Health Technology Assessment 2008; Vol. 12: No. 9

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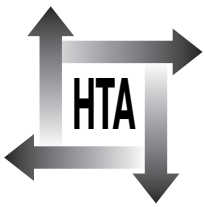
April 2008

Health Technology Assessment
NHS R&D HTA Programme
www.hta.ac.uk



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Declared competing interests of authors: none

Published April 2008

This report should be referenced as follows:

Loveman E, Frampton GK, Clegg AJ. The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review. *Health Technol Assess* 2008;**12**(9).

Health Technology Assessment is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE and *Science Citation Index Expanded (SciSearch®)* and *Current Contents®*/Clinical Medicine.

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The research reported in this issue of the journal was commissioned by the HTA Programme as project number 06/47/01. The contractual start date was in November 2006. The draft report began editorial review in May 2007 and was accepted for publication in October 2007. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

ISSN 1366-5278

Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.

Abstract

The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review

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Objective: To examine the clinical effectiveness of patient education models for adults with Type 2 diabetes.

Data sources: Electronic databases were searched from 2002 to January 2007.

Review methods: A systematic review of the literature on educational interventions in diabetes was undertaken. This was an update of a previous systematic review.

Results: Including studies identified in the previous systematic review, there were 13 published studies. Eight studies of education on multiple aspects of diabetes self-management were identified that provided education that was focused on a particular aspect of self-management. The quality of reporting and methodology of the studies was variable. Studies of multi-component educational interventions yielded mixed results. Some trials reported significant improvements on measures of diabetic control but others did not. Positive effects may be attributable to longer-term interventions with a shorter duration between the end of the intervention and the follow-up evaluation point. There may also be an effect of having a multi-professional team delivering the educational programme. Studies of focused educational interventions did not yield consistent results. Some effects were shown on measures of diabetic control in studies that focused on diet or exercise alone. Although the effects shown were generally small, those that were present did appear to be relatively long-lasting. This update review does not substantially alter the conclusions of the previous systematic review; for each outcome, the proportion of studies that demonstrated significant effects of education was similar.

Conclusions: Based on the evidence, it would seem that education delivered by a team of educators, with some degree of reinforcement of that education made at additional points of contact, may provide the best opportunity for improvements in patient outcomes. Educators need to have time and resources to fulfil the needs of any structured educational programme. There is also a need for education to have a clear programme at the outset. From the evidence reported it is unclear what resources would need to be directed at the educators themselves to ensure that they can deliver programmes successfully. Any future research should consider patient education within the context of overall diabetes care and as such follow guidelines for the development and evaluation of complex interventions. Good-quality, longer-term studies would be desirable, but these would require careful consideration around the nature of any control group. Information is needed to clarify the sensitivity of diabetes education programmes to the performance of the diabetes educators, in order to ensure success and cost-effectiveness of education programmes.

Contents

List of abbreviations and acronyms

AADE	American Association of Diabetes Educators
ADA	American Diabetes Association
ADDQoL	Audit of Diabetes-Dependent Quality of Life
AIC	academic in confidence
BDA	British Diabetic Association (former name for Diabetes UK)
BIPOD	Bangladeshi Initiative for Prevention of Diabetes
BG	blood glucose
BMI	body mass index
BP	blood pressure
CCT	controlled clinical trial
CI	confidence interval
CRD	Centre for Reviews and Dissemination
CVD	cardiovascular disease
DAFNE	Dose Adjustment For Normal Eating
DCCT	Diabetes Control and Complications Trial
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
DKNA	Diabetes Knowledge scale – form A
DQOL	Diabetes Quality of Life measure
DSN	diabetes specialist nurse
FBG	fasting blood glucose
GHb	glycated haemoglobin
GISED	Group of the Italian Society for Diabetes
GMS	General Medical Services
HbA_1, HbA_{1c}	glycated haemoglobin A_{1c}
HDL	high-density lipoprotein
IDDM	insulin-dependent diabetes mellitus
ITT	intention-to-treat
LDL	low-density lipoprotein
NICE	National Institute for Health and Clinical Excellence
NIDDM	non-insulin-dependent diabetes mellitus
NSF	National Service Framework
OHA	oral hypoglycaemic agent
PCT	Primary Care Trust
PEWG	Patient Education Working Group
QoL	quality of life
QWB	quality of well-being scale
RCT	randomised controlled trial
SD	standard deviation
SDIS	Stockholm Diabetes Intervention Study

continued

List of abbreviations and acronyms *continued*

SE	Standard error
SEM	standard error of the mean
SF-36	Short-Form with 36 Items
SMBG	self-monitoring of blood glucose
UKPDS	United Kingdom Prospective Diabetes Study
VAS	visual analogue scale

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

Diabetes is a chronic and progressive disorder that has an impact on almost every aspect of life. Type 2 diabetes is characterised by insulin resistance and relative insulin deficiency. It is commonly linked to being overweight or obese, and to physical inactivity. Type 2 diabetes primarily affects people over the age of 40 years and is becoming more common.

The basic targets in the treatment of diabetes are the normalisation of blood glucose levels, blood pressure control and lipid management, and studies have shown that good diabetic control is associated with a significant reduction in the risk of a number of complications. Control of diabetes is affected by both lifestyle factors and by pharmacological treatments and the management of diabetes is largely the responsibility of those affected. Supporting self-care is a crucial aspect of any diabetes service, and national guidance recommends structured education as fundamental to this.

The aim of patient education is to empower patients by improving knowledge, skills and confidence, enabling them to take increasing control of their condition. Structured educational programmes for diabetes self-management are often multifaceted interventions providing information and also management skills around diet, exercise, self-monitoring and medication use.

This review is an update of a previous systematic review which concluded that the diversity of the educational programmes for Type 2 diabetes did not yield consistent results. Some of the included trials reported significant improvements in metabolic control and/or quality of life or other psychological outcomes; however, many others did not report significant effects of educational interventions.

Objective

The objective was to examine the clinical effectiveness of patient-education models for adults with Type 2 diabetes.

Methods

A systematic review of the literature on educational methods in diabetes was undertaken. This was an update of a previous systematic review.

Data sources

Electronic databases (including Cochrane Library, MEDLINE, PsychINFO) were searched from 2002 to January 2007. Bibliographies of included studies and related papers were checked for relevant studies. Experts were contacted for advice and peer review, and to identify additional studies.

Study selection

A total of 1696 titles and abstracts were screened for eligibility by one reviewer and checked by a second. Inclusion criteria were applied to the full text of selected papers by two reviewers, with differences resolved through discussion. Studies were included if they fulfilled the following criteria:

- Interventions: educational interventions compared with usual care or another educational intervention.
- Participants: adults with Type 2 diabetes mellitus.
- Outcomes: must report glycated haemoglobin, hypoglycaemic episodes, diabetic complications, or quality of life. Other reported outcomes from included studies were discussed.
- Evaluation of outcomes $\geqslant$12 months from inception of intervention.
- Design: randomised controlled trials (RCTs) and controlled clinical trials (CCTs) with a concurrent control were included.
- Reporting: studies were only included if they reported sufficient detail of the intervention to be reproducible (e.g. topics covered, who provided the education, how many sessions were available).

Studies in non-English languages or available only as abstracts were excluded.

Data extraction and quality assessment

Data extraction and quality assessment were undertaken by one reviewer and checked by a second, with differences resolved through discussion. The quality of included studies was assessed using criteria set by the NHS Centre for Reviews and Dissemination.

Data synthesis

The clinical effectiveness data were synthesised through a narrative review with full tabulation of results. Meta-analysis was not undertaken due to differences in study populations and comparators.

Results

Number and quality of studies

Including studies identified in the previous systematic review, 13 published studies (11 RCTs, two CCTs) were identified that provided education on multiple aspects of diabetes self-management and eight studies (seven RCTs, one CCT) were identified that provided education that was focused on a particular aspect of self-management. The quality of reporting and methodology of the studies was variable.

Summary of benefits

Studies of multi-component educational interventions yielded mixed results. Some trials reported significant improvements on measures of diabetic control but others did not. Positive effects may be attributable to longer-term interventions with a shorter duration between the end of the intervention and the follow-up evaluation point. There may also be an effect of having a multi-professional team delivering the educational programme.

Studies of focused educational interventions did not yield consistent results. Some effects were shown on measures of diabetic control in studies that focused on diet or exercise alone. Although the effects shown were generally small, those that were present did appear to be relatively long-lasting. This update review does not substantially alter the conclusions of the previous systematic review; for each outcome, the proportion of studies that demonstrated significant effects of education was similar.

Discussion

Overall, the results of educational interventions aimed at patients with Type 2 diabetes are difficult to interpret due to differences in the interventions, the populations, the study designs and the outcomes reported. There is little evidence to suggest whether and how educational programmes might currently be directed to achieve maximal benefit for patients with Type 2 diabetes. Multi-component educational interventions appear to have better effects on outcomes than those focused on particular aspects of diabetes self-care alone, and this is currently reflected in national guidance for diabetes education.

There are a number of issues around the complexity of the intervention, the possibility of confounding, and methodological issues around study designs which need to be taken into account in any interpretation of the results of this review.

The review has a number of strengths which should minimise bias: a research protocol defined the research question and the inclusion criteria; consistent methods of critical appraisal were applied; and the work was informed by an advisory group. Limitations of the review are that, owing to time and resource restrictions, authors of trials were not contacted for further information. Also, perhaps due to publishing word length limits in the primary literature, details of some trials were not reported. It is unlikely, however, that these limitations would have made a difference to the overall results of the review.

