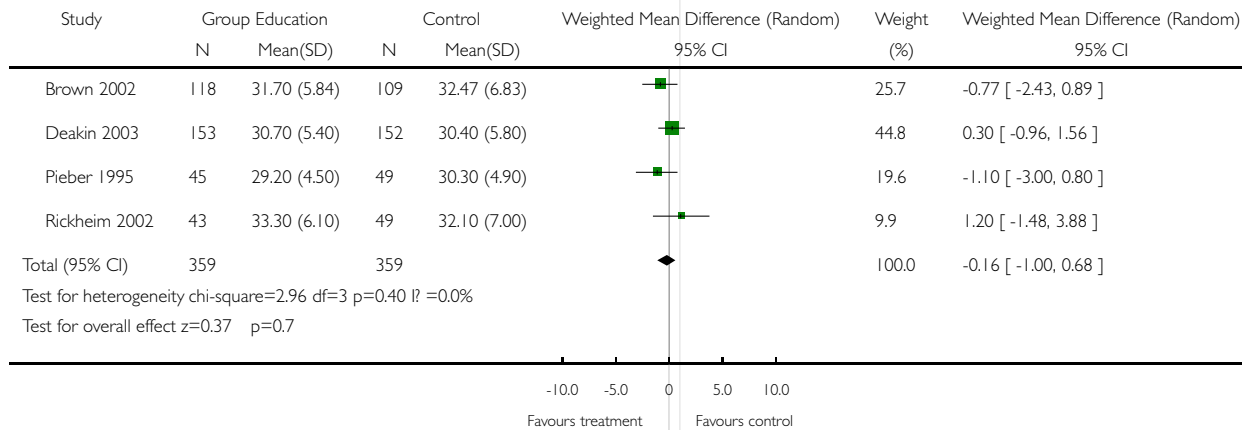


Fig. 10. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.10 Body Mass Index (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 10 Body Mass Index (12-14 months)

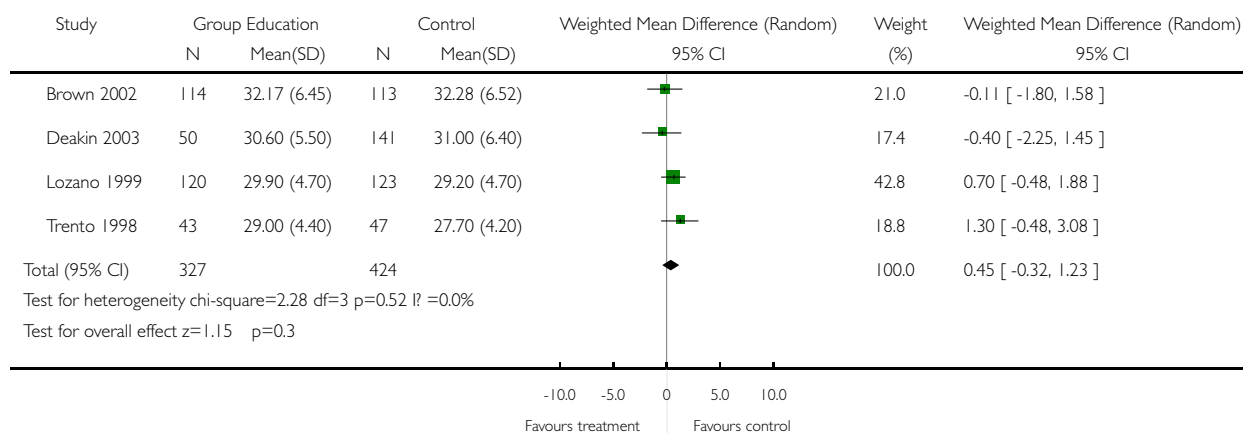


Fig. 11. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.11 Diabetes knowledge (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 11 Diabetes knowledge (12-14 months)