Conclusions

Implications for service provision

Based on the evidence reviewed in this report, it would seem that education delivered by a team of educators, with some degree of reinforcement of that education made at additional points of contact, may provide the best opportunity for improvements in patient outcomes. Educators need to have time and resources to fulfil the needs of any structured educational programme. There is also a need for education to have a clear programme at the outset. From the evidence reported it is unclear what resources would need to be directed at the educators themselves to ensure that they can deliver programmes successfully.

Recommendations for further research

Any future research should consider patient education within the context of overall diabetes care and as such follow guidelines for the development and evaluation of complex interventions. Good-quality, longer-term studies would be desirable but these would require careful consideration around the nature of any control group. Information is needed to clarify the sensitivity of diabetes education programmes to the performance of the diabetes educators, in order to ensure success and cost-effectiveness of education programmes.

Chapter 1

Aim of the review

This research updates a previous systematic review of structured education for diabetes. It was commissioned to inform the National Institute for Health and Clinical Excellence (NICE) Type 2 diabetes guideline update.

The aim of the study is to provide a review of the clinical effectiveness of current models of diabetes self-management education.

The potential clinical benefit of an effective programme of education would be better self-management. This may be measured in the long term by a reduced level of diabetes-related complications and in the short term by maintenance of recommended levels of blood glucose (BG) control, as reflected by glycated haemoglobin (GHb) levels. Other potential benefits would be greater flexibility of lifestyle and hence better quality of life (QoL).

Chapter 2
Background

Description of underlying health problem

Diabetes mellitus (diabetes) is a state of chronic hyperglycaemia (raised blood sugar), due to an absolute or relative deficiency of insulin, a hormone for metabolism.

There are two main types of diabetes that are distinguished by their pathological mechanisms:

- Type 1: Type 1 diabetes is a condition in which most or all of the insulin-producing cells in the pancreas have been destroyed, usually due to an auto-immune process. Patients with Type 1 diabetes are 'insulin dependent' and need insulin for survival; it was formerly called insulin-dependent diabetes (IDDM).[1] Type 1 diabetes will not be addressed in this report.
- Type 2: Type 2 diabetes is caused by a defect in the way the body responds to insulin – insulin resistance – or by a relative reduction in insulin production, or a combination of both. The pancreas may initially produce more insulin than normal in order to overcome the insulin resistance, but over time the production may fail. This type of diabetes was formerly called 'non-insulin-dependent' diabetes (NIDDM).[1]

Other types of diabetes, including gestational diabetes and less common types such as maturity onset diabetes of the young, will not be addressed in this report. Diabetes can also be secondary to other diseases such as pancreatitis or other endocrine disorders.

The symptoms of diabetes can include increased thirst, increased urination, extreme tiredness, weight loss, genital itching and blurred vision. However, Type 2 diabetes may also be symptomless.

Complications

The adverse effects of diabetes have traditionally been known as 'complications', although this term usually refers to effects that appear over the longer term. The effects fall into three main groups – acute metabolic upsets such as ketoacidosis or hypoglycaemia; microvascular disorders specific to diabetes; and an increased risk of large vessel disease such as heart disease.

Ketoacidosis

Without adequate supplies of insulin the body cannot use glucose effectively, and may break down fat and muscle for energy in an inefficient way, leading to acidosis, a disturbance of the acid–base balance. Ketoacidosis requires prompt hospital treatment, and can result in coma and occasionally death; however, this is relatively uncommon in Type 2 diabetes.[2]

Hypoglycaemia

Hypoglycaemia means that the BG has fallen too low. This is chiefly caused by the inadequacy of current methods of insulin delivery, but can also be due to too high a dose of oral hypoglycaemic agents (OHAs), inadequate food intake or sudden or sustained exercise, or it can occur without any apparent cause. It is not seen in patients controlled by diet alone and rates in Type 2 diabetes are substantially lower than in Type 1 diabetes.[3] Falling glucose concentrations cause an array of symptoms, which include shakiness, sweating and irritability. If not corrected by food or sugary drinks, these can progress to confusion, faintness, headache and disturbances of vision. Hypoglycaemia can cause loss of consciousness and convulsions if corrective steps are not taken.[3]

More long-term or 'late' complications from persistently raised BG levels include damage to large and small blood vessels and nerves.

Microvascular

Damage to small blood vessels (microangiopathy) can affect the eyes (diabetic retinopathy), kidneys (nephropathy) and nerves (neuropathy).[4] Diabetes is the single most common cause of blindness among adults aged 16–64 years.[5] Nephropathy may develop in 20–25% of people with diabetes and may progress to kidney failure.[5] The principal forms of neuropathy are sensorimotor peripheral neuropathy and autonomic neuropathy.

Macrovascular

Damage to large blood vessels (macroangiopathy) can lead to ischaemic heart disease, cerebrovascular disease, intermittent claudication, or gangrene of the feet. Patients with diabetes have a two- to three-fold higher risk of coronary heart disease in men and a four- to five-fold

increased risk in premenopausal women.[5] Stroke risk is increased two- to three-fold.[5]

People with diabetes are prone to foot ulceration and gangrene of the lower limb (which can result in amputation).[6] Other complications can affect the skin, joints and tendons, gastrointestinal tract, and sexual function.

Mortality is higher in people with diabetes than in people of similar age and sex, although diabetes is not usually recorded as the cause of death. Therefore, the contribution of diabetes to mortality is likely to be four to five times greater than reported in routine mortality statistics.[7] The main cause of death in diabetes is heart disease.[8–10]

Management

The three main goals in the treatment of diabetes are the normalisation of BG levels, blood pressure control, and lipid management. There is good evidence to show that tight control of BG and blood pressure (BP) can prevent or delay diabetic complications [as reported in the United Kingdom Prospective Diabetes Study (UKPDS)[11] and the Diabetes Control and Complications Trial (DCCT)[12]]. Blood glucose levels can be controlled by diet, oral hypoglycaemic drugs and/or insulin injections.

One of the features of diabetes care is that it aims to empower the patient to take charge of the disease. This is because of the chronic nature of diabetes and the relation between BG and factors such as diet and exercise (i.e. lifestyle). People with diabetes must monitor BG levels, either directly or via urine testing, take appropriate medication and/or insulin, eat a healthy diet aimed at both minimising BG levels and reducing future heart disease risk, engage in activity or exercise to maintain a healthy weight and to improve insulin sensitivity, and avoid smoking.

Diet plays a major role in the management of diabetes. Patients are advised to have a high-carbohydrate, high-'viscous'-fibre, low-fat and, if overweight, low-calorie diet. This kind of diet is difficult for patients to maintain. Attention to factors such as how rapidly different foods are metabolised (as reflected in the 'glycaemic index' of how rapidly BG levels rise after eating) can also help, but adds another complexity to the diet.

Exercise also plays an important part in diabetes management. Exercise helps overweight patients with Type 2 diabetes to bring their weight under control. Regular exercise can improve glycaemic (and BP) control.

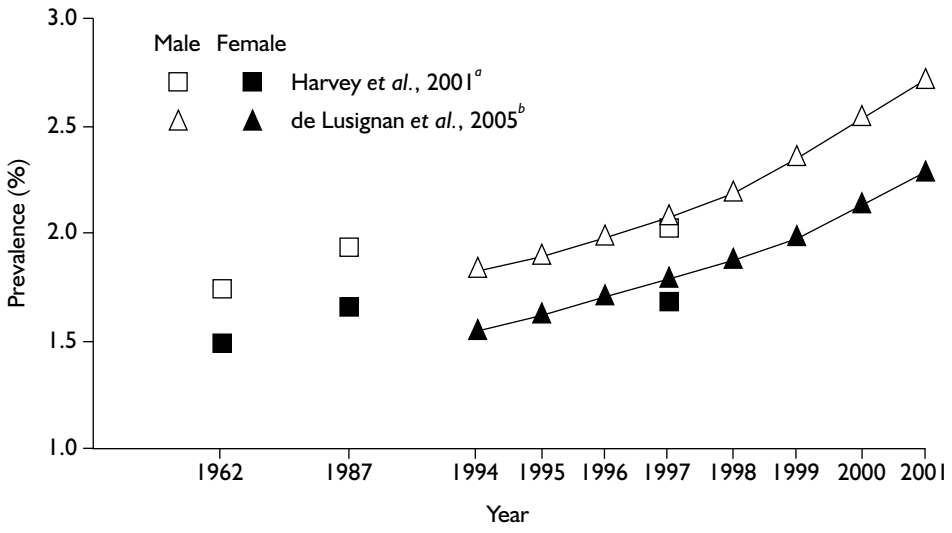
OHAs are often prescribed in Type 2 diabetes. Sulfonylureas sensitise the insulin-secreting cells and may upregulate insulin receptors and increase their number.[1] Metformin reduces BG predominantly by improved regulation of hepatic glucose production, which shows little dependence on the residual effectiveness of insulin-secreting cells.[1] Metformin is commonly prescribed as the first-line treatment of choice.[13,14] Other oral agents, such as the glitazone drugs, are available and are used as an adjunct to sulfonylureas and metformin. Sometimes, insulin and metformin are used in combination (e.g. for obese patients).

Insulin therapies and regimens vary. Depending on the goals of therapy, the frequency of insulin dosing can vary. Recent evidence that tight control of blood glucose levels can prevent or delay serious complications has led to regimens that involve more complex patterns of daily insulin treatment.

Incidence and prevalence

Diabetes is one of the most common chronic disorders, but estimates of incidence and prevalence vary. It has been estimated that over two million people in the UK today have diagnosed diabetes and a further 750,000 have diabetes without knowing it.[15] More than one-fifth of older white British citizens have either undiagnosed Type 2 diabetes or impaired fasting glucose.[16] Cases of Type 2 diabetes are much more common than those of Type 1 and estimates suggest that 85–95% of people with diabetes have Type 2.[15] The number of patients with diagnosed diabetes has been increasing significantly in recent years in the UK and worldwide. Between 1994 and 2001, the prevalence of Type 2 diabetes in the UK increased, on average, by 0.11% per annum in the male population and by 0.09% per annum in the female population, with signs that the rate of increase is rising (*Figure 1*).[17]

Based on these data[17] and assuming a constant rate of increase since 1994, approximately 3.5% of the male population and 3% of the female population would be expected to have Type 2 diabetes in the UK by 2008. This would equate (using a population projection from the Office of National Statistics) to over 1.63 million people with Type 2 diabetes in England in 2008.[17] It has been estimated that the number of people in the UK with diabetes will reach 3 million by 2010.[19] Rising levels of obesity and an ageing population



[a] Standardised to the age distribution of the 1997 population, based on 74 general practices in Wales
[b] Standardised to the age distribution of the 2001 population, based on 74 general practices in the UK

FIGURE 1 *Prevalence of Type 2 diabetes in the UK, 1962–2001, based on records from general practices. Data from Harvey and colleagues[18] and de Lusignan and colleagues.[17] Note that in the study by de Lusignan and colleagues,[17] the age-standardised prevalence rates were almost identical with the crude overall prevalence rates.*

are thought to be largely responsible, although changes in the definition of diabetes may have had some effect.[17]

Table 1 demonstrates the prevalence of insulin- and non-insulin-treated diabetes per 1000 patients in 1998. It is important to note that insulin-treated patients are likely to be a mix of patients with Type 1 diabetes and patients with Type 2 diabetes.

Table 2 presents data on the prevalence of Type 2 diabetes reported by family practices in the UK in 2001 by age and gender from the study by de Lusignan and colleagues.[17] Type 2 diabetes primarily affects people over age 40 years as seen in *Table 2*, although increasingly it is appearing in young people and young adults.[20–22] Type 2 diabetes tends to have a more gradual onset than Type 1 diabetes and may be found incidentally, for example at routine health checks.[5]

Risk factors for Type 2 diabetes include being overweight, having a close relative with diabetes, or having gestational diabetes during pregnancy. It is more common in some ethnic groups, particularly Asians.

TABLE 1 *Prevalence of insulin- and non-insulin-treated diabetes per 1000 patients*

	Age (years)									
	0–4	**5–15**	**16–24**	**25–34**	**35–44**	**45–54**	**55–64**	**65–74**	**75–84**	**85+**
Prevalence of insulin-treated diabetes per 1000 patients, by age and gender in 1998										
Males										
Rate/1000	0.2	1.7	3.5	4.6	6.2	7.2	10.0	13.3	10.9	6.8
Females										
Rate/1000	0.3	1.9	3.2	4.3	5.2	5.7	9.4	12.1	9.4	5.9
Prevalence of non-insulin-treated diabetes per 1000 patients, by age and gender in 1998										
Males										
Rate/1000	0	0	0.2	0.6	3.6	11.8	30.5	47.5	47.4	43.1
Females										
Rate/1000	0	0	0.2	0.6	2.8	7.9	20.3	35.7	37.1	33.8

Source: Office for National Statistics.

TABLE 2 *Prevalence (per 1000) of Type 2 diabetes reported by family practices in the UK in 2001 (adapted from de Lusignan and colleagues[17])*

	Age (years)						
	0–34	**35–44**	**45–54**	**55–64**	**65–74**	**75–84**	**85+**
Male	1	9	27	57	101	109	89
Female	2	9	19	40	73	76	68

Type 2 diabetes is more common in men than women (*Figure 1*, *Table 2*). Diabetes seems to remove women's natural protection against heart disease and stroke before the menopause.[20] In a population-based study in Finland (1986–8) in women aged 65–74 years, the age-adjusted prevalence of ischaemic heart disease was 65.9% in those with Type 2 diabetes compared with 39.7% in the non-diabetic population.[23]

Diabetes is three to five times more common among people of African-Caribbean and Asian origin living in the UK.[24] Diabetes in these groups tends to develop at a younger age and may be related to different underlying mechanisms.[25]

Type 2 diabetes is more prevalent among less affluent populations. Those in the most deprived one-fifth of the population are 1.5 times more likely than average to have diabetes at any given age.[20] Prevalence of diabetes overall (Type 1 and 2) in England varies both with household income (higher prevalence with lower household income) and geographical location (lower prevalence in northern England).[26]

Education

The goals of management for patients with diabetes include optimisation of BG control, prevention of immediate complications, and prevention of long-term complications (by good BP management and lipid control).[27] All of the treatment factors, diet, medication, and exercise, must be carefully managed on a daily basis by patients themselves. Patients must also be able to recognise when they need professional help. Good self-management depends on initial education about the interaction of all the treatment factors and ongoing support and reinforcement.

Education of patients with diabetes is considered a fundamental aspect of diabetes care.[28] Because patients are responsible for the day-to-day control of their diabetes, it is critical that patients understand the condition and how to treat it.[29] All members of the diabetes care team play a role in education. Education can be on a one-to-one basis or in groups, or both. All contacts between patients and practitioners can be an opportunity for education.

For patients treated with insulin, monitoring BG levels is necessary to try to maintain levels as consistently near normal as possible.[11,12] BG can be checked by means of a simple blood test or, less sensitively, by testing the urine. Learning when and how to monitor and how to interpret BG is an important aspect of self-management, particularly for insulin-treated patients, who are at risk from hypoglycaemia and ketoacidosis.

Current service provision

The National Service Framework (NSF) for diabetes, published in 2001, identified the importance of patient-centred care in the management of diabetes and the need to empower people to take responsibility for managing their condition on a daily basis.[20] This was outlined in standard 3, which states that "all children, young people and adults with diabetes will receive a service which encourages partnership and decision-making, supports them in managing their diabetes and helps them adopt and maintain a healthy lifestyle".[30] The complexities of self-care and the vital role of education in providing people with the knowledge and skills necessary to manage their diabetes were recognised in the NSF for diabetes delivery strategy.[31] The delivery strategy stated that treatment in line with the NSF standards for diabetes should include referral to structured education. Other national policy initiatives linked to the NSF for diabetes have echoed the valuable role of education programmes in improving health and the need for establishing standards.[32–36]

Since the publication of the NSF standards and delivery strategy, several initiatives have been

developed to provide guidance and recommendations to the NHS and to patients. NICE undertook an appraisal of the use of patient-education models for diabetes, publishing guidance in April 2003.[28] NICE recommended that "structured patient education is made available to all people with diabetes at the time of initial diagnosis and then as required on an ongoing basis, based on a formal, regular assessment of need".[28] Although initially this guidance was not mandatory, from January 2006 it became a legal obligation for Primary Care Trusts (PCTs) to make funds available for this guidance to be followed. This is important as it was recognised that patient-education programmes were not delivered in a formal, comprehensive and standardised way in England and Wales.[28,37] Differences were evident in the length, content and style of education programmes available, with many being unstructured, unevaluated and delivered by health professionals with no specific training.[19]

The Patient Education Working Group (PEWG) for diabetes, established in May 2004 by the Department of Health and Diabetes UK, has reported recommendations for establishing high-quality patient-education programmes.[32] The framework has been developed from current best practice and provides a basis for local services to meet the recommendations made in the NSF for diabetes and NICE guidance. It presents advice on quality standards, health professional training and quality assurance in addition to reporting on current education programmes. The key priority for PEWG was to establish quality standards for patient-education programmes. It recognised that programmes should be evidence based, dynamic and flexible to individual needs, and involve users in their development. The report recommended that programmes should support self-management attitudes, beliefs, knowledge and skills for the learner, their family and their carers, and also that programmes should have specific aims and learning objectives which are shared with the patient, carers and family. Importantly, patient-education programmes should have a structured, written curriculum, be delivered by trained educators, undergo quality assurance and be audited. Specific guidance on course content has been recommended by Diabetes UK,[38] including information on the nature of diabetes, day-to-day management, specific issues, living with diabetes, and sick-day rules. Monitoring of progress against PEWG's quality standards was considered important and it was felt this could be achieved through use of the Diabetes Continuing Care Reference Dataset, which brings together relevant data from the National Diabetes Audit, General Medical Services (GMS) Quality and Outcomes Framework, DiabetesE performance management tool, and the Better Metrics Performance Indicator Project.

Underlying patient-education programmes is the need to ensure appropriate training for health professionals which aims at encouraging promotion of behaviour change among patients. Education programmes for educators have been developed internationally by the International Diabetes Federation and, in England and Wales, within the Dose Adjustment For Normal Eating (DAFNE) (for Type 1 diabetes), Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND), and Diabetes X-PERT programmes and other local initiatives (e.g. in Bournemouth and Warwick). These programmes address the theoretical basis and underlying philosophy of structured education, and include observation of an education programme and quality assurance. PEWG identifies the importance of quality assurance in ensuring the quality and validity of any education programme, maintaining standards and allowing further development. The PEWG report provides recommendations for internal and external quality assurance and accreditation of programmes.