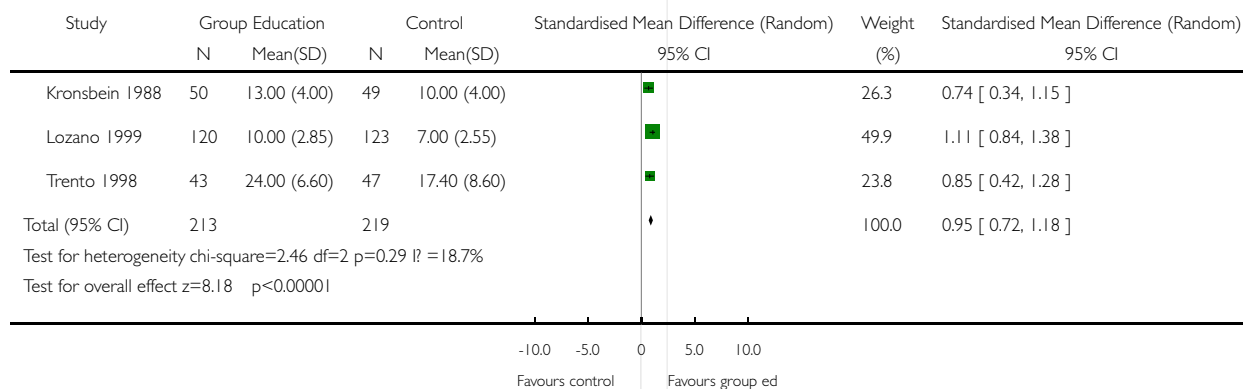


Fig. 12. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.12 Systolic blood pressure (4-6 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 12 Systolic blood pressure (4-6 months)

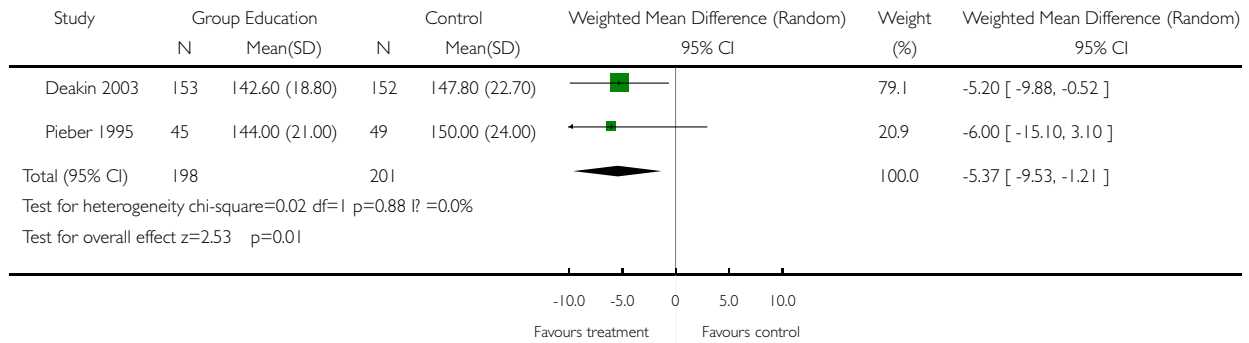


Fig. 13. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.13 Diastolic blood pressure (4-6 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 13 Diastolic blood pressure (4-6 months)

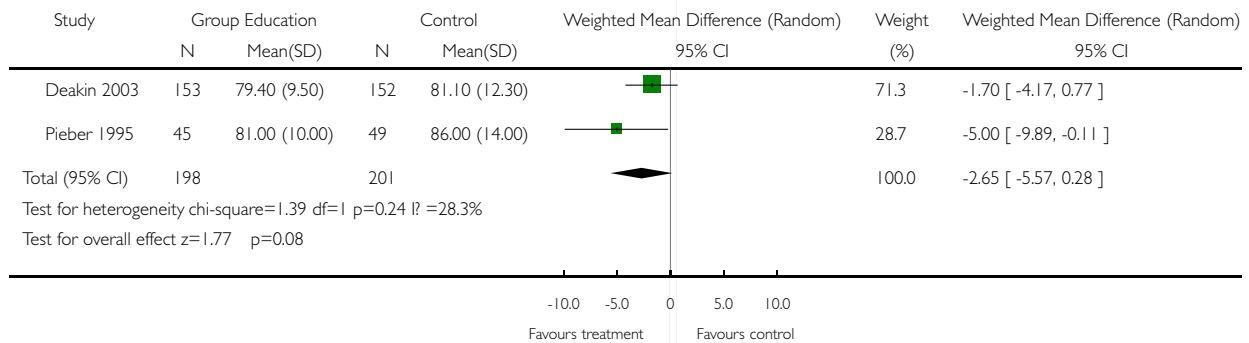


Fig. 14. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.14 Systolic blood pressure (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 14 Systolic blood pressure (12-14 months)