Further guidance has emerged from the Department of Health, National Diabetes Support Team, and Diabetes UK initiative in the form of toolkits to assist commissioners and local diabetes groups in developing structured diabetes education programmes and commissioning services.[39,40]

Patient-education programmes in the UK

When NICE undertook their appraisal of patient-education models for Type 2 diabetes, they identified a lack of evaluated UK-based programmes, something already recognised by the Audit Commission.[19] Some local programmes had developed in Bournemouth, Leicester, Northumbria, Portsmouth, and St Helens and Knowsley. Details of the Bournemouth and St Helens and Knowsley programmes are discussed elsewhere.[37] However, limited formal evaluation of these programmes meant an inadequate evidence base from which to adopt a model of good practice nationwide. As a consequence, the DESMOND collaboration was established in

2002–3. DESMOND has devised, developed and is evaluating a programme of patient education targeted at newly diagnosed patients through a pilot phase involving 15 PCTs in England. A full evaluation through a randomised controlled trial (RCT) of 1000 patients from 12 PCTs in England and two Community Health Partnerships in Scotland was due to report in 2007. DESMOND has a theoretical and philosophical base, supporting people in identifying their own health risks and setting their own behavioural goals. Also, it will examine development of an education programme for ethnic or cultural minorities. Despite the fact that evaluation of the DESMOND programme is ongoing and preliminary results have not been released, it is at the time of writing undergoing phase one of a national roll-out. By the end of April 2006, 50 PCTs had DESMOND-trained educators and a further 20 PCTs were planned to be included by the end of 2006.[31] It will be essential to ensure that results from the RCT evaluation of DESMOND inform future development of local programmes, whether based on DESMOND or other initiatives.

Another programme, the Diabetes X-PERT Programme, has been developed by Burnley, Pendle and Rossendale PCT. It is an award-winning initiative based on theories of empowerment and discovery learning.[41] The programme was developed systematically over 5 years and has been evaluated through an RCT, showing positive impacts on clinical, lifestyle and psychosocial outcomes. Other RCT evaluations of structured education programmes for Type 2 diabetes are under way in the UK, although these are limited in number. In Warwick, an RCT of a structured education programme is under way using a diabetes manual given to patients in general practice, backed up by one-to-one consultations between patients and health professionals. Another structured education programme for black and minority groups is being undertaken by the Royal London Hospital, focusing on Bangladeshi communities [Bangladeshi Initiative for Prevention of Diabetes (BIPOD)]. BIPOD focuses on determining knowledge of risk, and developing understanding of the relationship between eating, activity and prevention of diabetes. Established local education programmes have had to undergo quality assurance to ensure the programmes meet the requirements established as part of the NSF for diabetes (e.g. in Poole, Bournemouth and Torbay) (Carter L, Somerset PCT; personal communication, 2007). Despite these initiatives, more research is required into education programmes to assess the importance of one-to-one education and ongoing support in children and adolescents, black and minority ethnic groups, carers, pregnant women and other groups who have special needs.[32]

Despite the lack of an evaluated nationally led diabetes education programme in the UK, PCTs were legally obligated from January 2006 under NICE guidance to fund and provide a patient-education programme for people with diabetes. For those who do not already operate a quality-assured local education programme, DESMOND and X-PERT programmes provide a framework. It is thought that many PCTs and local diabetes communities have adopted these programmes, in some instances replacing existing local initiatives. Concerns have been raised that DESMOND and X-PERT may not meet the needs of different communities, which may be better served by programmes tailored to their specific requirements. Further research may be necessary to assess the comparative performance of DESMOND and X-PERT against other locally developed patient-education programmes, although this is unlikely to be through controlled trials. It is important that structured education programmes are flexible and responsive to the needs of individuals and their communities, irrespective of whether they are a nationally recommended or a locally developed programme. Evaluation of the different methods of delivery of structured education programmes may be justified, comparing aspects such as the staff and setting for delivering the programme. Despite this legal obligation, funding of NICE guidance is a common concern. Provision of the structured diabetes education programmes has led to concerns that developing and implementing such programmes will be at the cost of other aspects of the diabetes service.

Description of the interventions considered in this review

Education for people with diabetes aims to improve their knowledge and skills, enabling them to take control of their own condition and to integrate self-management into their daily lives. Self-management also occurs within the context of overall health management. Education is a foundation for understanding how (and whether) to regulate one's own diabetic medication and often cannot be evaluated outside the context of treatment modifications. For these reasons, it is somewhat artificial to consider the effects of

education alone, as the aim of education is to enable patients to use the various therapies better.

The educational interventions considered in this review are all aimed at educating adults with Type 2 diabetes. A number of differences can be observed between the included interventions, such as the duration of the intervention, and the specific topics covered. However, all can be described as structured educational interventions for diabetes self-management, and have met a number of criteria assessing their reproducibility (see the section 'Methods for reviewing effectiveness', p. 11).

Interventions for Type 2 diabetes fall into two basic categories: those in which the aim of the intervention was to educate patients on a range of topics related to diabetes self-management, and those in which the intervention was focused on one or two aspects of self-management alone (e.g. diet and/or exercise).

Due to the differences in the interventions within each of these groups, a summary only has been provided here; more detailed descriptions of interventions are given with the assessment of clinical effectiveness (see Chapter 3).

Chapter 3

Assessment of clinical effectiveness

Methods for reviewing effectiveness

The *a priori* methods for systematically reviewing the evidence of clinical effectiveness are described in the research protocol (Appendix 1), which was sent to experts for comment. Although helpful comments were received relating to the general content of the research protocol, there were none that identified specific problems with the methods of the review. The methods outlined in the protocol are briefly summarised below.

Search strategy

Sources of information, search terms and a flow chart outlining the identification of studies are presented in Appendix 2.

Inclusion and data extraction process

Titles and abstracts of studies identified by the search strategy were assessed for potential eligibility by two reviewers. The full text of relevant papers was then obtained and inclusion criteria were applied by one reviewer and checked by a second reviewer. Data were extracted by one reviewer using a standard data extraction form and checked by a second reviewer.

The quality of included RCTs and controlled clinical trials (CCTs) was assessed using criteria recommended by NHS Centre for Reviews and Dissemination (CRD)[42] (Appendix 4). Quality criteria were applied by one reviewer and checked by a second reviewer.

At each stage, any differences in opinion were resolved through discussion or consultation with a third reviewer.

Inclusion criteria

Design

RCTs and CCTs that compared a specific educational programme with usual care or with another educational programme were included. Because diabetes care is constantly evolving, CCTs were required to have a concurrent control group. RCTs or CCTs that compared models of group education with individual education were included.

Interventions

The review was limited to educational interventions, that is, the dissemination of knowledge and skills brought about using a number of approaches, which can be carried out with the normal range of personnel available in diabetes care. Trials that only evaluated specific, specialised psychological interventions aimed at changing an individual's perceptions, such as cognitive/behavioural or psychoanalytic therapy, or counselling, were excluded. Educational interventions that included a psychological component were included. Studies of education solely about specific complications (e.g. foot care) were not included.

Reporting

In order potentially to inform practice, included studies were required to have been reported with sufficient detail to be reproducible. They were required to have described the main components of the educational programme, such as:

- what the intervention is, with some description of the topics covered
- who provides instruction (e.g. post and qualification)
- how is education delivered (e.g. in person, or by computer)
- group or individual
- length of intervention and number of sessions
- target audience (e.g. Type 2; newly diagnosed)
- didactic or interactive instruction
- training for the educators.

Educational interventions that were not described in sufficient detail to allow them to be reproduced were not included.

Participants

Participants should have been diagnosed with Type 2 diabetes using the standard diagnostic criteria in effect at the inception of the study. Both newly diagnosed and patients with established diabetes were included. Participant populations should have been described as 'adults' or comprised a minimum of 80% at 18 years of age or older.

Outcomes

A range of outcomes was assessed for the included trials as stated *a priori* in the research protocol. As diabetes is a chronic condition and complications may not appear for years after diagnosis, it is important that an intervention has a lasting effect. The effects on lifestyle interventions in chronic conditions are often difficult to maintain over a long period.[43]

Included studies were required to report results from a minimum of 1 year after the beginning of the intervention. For ease of understanding, these will be discussed within each subsection of the clinical effectiveness sections, in three categories: diabetic control, diabetic end-points, and QoL and cognitive measures.

Diabetic control outcomes

These outcomes are physiological measures that are indicative of metabolic control, lifestyle modifications or cardiovascular risk. They are important indicators of self-management success and serve as surrogate indicators of the risk of long-term complications:

- GHb (e.g. HbA_{1c}) is a measure that reflects glucose levels in the blood over a relatively long interval (6–8 weeks), and therefore provides a much better guide to diabetes control than simple BG measurements.
- BP and blood lipids (cholesterol and triglycerides) are risk factors for cardiovascular disease (CVD).
- Body mass index (BMI) and weight are related to the development of problems in glycaemic control initially and are also risk factors for the development of cardiovascular disease (CVD).
- In Type 2 diabetes, patients may be able to control their BG (at least early in the disease) by modifying lifestyle factors such as diet and exercise. Therefore, an important treatment goal and indicator of intervention success may be reductions (or lack of increases) or other changes in the level of oral hypoglycaemic agents used by patients.

Diabetic end-points

Certain variables are indicators of the progression of diabetes into the associated complications discussed previously, or the general deterioration of health or diabetic status:

- Episodes of hypoglycaemia or ketoacidosis: patients may have too little glucose in the system or too much. In Type 2 diabetes these are relatively rare occurrences; however, where a study reported these outcomes they have been discussed.
- Retinopathy and nephropathy are long-term complications associated with long-term poor regulation of BG. Neuropathy can be an acute or long-term complication. Many studies will be too short in duration to measure these long-term complications.
- Rates of hospital admission are an indication of the general health of patients and whether BG is under control.

Quality of life and cognitive measures

Interventions can affect how patients feel about themselves, how they are functioning in society, and their perceived control of their health status. QoL has been measured with a number of validated instruments. Some instruments are disease-specific to assess QoL in relation to diabetes whereas others are generic measures.

Some of the studies used assessment instruments that were not validated and this may mean that the instruments may not be measuring what they claim to. Results of non-validated instruments were not data extracted and will not be discussed.

Cognitive outcome measures include attitudes toward diabetes, and diabetes knowledge. Increased knowledge of diabetes may contribute as much or more to patients' perceived control of diabetes as to metabolic control. Patients who are more knowledgeable may feel better about their diabetes and their ability to self-manage.

Validated measures of QoL, knowledge and other cognitive measures that were used in the included studies are described in more detail in Appendix 7.

Quality considerations

As for most interventions, it is important to consider the effects of diabetes education relative to a control group. Ideally, to minimise bias, patients should be randomly assigned to intervention and control groups (RCTs). In this review, CCTs are also considered provided that a control group was evaluated concurrently with the intervention group(s). Although many studies of diabetes interventions have used designs that have not used a control group and relied upon before-and-after measures, this is not a satisfactory approach. Other factors could be confounded with the intervention such that after measures would differ from before measures. These differences cannot be attributed

to the intervention and cannot be evaluated in uncontrolled designs.

It is important that statistical comparisons are made between the intervention and control groups rather than considering only within-group changes from baseline. If within-group changes are reported, they may reflect not only the effect of an intervention, but also effects of the study conditions or other factors that co-vary with the intervention. In newly diagnosed patients with diabetes, it might be expected that various measures will change simply as patients adjust to the diagnosis and attempt to make recommended adjustments to lifestyle and/or medication. The natural evolution of Type 2 diabetes is for diabetic control to worsen over time, and methods to compare results appropriately between intervention and control groups are crucial. For example, maintaining diabetic control in an intervention group relative to deteriorating control in a control group may be a valuable outcome.

Data synthesis

Data were synthesised through a narrative review with tabulation of results of all included studies. Full data extraction forms are presented in Appendix 5. It was not considered appropriate to combine the included studies in a meta-analysis due to heterogeneity of the patient groups and comparator treatments.

Results

Quantity and quality of research available

Included studies of educational effects in Type 2 diabetes have generally focused on evaluations of metabolic control, diabetic end-points such as late complications, and QoL. There are some circumstances in which some of the basic treatment goals are not sought. For instance, in older patients the goal of normoglycaemia may not be as prominent. In most patients with Type 2 diabetes, a treatment goal is to minimise or avoid the use of OHAs for as long as possible and therefore some studies measured the use of OHAs as an end-point (for full details see the next section and the section 'Trials of focused self-management interventions', p. 29).

Twenty-one published trials **[academic in confidence (AIC) data removed]** that included only participants with Type 2 diabetes met the inclusion criteria. These trials fell into two categories: those in which the intervention was a more or less complete self-management approach (13 published trials, **[AIC data removed]** see *Table 3*) and those in which the intervention was focused on one or two aspects of self-management (e.g. diet and/or exercise) (eight trials; see *Table 12*, p. 30). The clinical effectiveness of the two categories of trials will be discussed separately followed by a summary of findings from interventions directed at Type 2 diabetes generally.

The nature of interventions aimed at Type 2 diabetes is variable. There are variations in the characteristics of patients recruited, the focus of the intervention, the intensity and duration of the intervention, the theoretical foundation (if any) for the intervention, the providers and the setting. There is very little consistency among studies, which makes it difficult to fully summarise the results.

Trials of self-management interventions

Of the 13 studies that compared self-management education for patients with Type 2 diabetes and met the inclusion criteria for the review, 11 were RCTs and two were CCTs (*Table 3*; Appendix 5). The number of participants recruited varied from 51 to 437 in the published RCTs and from 124 to 127 in the CCTs. **[AIC data removed]**. Interventions were very similar in two of the published RCTs[49,52] and for the two CCTs (*Table 3*). One of the published RCTs compared education in more than two groups of patients.[51] Another published RCT compared 'extended' and 'compressed' versions of an intervention.[52] All the remaining published trials compared an intervention group with a usual-care control group. In three of these studies (altogether six publications) the usual care group was randomised to a waiting list.[49,50,56–58,60] **[AIC data removed]**. Six of the published trials were carried out in primary care,[46,49,52,61,63,64] two in secondary care,[59,62] one in a university clinic (three publications),[53–55] one in pharmacies,[60] one across both primary and secondary care (three publications)[56–58] and one which started in secondary care but continued reinforcement interventions after hospital discharge.[45] One trial did not report the setting for the study.[51] **[AIC data removed]**.

In two published studies the duration of diabetes was within 1 year of diagnosis[51,59] **[AIC data removed]**. The duration of diabetes in the remaining trials ranged from 2.6 years[60] to 9.8 years.[53–55] In 12 of the published studies

TABLE 3 *Included studies of self-management education interventions for Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)]*

Reference and design	Intervention	No. of participants	Duration of intervention	Timing of evaluation[a]
[44][AIC data removed]				
Ko *et al*., 2007[45] RCT	Two groups: 1. Self-management education delivered to inpatient groups by 8 professional diabetes health providers; 30 hours over 5 days in hospital followed by one 3-hour outpatient education reinforcement session per year 2. Same as intervention but given only the first 4 hours of inpatient education and with no education reinforcement during annual 3-hour follow-up sessions	437	5 days inpatient followed by annual 3-hour outpatient sessions	2 months then at 3-monthly intervals after discharge (data reported for 6 months and annually up to 4 years)
Deakin *et al*., 2003, 2006[46–48] RCT	Two groups: 1. Self-management education in groups delivered by a diabetes research dietician in six, weekly, 2-hour sessions 2. Usual care plus diabetes education and individual review with (separately) a dietician (30 minutes), practice nurse (15 minutes) and GP (10 minutes)	314	6 weeks	14 months
Brown *et al*., 2002[49,50] RCT	Two groups: 1. Self-management education. Team provided group education for 52 contact hours 2. Usual care by physicians and waiting list	256	9 months + 3 months of support group sessions = 1 year	1 year
Campbell *et al*., 1996[51] RCT	Four groups: 1. Minimal instruction. Team-delivered with 2 contact hours 2. Individual education. Team-delivered with 8 contact hours 3. Group education. Team-delivered with ~4 days total contact time 4. Behavioural programme. One nurse provided at least 6 contact hours	238	Differed between and within groups. Up to 1 year	1 year
Brown *et al*., 2005[52] RCT	Two groups: 1. Self-management, didactic and interactive, group education delivered by a team (nurses, dieticians and community workers) with 52 hours of contact over 12 months 2. Similar intervention components to (1) but compressed to 22 hours of contact over 12 months based on information from focus groups	216	1 year	3 years (but extractable data not given for >1 year)
Trento *et al*., 2001;[53] 2002;[54] 2004[55] RCT	Two groups: 1. Self-management education in groups by a team (1 or 2 physicians and an educationalist). Up to 32 contact hours over first 2 years; contact continued over the following three years (details unclear) 2. Usual care (seen by physicians every 3 months). Also kept weekly weight and nutrition diaries, and received individual education sessions from a nutritionist (details not given)	112	Varied amongst patients; up to 5 years	5 years

continued

TABLE 3 *Included studies of self-management education interventions for Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)] (cont'd)*

Reference and design	Intervention	No. of participants	Duration of intervention	Timing of evaluation[a]
Cooper *et al*., 2002;[56] 2003[57,58] RCT[b]	Two groups: 1. Self-management, mainly interactive, group education delivered by DSNs with 16 hours of contact 2. Usual care and randomised to a waiting list for 12 months	89	8 weeks	1 year
Heller *et al*., 1988[59] RCT	Two groups: 1. Self-management group education (weight loss focus). Delivered by dietician and DSN with 7.5 contact hours 2. Usual care with physician and also saw dietician every 3 months	87	6 months	1 year
Sarkadi and Rosenqvist, 2004[60] RCT	Two groups: 1. Self-management, didactic and interactive, group education delivered by specially trained pharmacists, initially with a DSN (contact time not reported) 2. Patients randomised to a waiting list for two years (no other details)	77	1 year	2 years
Goudswaard *et al*., 2004[61] RCT	Two groups: 1. Self-management (assume mainly didactic) individual education, delivered by one-to-one contact with DSNs. Approximately 2.5 hours of total contact over 6 months 2. Usual care according to the Dutch Guideline on Type 2 diabetes, with education given during normal medical appointments	58	6 months	18 months
Raz *et al*., 1988[62] RCT	Two groups: 1. Self-management group education. Team-delivered. Minimum of 12 contact hours 2. Usual care. Follow-up every 2 months	51	1 year	1 year
Kronsbein *et al*., 1988[63] CCT (groups from medical practices, waiting-list controls)	Two groups: 1. Self-management education. Group education by physician assistants. ~7 contact hours 2. Usual care with GP. No details	127	1 month	1 year
Domenech *et al*., 1995[64] CCT (groups from similar medical practices)	Two groups: 1. Self-management education. Group education by physicians. ~7 hours contact time 2. Usual care. No details	124	1 month	1 year

DSN, diabetes specialist nurse.
[a] Based on the start of the intervention.
[b] Cooper *et al*.[65] also refer to this trial but duplicate existing information.