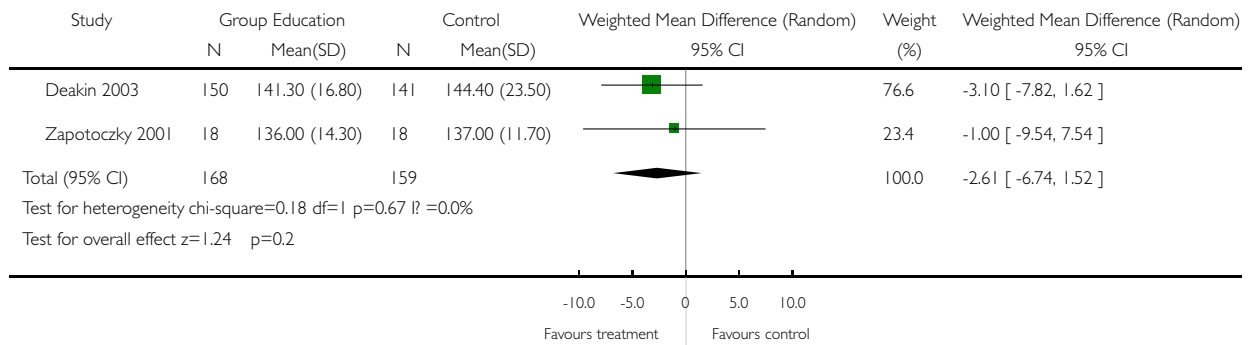


Fig. 15. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.15 Total cholesterol (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 15 Total cholesterol (12-14 months)

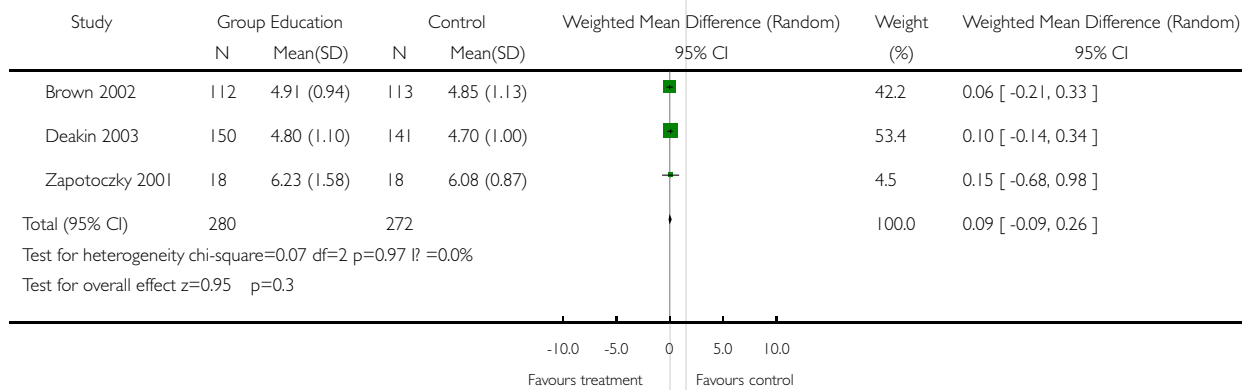


Fig. 16. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.16 Triglycerides (4-6 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 16 Triglycerides (4-6 months)