[AIC data removed] diabetes duration was similar in the intervention and control groups (difference <0.6 year). In the remaining published trial,[60] the difference was larger (5.9 years in the intervention group compared with 2.6 years in the control group), but it is unclear whether this was statistically significant. The mean age of the participants in all published studies was in the range 49.6–66.5 years; **[AIC data removed]**. In the majority (eight) of the published studies, the maximum period of follow-up from inception was 1 year (i.e. the minimum period eligible for inclusion in this review), **[AIC data removed]**. The longest periods of follow up were 5 years,[53–55] 4 years,[45] 2 years,[46,47] 18 months[61] and 14 months.[60]

The quality of reporting and methodology of the included studies was generally poor (*Tables 4* and *5*), perhaps reflecting publication word limits. The method of randomisation was unknown for all but five of the published RCTs, by Trento and colleagues,[53–55] Goudswaard and colleagues,[61] Heller and colleagues,[59] Ko and colleagues,[45] and Cooper and colleagues[56] **[AIC data removed]**. Concealment of allocation was adequately reported in only four of the published trials,[46,56,59,61] **[AIC data removed]**, and only three published trials reported whether outcome assessors were blinded to treatment identity.[46,62,45] The similarity of groups at baseline was reported in all included published trials **[AIC data removed]**, but only one of the published studies reported an analysis by intention-to-treat (ITT) that was assessed as adequate.[49]

Description of the interventions

Although most of the trials developed their interventions independently, the interventions were broadly similar in educating patients about a wide range of components of self-management in diabetes. Unfortunately, the descriptions of interventions were often limited and vague. This is despite an attempt to include only trials that provided some detail as to the nature of the intervention. An overview of the different interventions is provided here but for further detail see Appendix 5.

Topics that were covered in the intervention arm(s) of all of these studies included nutrition, diet and self-monitoring (blood and/or urine). Only two studies did not specifically include the importance of body weight in their education intervention,[52,60] and only two studies did not include exercise or physical activity.[53–55,59] The majority of studies (apart from four[51,61,62,64]) also discussed diabetes complications and/or management of complications. Seven studies described education for foot care specifically,[45,49,51,52,56,63,64] and five included consideration of how to handle sick days.[45,49,56,63,64] Two studies[63,64] trained patients to reduce or stop oral agents in the case of hypoglycaemia (Mühlhauser I, University of Dusseldorf: personal communication, 2002). Several other topics were incorporated into only one study each. Coverage of these topics might have been underestimated in this review, however, as the brief methodological summaries in many of the studies might not have described all the relevant intervention components (for example, provision of basic information to patients on the causes and treatment of diabetes was mentioned in only five of the 13 published studies of self-management interventions[45,51,61–63]) **[AIC data removed]**.

In eight published studies **[AIC data removed]** the training was provided by a team. The most frequent health professionals who delivered education in teams were nurses (eight studies)[49,51,52,56–62] and dieticians (five studies).[49,51,52,59,62] All teams that had dieticians also included nurses. Other members of the education teams were physicians (three studies),[53–55,62,45] community workers (two studies),[49,52] pharmacists (two studies),[60,45] and an educationalist and medical students (one study).[53–55] **[AIC data removed]**. In four studies, the training (description of which was often vague) appears to have been provided by one person. The individual trainers were a diabetes research technician,[46] diabetes nurse,[61] physician,[64] or physician assistant.[63] In the remaining study it is unclear how many people provided the training.[60]

Only three published studies **[AIC data removed]** mentioned that they trained educators. In two studies by Brown and colleagues,[49,52] nurses and dieticians attended seminars on diabetes education and participated in a supervised clinical practicum with outpatients, and community workers with Type 2 diabetes participated in an 8-week programme on diabetes self-management. In the study by Cooper and colleagues,[56] nurse trainers trained together, were provided with a training manual, and each ran a supervised pilot course to ensure standardisation of content and reduce potential treatment heterogeneity. **[AIC data removed]**.

There was considerable variation in the number of hours of contact between the patient(s) and

TABLE 4 *Quality assessment of RCTs of education for Type 2 diabetes (CRD criteria) [ordered by type (RCT, CCT) and size (largest first)]*

Study	Randomisation	Concealment of allocation	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values
[AIC data removed]								
Ko *et al.*, 2007[45]	Adequate	Inadequate	Reported	Yes	Adequate	Adequate	Inadequate	Partial
Deakin *et al.*, 2003, 2006[46–48]	Partial	Adequate	Reported	No	Adequate	Adequate	Inadequate	Adequate
Brown *et al.*, 2002[49,50]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Adequate	Partial
Campbell, *et al.*, 1996[51]	Unknown	Unknown	Reported	Yes	Unknown	Partial	Unknown	Partial
Brown *et al.*, 2005[52]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Inadequate	Inadequate
Trento *et al.*, 2001–4[53–55]	Adequate	Unknown	Reported	Yes	Inadequate	Adequate	Inadequate	Adequate
Cooper *et al.*, 2002–3[56–58]	Adequate	Adequate	Reported	Yes	Unknown	Adequate	Inadequate	Partial
Heller *et al.*, 1988[59]	Adequate	Adequate	Reported	Yes	Partial	Adequate	Unknown	Adequate
Sarkadi and Rosenqvist, 2004[60]	Partial	Unknown	Reported	Yes	Unknown	Partial	Inadequate	Partial
Goudswaard *et al.*, 2004[61]	Adequate	Adequate	Reported	Yes	Unknown	Adequate	Inadequate	Adequate
Raz *et al.*, 1988[62]	Unknown	Unknown	Reported	Yes	Adequate	Inadequate	Unknown	Adequate

TABLE 5 *Quality assessment of CCTs of education for Type 2 diabetes (CRD criteria)*

Study	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values	Representativeness
Domenech *et al.*, 1995[64]	Reported	Yes	Unknown	Partial	Unknown	Adequate	Yes
Kronsbein *et al.*, 1988[63]	Reported	Yes	Unknown	Adequate	Unknown	Partial	No

provider(s) for each intervention. This ranged from approximately 2.5 hours (in a 6-month intervention)[61] to 52 hours [in a 1-year intervention (in two studies)].[49,52] Some interventions began with 2–4 intensive sessions of 90–120 minutes followed up with additional sessions at, for instance, 3 and 6 months.[51,59,62] One study included four interventions (three included in this review) that varied in duration and other characteristics, with the shortest intervention being 2 hours and the longest approximately 30 hours of contact.[51] The interventions also varied considerably in whether sessions were provided over a short interval or were spaced out over time. In one of the longest studies,[53–55] the interventions were spread throughout a 4-year period but the timing varied among patients (details are clearly reported only for the first 2 years). The briefest interventions in the published studies lasted for 1 month.[63,64] **[AIC data removed]**. In two studies the total contact time is unclear[51,53–55] and in two studies it was not reported.[60,62]

Interventions were provided to groups of participants in all but two of the studies.[51,61] Of three interventions compared by Campbell and colleagues[51] that are eligible for inclusion in this review, two involved individual instruction and one was a group intervention.

Six of the studies did not mention that they were based on any particular theory of health psychology or behaviour change. Of the remaining seven published studies, **[AIC data removed]** two were based on patient empowerment,[46,56–58] two developed a culturally specific intervention aimed at Mexican-Americans based on four meta-analytic reviews of previous diabetes education interventions,[49,50,52] two used cognitive-behavioural strategies in a behaviour change intervention,[45,51] and one used an experience-based learning intervention with a pedagogical principle that problems would be solved by the group rather than by the leader.[60] **[AIC data removed]**. Limited detail of the theory underpinning the educational intervention was provided in the majority of these studies but any additional information can be seen in the relevant section of Appendix 5. Details are as described by the trial authors and the reviewers have not attempted to comment on the validity or the nature of these theories.

All of these studies attempted to address multiple components of diabetes self-management, but there were no specific manipulations of medical treatment associated with the educational interventions. Individual patients were followed by their physicians or trialists and may have had their medical treatment varied as deemed necessary, but patients were not being trained to self-regulate their own medication, for instance. There were also variations in how many patients were receiving medications.

Outcomes reflecting diabetic control

Table 6 shows the results for GHb for the included studies of self-management education in Type 2 diabetes.

Six published studies reported statistically significant differences between intervention and control groups in GHb.[45–47,49,53,60,62] **[AIC data removed]**. All six of these were RCTs (*Table 6*). Ko and colleagues[45] reported a lower (better) percentage of GHb in the intervention than the control group on all occasions after the intervention. This difference was statistically significant after 6 months (data not shown here) and after the third and fourth years, but not at the end of the first and second years. On observation of the data, it is apparent that these participants started with a high HbA_{1c}, which is likely to be a reflection of the fact that they were inpatients, hospitalised due to poor glycaemic control. In this study, there was a reduction in HbA_{1c} in both the intervention and control groups over the duration of the RCT. Fourteen months after the intervention in the Deakin and colleagues trial,[46–48] the change from baseline in HbA_{1c} differed significantly between the intervention arm and the control arm: the change was negative in direction (improvement) in the intervention arm, compared with a slight increase in the control arm. In this study there was a higher level of participant drop-out in the control group, which may bias the result shown. At the 12-month evaluation, the intervention group in the Brown and colleagues study[49] had HbA_{1c} approximately 0.75% lower than the control group. In this study, the baseline HbA_{1c} of participants in both groups was high. The intervention group in the Trento and colleagues study[53] had HbA_{1c} 0.8% lower than the control group at 2 years and 1.8% lower at 5 years. The intervention in the Trento and colleagues study seems to have prevented the deterioration of BG levels rather than improving BG. The intervention group's BG remained approximately the same whereas the control group had lower BG at the end of the trial. The intervention group in the Raz and colleagues study[62] had HbA_{1c} approximately 1.35% lower than the control group at 12 months. In the Sarkadi and Rosenqvist[60] trial, HbA_{1c} was

TABLE 6 *Glycated haemoglobin in studies of self-management education in adults with Type 2 diabetes. Data may represent HbA_1 or HbA_{1c} (details in Appendix 5). The studies are ordered by type (RCT, CCT) and size (largest first)*

Study and design	Time-point	Mean (SD) (unless stated) HbA_1 or HbA_{1c} (%)		Difference between groups
		Intervention	Control	
[AIC data removed]				
Ko *et al.*, 2007[45] RCT	Baseline	9.4 (2.0) (n = 219)	9.2 (1.9) (n = 211)	NS
	1 year	7.9 (1.7) (n = 174)	8.1 (1.5) (n = 187)	NS
	2 years	7.9 (1.5) (n = 168)	8.2 (1.5) (n = 169)	NS
	3 years	7.8 (1.5) (n = 167)	8.4 (1.6) (n = 148)	p = 0.004
	4 years	7.9 (1.2) (n = 161)	8.7 (1.6) (n = 147)	p = 0.0001
Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline	7.7 (1.6) (n = 157)	7.7 (1.6) (n = 157)	NS[a]
	14 months	7.1 (1.1) (n = 150)	7.8 (1.6) (n = 141)	$p < 0.05$[a]
	Change	–0.6	0.1	$p < 0.001$
Brown *et al.*, 2002[49,50] RCT	Baseline	11.81 (3.0) (n = 128)	11.8 (3.02) (n = 128)	–
	1 year	10.89 (2.56) (n = 112) adjusted 10.87	11.64 (2.85) (n = 112) adjusted 11.66	$p < 0.05$
Campbell *et al.*, 1996[51] RCT	Mean (SEM) change from baseline	Individual education group n = 57 at baseline, n = 25 at end-point –3.3 (0.9) Group education group n = 66 at baseline, n = 19 at end-point –3.0 (1.1) Behavioural education group n = 56 at baseline, n = 39 at end-point –4.8 (0.7)		NS (all pairwise contrasts)
Brown *et al.*, 2005[52] RCT		Extended intervention	Compressed intervention	
	Baseline	11.5 (3.5) (n = 102)	11.8 (3.4) (n = 114)	–
	1 year	10.5 (3.0) (n = 89)	11.1 (3.2) (n = 96)	–
	Change	–1.0	–0.7	NS
Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline	7.4 (1.4) (n = 56)	7.4 (1.4) (n = 56)	–
	2 years	7.5 (1.4) (n = 43)	8.3 (1.8) (n = 47)	$p < 0.01$
	5 years	7.3 (1.0) (n = 42)	9.0 (1.6) (n = 42)	–
	Change 0–5 years	–0.1 (95% CI –0.5 to 0.4)	1.7 (95% CI 1.1 to 2.2)	$p < 0.001$
Cooper *et al.*, 2002;[56] 2003[57,58] RCT	Baseline	7.9 (range 4.5–11) (n = 53)	7.0 (range 4.6–10.6) (n = 36)	–
	1 year	7.9 (2.1) (n = 48)	7.2 (1.6) (n = 30)	NS
Heller *et al.*, 1988[59] RCT	Baseline	12.3 (95% CI 11.4 to 13.2) (n = 40)	12.7 (95% CI 11.9 to 13.5) (n = 47)	–
	1 year	9.0 (95% CI 8.2 to 9.8) (n = 36)	9.9 (95% CI 8.9 to 10.9) (n = 39)	NS

continued

TABLE 6 *Glycated haemoglobin in studies of self-management education in adults with Type 2 diabetes. Data may represent HbA_1 or HbA_{1c} (details in Appendix 5). The studies are ordered by type (RCT, CCT) and size (largest first) (cont'd)*

Study and design	Time-point	Mean (SD) (unless stated) HbA_1 or HbA_{1c} (%)		Difference between groups
		Intervention	Control	
Sarkadi and Rosenqvist, 2004[60]	Baseline	~6.5 (n = 39)	~6.5 (n = 38)	NS
	1 year	6.2 (95% CI 5.7 to 6.7) (n = 33)	6.4 (95% CI 5.8 to 7.0) (n = 31)	NS
RCT	2 years	6.1 (95% CI 5.5 to 6.7) (n = 33)	6.6 (95% CI 6.0 to 7.2) (n = 31)	$p < 0.01$
		Baseline means and all CI estimated from graph		
Goudswaard *et al.*, 2004[61]	Baseline	8.2 (1.1) (n = 28)	8.8 (1.5) (n = 30)	–
	18 months	7.8 (0.9) (n = 25)	8.2 (1.4) (n = 29)	–
RCT	Change	–0.4 (adjusted)	–0.6 (adjusted)	NS
Raz *et al.*, 1988[62]	Baseline	10.0 (2.7) (n = 25)	9.6 (2.6) (n = 26)	–
	1 year	8.25 (n = 23) (estimated from graph)	9.6 (n = 26) (estimated from graph)	–
RCT	Change	–1.75 (estimated from graph)	0 (estimated from graph)	$p < 0.05$
Kronsbein *et al.*, 1988[63]	Baseline	7.1(1.6) (n = 65)	6.5 (1.6) (n = 62)	–
	1 year	7.1 (1.6) (n = 50)	6.7 (1.5) (n = 49)	NS
CCT				
Domenech *et al.*, 1995[64]	Change from baseline	–0.2% (0.4) (n at baseline 53, n at end-point 40)	0.8% (0.4) (n at baseline 71, n at end-point 39)	NS
CCT				

NS, not statistically significant; SD, standard deviation; SEM, standard error of the mean.
[a] Based on 95% confidence interval (CI) ($p > 0.05$ if CI for a difference includes zero).

not statistically significantly different between the intervention group and control group at 12 months but was statistically significant at 24 months.

The other published studies of this kind reported no statistically significant differences between intervention and control groups on measures of GHb, despite what would seem to be relatively large differences in mean levels of GHb between the intervention and control groups in some of the studies. **[AIC data removed]**. In the trial by Brown and colleagues,[52] the aim of the study was to compare two different versions of the intervention (one 'compressed') rather than to compare the intervention with a control group of usual care. In this study, no statistically significant differences were demonstrated between the two interventions although both interventions did reduce HbA_{1c} at 12 months.

It should be noted that although the Campbell and colleagues study[51] did not report significant differences in GHb between the three intervention groups that were evaluated, it would appear that these interventions did improve BG. These findings should, however, be interpreted with caution because no control group (who might also have shown improvement) was available for comparison. Furthermore, there was a very high attrition rate in this study. Improvements in outcomes through time may be attributable to the most motivated patients remaining in the study.

Of the studies that demonstrated statistically significant results, five were interventions delivered by a team of different professions, which might suggest a broader range of presented information and provider expertise, but two studies using such teams did not produce significant differences in GHb and one study with significant results had a single provider only.[46–48] In the studies demonstrating a statistically significant effect of education on HbA_{1c}, the difference between the intervention and control groups was on or around 1%, which may represent

a clinically significant difference. Four of the studies with statistically significant results continued some contact with the intervention groups over the period of follow-up and, speculatively, this may have had a role in maintaining the benefits shown.

Blood pressure

BP was reported in three studies.[46,47,51,53] The results are shown in *Table 7*.

The behavioural intervention in the Campbell and colleagues study[51] resulted in greater decreases in diastolic BP than in standard group or individual self-management interventions. As to whether this is a meaningful difference, or whether this effect would be maintained in the long term, is unclear and care is required in interpretation as there were large drop-out rates in this study. In the Deakin and colleagues trial,[46,47] no statistically significant differences in systolic or diastolic BP were observed at the end of the 14-month study between the intervention group and the control group. In the Trento and colleagues study,[53] more patients in the intervention group were no longer considered hypertensive at the end of the study than in the control group. This difference was not statistically significant; however, there may have been a lack of power to detect differences in this outcome. **[AIC data removed]**.

BMI or weight

Outcomes relating to weight or BMI were reported in nine included trials and are given in *Table 8*.