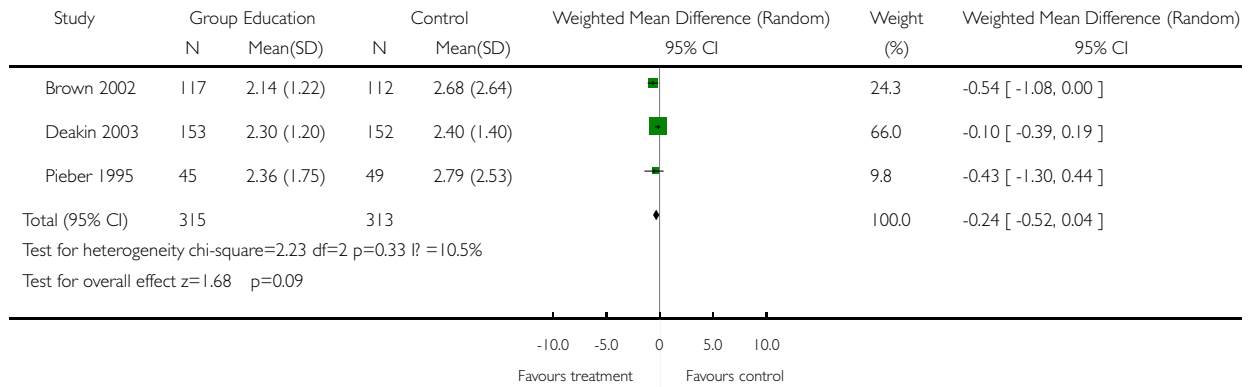


Fig. 17. Comparison 01. Group-based diabetes education programme versus individual routine treatment

01.17 Triglycerides (12-14 months)

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 01 Group-based diabetes education programme versus individual routine treatment

Outcome: 17 Triglycerides (12-14 months)

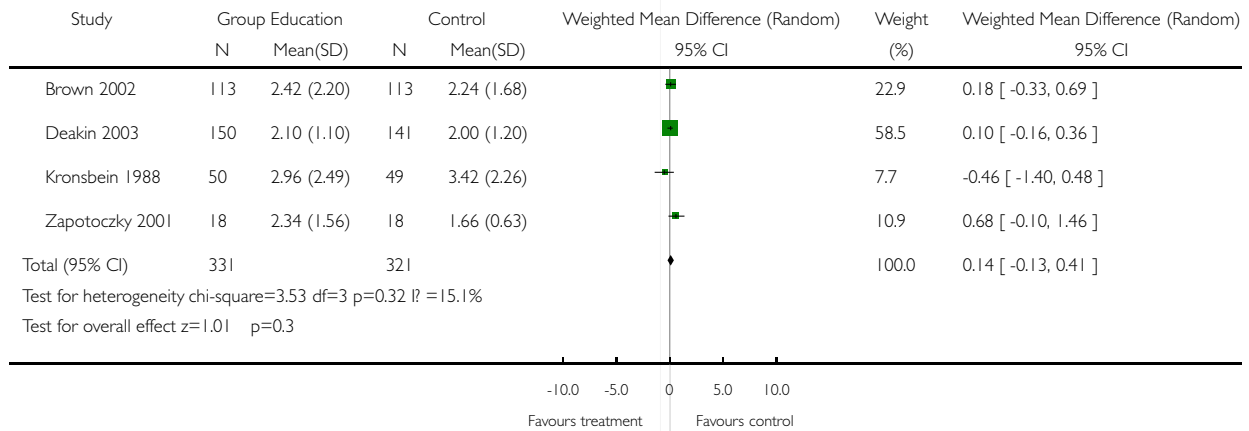


Fig. 18. Comparison 02. Sub-group analyses

02.01 Ethnicity: glycated haemoglobin 4-6 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 02 Sub-group analyses

Outcome: 01 Ethnicity: glycated haemoglobin 4-6 months

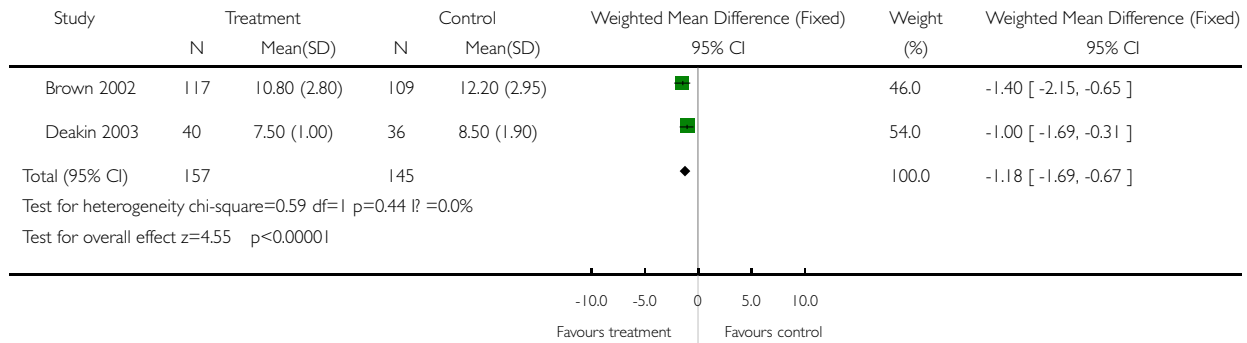


Fig. 19. Comparison 02. Sub-group analyses

02.02 Ethnicity: glycated haemoglobin 12-14 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 02 Sub-group analyses

Outcome: 02 Ethnicity: glycated haemoglobin 12-14 months

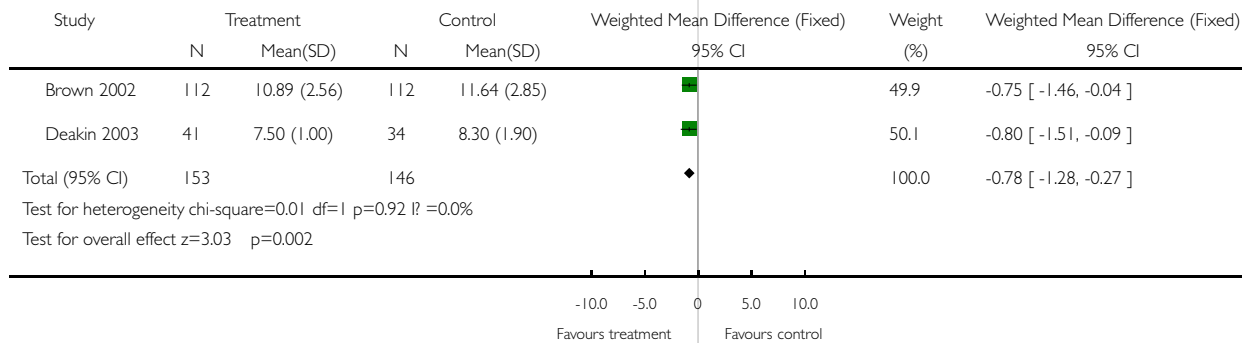


Fig. 20. Comparison 02. Sub-group analyses

02.03 Theoretical model: glycated haemoglobin 4-6 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 02 Sub-group analyses

Outcome: 03 Theoretical model: glycated haemoglobin 4-6 months

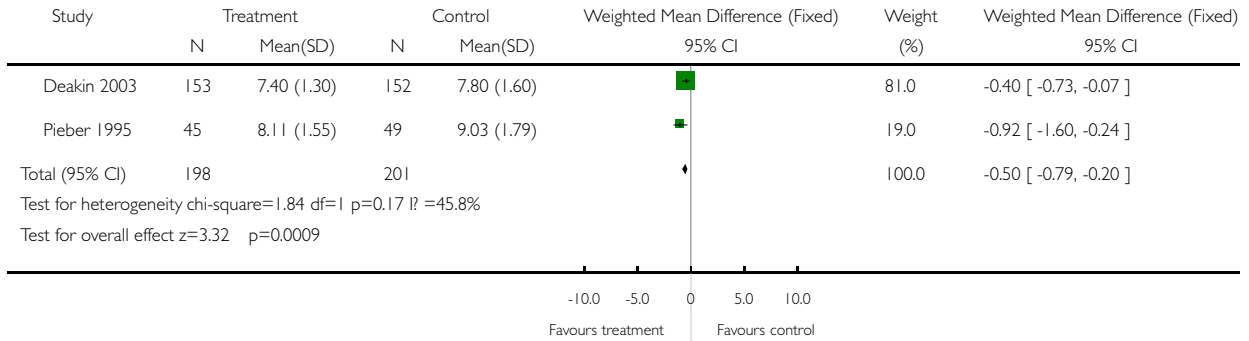


Fig. 21. Comparison 02. Sub-group analyses

02.04 Educator: glycated haemoglobin 12-14 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 02 Sub-group analyses

Outcome: 04 Educator: glycated haemoglobin 12-14 months

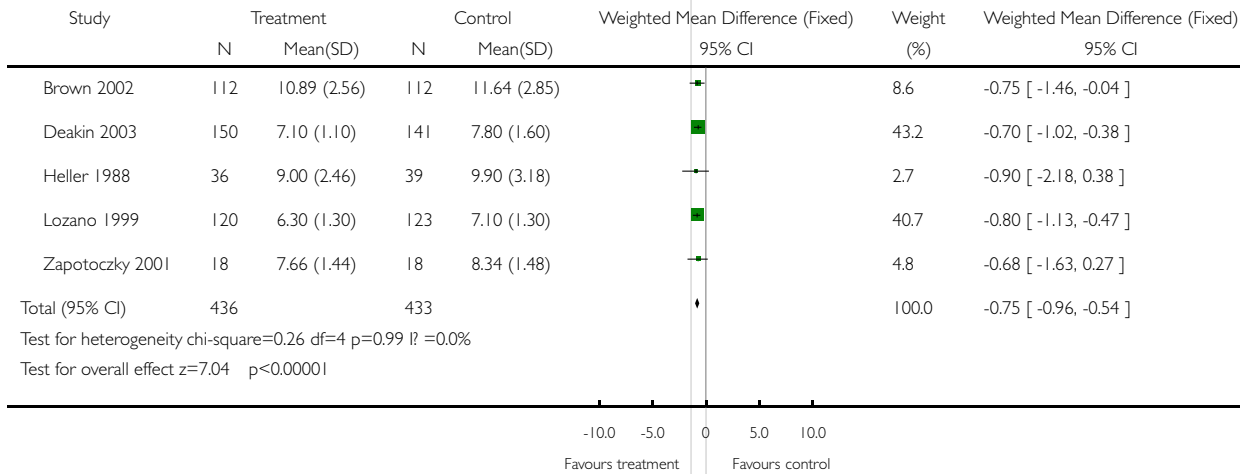


Fig. 22. Comparison 02. Sub-group analyses

02.05 Primary care intervention: glycated haemoglobin 4-6 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 02 Sub-group analyses

Outcome: 05 Primary care intervention: glycated haemoglobin 4-6 months

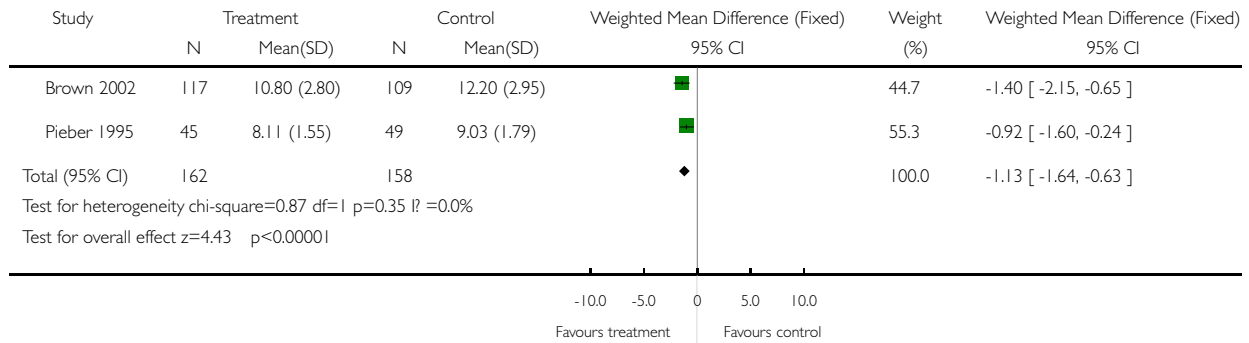


Fig. 23. Comparison 02. Sub-group analyses

02.06 Primary care intervention: glycated haemoglobin 12-14 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 02 Sub-group analyses

Outcome: 06 Primary care intervention: glycated haemoglobin 12-14 months

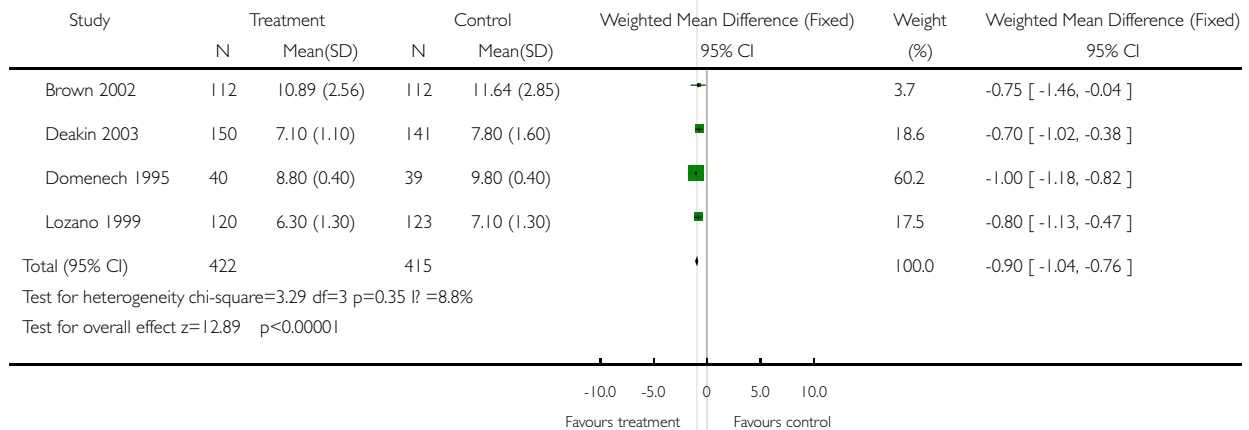


Fig. 24. Comparison 03. Sensitivity analyses

03.01 Published studies: glycated haemoglobin 12-14 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 03 Sensitivity analyses

Outcome: 01 Published studies: glycated haemoglobin 12-14 months

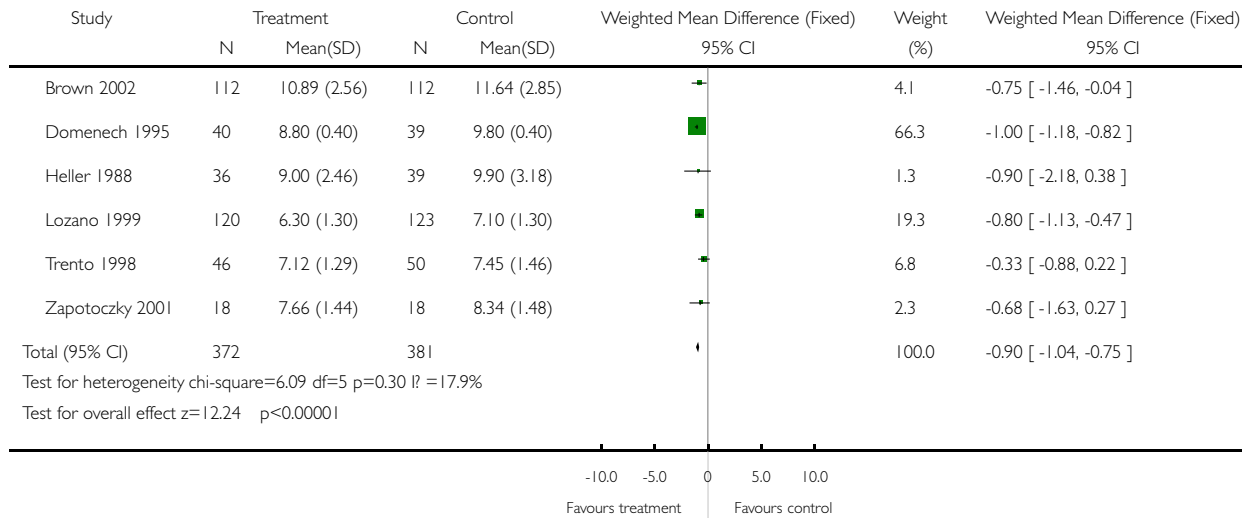


Fig. 25. Comparison 03. Sensitivity analyses

03.02 Study quality:glycated haemoglobin 12-14 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 03 Sensitivity analyses

Outcome: 02 Study quality:glycated haemoglobin 12-14 months

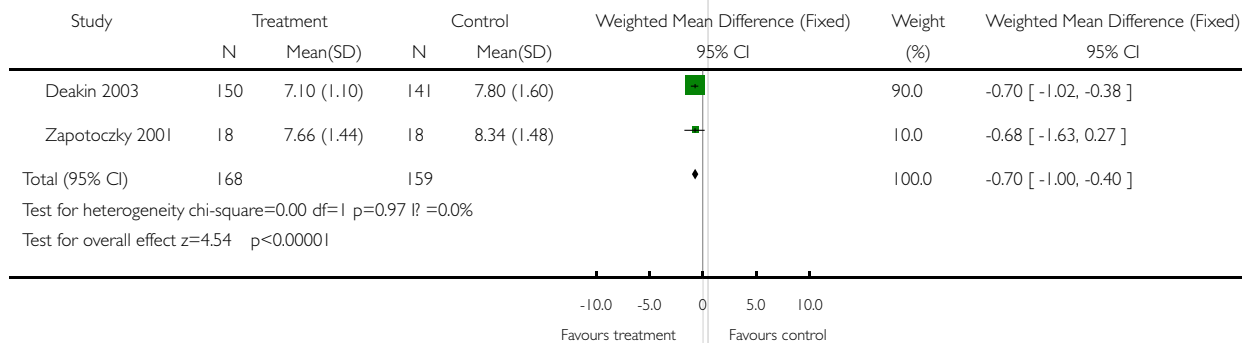


Fig. 26. Comparison 03. Sensitivity analyses

03.03 Non-translated publications: glycated haemoglobin 12-14 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 03 Sensitivity analyses

Outcome: 03 Non-translated publications: glycated haemoglobin 12-14 months

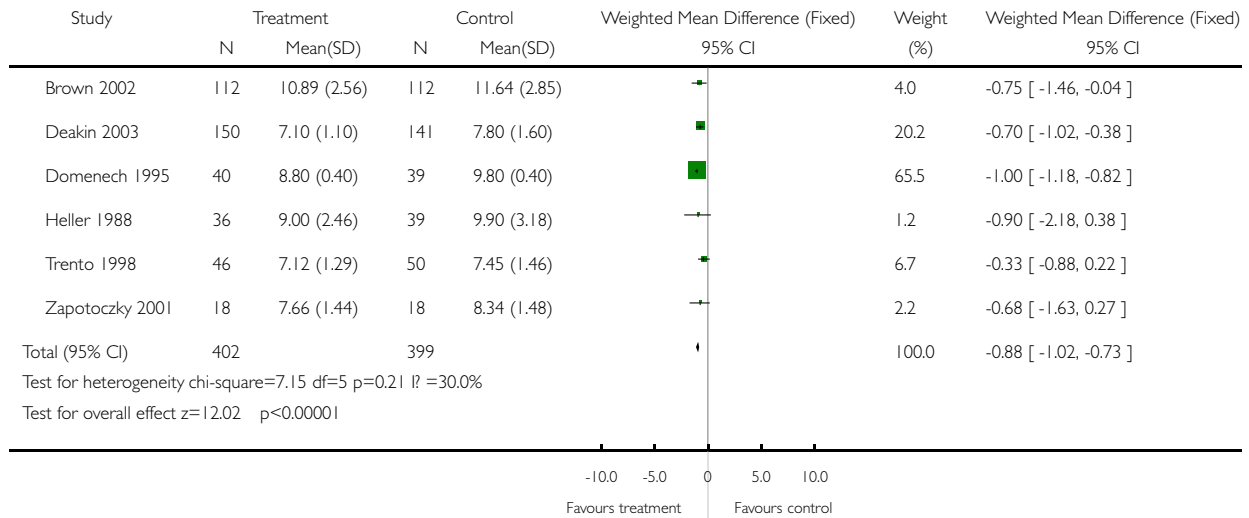


Fig. 27. Comparison 03. Sensitivity analyses

03.04 Studies with more than 100 participants: glycated haemoglobin 12-14 months

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 03 Sensitivity analyses

Outcome: 04 Studies with more than 100 participants: glycated haemoglobin 12-14 months