TABLE 7 *Blood pressure characteristics in studies of self-management education in adults with Type 2 diabetes*

Study and design	Time-point	Mean (SD) BP (mmHg) (unless stated)		Difference between groups
		Intervention	Control	
[AIC data removed]				
Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Systolic BP:			
	Baseline	147.5 (19.8) (n = 157)	147.8 (23.7) (n = 157)	NS[a]
	14 months	141.3 (16.8) (n = 150)	144.4 (23.5) (n = 141)	NS
	Diastolic BP:			
	Baseline	82.6 (11.0) (n = 157)	82.2 (12.2) (n = 157)	NS[a]
	14 months	78.4 (9.6) (n = 150)	80.2 (10.9) (n = 141)	NS
Campbell *et al.*, 1996[51] RCT	Systolic BP: Mean (SEM) change from baseline	Individual education (n at baseline 57, n at end-point 16) –6.8 (5.8) Group education (n at baseline 66, n at end-point 11) –12.4 (6.8) Behavioural education (n at baseline 56, n at end-point 37) –16.9 (3.8)		NS (all pairwise contrasts)
	Diastolic BP: Mean (SEM) change from baseline	Individual education (n at baseline 57, n at end-point 16) –5.3 (3.0) Group education (n at baseline 66, n at end-point 11) –5.0 (4.0) Behavioural education (n at baseline 56, n at end-point 37) –7.9 (2.6)		Individual and group vs behavioural: both $p < 0.05$; Individual vs group: NS
Trento *et al.*, 2001[53] RCT	No. hypertensive:			
	Baseline	34 (n = 56)	25 (n = 56)	–
	2 years	26 (n = 43)	22 (n = 47)	NS

NS, not statistically significant.
[a] Based on 95% CI ($p > 0.05$ if CI for a difference includes zero).

TABLE 8 *Body mass characteristics (BMI and weight) in studies of self-management education in adults with Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)]*

Outcome	Study and design	Time-point	Mean (SD) (unless stated)		Difference between groups
			Intervention	Control	
BMI (kg/m^2)	**[AIC data removed]**				
	Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline 14 months Change	30.8 (5.3) (n = 157) 30.6 (5.5) (n = 150) –0.2	30.6 (5.7) (n = 157) 31.0 (6.4) (n = 141) 0.4	NS[b] NS[b] $p < 0.001$
	Brown *et al.*, 2002[49,50] RCT	Baseline 1 year	32.33 (5.97) (n = 128) 32.17 (6.45) (n = 113)	32.12 (6.35) (n = 128) 32.28 (6.52) (n = 114)	NS
	Campbell *et al.*, 1996[51] RCT	Mean (SEM) change from baseline	Individual education (baseline n = 57, end-point n = 30) –2.0 (0.4) Group education (baseline n = 66, end-point n = 25) –1.4 (0.5) Behavioural education (baseline n = 56, end-point n = 41) –2.6 (0.5)		NS (all pairwise contrasts)
	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years 5 years Change 0–5 years[c]	29.7 (4.5) (n = 56) 29.0 (4.4) (n = 43) 28.6 (4.1) (n = 42) –1.4	27.8 (4.1) (n = 56) 27.6 (4.2) (n = 47) 27.6 (4.4) (n = 42) –0.1	– $p = 0.06$ – NS
	Cooper *et al.*, 2002;[56] 2003[57,58] RCT	Baseline 1 year	32.5 (6.7) (n = 53) 31.3 (5.7) (n = 48)	32.1 (6.1) (n = 36) 30.5 (3.9) (n = 30)	– NS
Weight (kg)	**[AIC data removed]**				
	Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline 14 months Change	83.2 (14.5) (n = 157) 82.7 (14.8) (n = 150) -0.5	82.8 (17.6) (n = 157) 83.9 (18.8) (n = 141) 1.1	NS[b] NS[b] $p < 0.001$
	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years 5 years Change 0–5 years[c]	77.4 (13.1) (n = 56) 76.0 (13.4) (n = 43) 76.1 (12.9) (n = 42) –3.50	78.2 (14.6) (n = 56) 77.1 (14.7) (n = 47) 77.3 (16.0) (n = 42) –0.24	– NS – $p = 0.015$

continued

TABLE 8 *Body mass characteristics (BMI and weight) in studies of self-management education in adults with Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)] (cont'd)*

Outcome	Study and design	Time-point	Mean (SD) (unless stated)		Difference between groups
			Intervention	Control	
	Heller *et al.*, 1988[59] RCT	Mean (95% CI) change from baseline	–5.5 (4 to 6.5) (n = 40 at baseline, n = 36 at end-point)	–3 (2 to 4) (n = 47 at baseline, n = 39 at end-point)	$p < 0.05$
	Raz *et al.*, 1988[62] RCT	Baseline 1 year Change	75.4 (11.7) (n = 25) 73 (n = 23) (estimated from graph) –2.4 (estimated from graph)	73.4 (11.5) (n = 26) 73 (n = 26) (estimated from graph) –0.4 (estimated from graph)	– – $p < 0.05$
	Kronsbein *et al.*, 1988[63] CCT	Baseline 1 year	76.5 (12.6) (n = 65) 73.8 (12.6) (n = 50)	75.1 (12.9) (n = 62) 74.8 (13.2) (n = 49)	Difference in change from baseline: $p < 0.01$
	Domenech *et al.*, 1995[64] CCT	Change from baseline	–2.4 (0.5) (n = 53 at baseline, n = 40 at end-point)	–0.4 (0.5) (n = 71 at baseline, n = 39 at end-point)	$p < 0.01$

NS, not statistically significant.
[a] Based on calculation adjusted for cluster effects, not statistically significant on unadjusted calculation.
[b] Based on 95% CI ($p > 0.05$ if CI for a difference includes zero).
[c] Based on baseline values for those participants followed up to end-point.

One trial[46,47] showed a statistically significant difference in BMI between the intervention group and the control group after 14 months where BMI was shown to have increased in the control group compared with a decrease in the intervention group. This study had differential drop-out rates between the two arms of the trial with more participants dropping-out in the control group. In one study,[53] the intervention group had a higher BMI than the control group at baseline and at the 2- and 5-year evaluation but this was not statistically significantly different. **[AIC data removed]**. Six published studies[46,47,53,59,62–64] reported statistically significant differences in weight (or changes in weight) between the intervention and control groups. In five studies weight loss was greater in the intervention group than the control group. In one study,[46,47] weight increased in the control group compared with a decrease in the intervention group. **[AIC data removed]**. Most of the weight losses were not of great magnitude with the exception of those in the Heller study.[59] This study, although educating on multiple aspects of self-management, was primarily directed at weight loss. The programme, starting with individualised weight targets, did produce significant weight loss in the intervention group (mean 5.5 kg); however, the control group in the study also lost a mean of 3 kg. In one study with a positive effect on weight the analysis was based on a change from baseline value, although this was only calculated from values of those who were followed up to end-point.[53]

Cholesterol and triglycerides

Five published studies **[AIC data removed]** reported other physiological outcomes[46,47,49,51,53,62] shown in *Table 9*.

Only two published trials reported any significant differences in cholesterol or triglycerides between intervention and control groups. Trento and colleagues[53] reported in the text that high-density lipoprotein (HDL) cholesterol was lower in intervention patients at 24 months, but this was inconsistent with values reported in a results table in which an increase in HDL cholesterol was reported for intervention patients between baseline and follow-up whereas it remained the same in control participants. The same study reported that triglycerides were marginally lower in the intervention patients than in control patients. Values reported in the results table suggest that triglycerides were reduced in the intervention group whereas they remained the same in the control group. However, triglycerides were higher at baseline and at follow-up for the intervention group than

TABLE 9 *Lipid characteristics (cholesterol and triglyceride) in studies of self-management education in adults with Type 2 diabetes. In studies where concentrations were reported in mg/dl, these were converted to mmol/l (1 mg/dl = 0.0555 mmol/l). The studies are ordered by type (RCT, CCT) and size (largest first)*

Outcome	Study and design	Time-point	Mean (SD) (unless stated)		Difference between groups
			Intervention	Control	
Total cholesterol (mmol/l)	**[AIC data removed]**				
	Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline 14 months Change	5.1 (1.1) (n = 157) 4.8 (1.1) (n = 150) –0.3	4.9 (1.0) (n = 157) 4.7 (1.0) (n = 141) –0.2	NS[a] NS[a] p = 0.01
	Brown *et al.*, 2002[49,50] RCT	Baseline 1 year	21.7 (2.5) (n = 128) 10.5 (2.0) (n = 112)	11.3 (2.7) (n = 128) 10.4 (2.4) (n = 113)	– NS
	Campbell *et al.*, 1996[51] RCT	Mean (SEM) change from baseline	Individual education (baseline n = 57, end-point n = 23) 0.12 (0.20) Group education (baseline n = 66, end-point n = 19) 0.16 (0.16) Behavioural education (baseline n = 56, end-point n = 34) –0.33 (0.15)		NS (all pairwise contrasts)
	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years 5 years Change 0–5 years[b]	5.8 (1.1) (n = 56) 5.7 (1.2) (n = 43) 5.50 (1.06) (n = 42) –0.32	5.5 (0.9) (n = 56) 5.6 (1.2) (n = 47) 5.27 (1.13) (n = 42) –0.43	– NS – NS
	Raz *et al.*, 1988[62] RCT	Baseline 1 year	12.5 (2.4) (n = 25) 11.8 (2.1) (n = 23)	12.2 (3.1) (n = 26) 12.5 (3.4) (n = 26)	– NS
HDL cholesterol (mmol/l)	**[AIC data removed]**				
	Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline 14 months	1.3 (0.3) (n = 157) 1.1 (0.4) (n = 150)	1.3 (0.4) (n = 157) 1.1 (0.4) (n = 141)	NS[a] p = 0.3
	Campbell *et al.*, 1996[51] RCT	Mean (SEM) change from baseline	Individual education (baseline n = 57, end-point n = 21) 0.02 (0.04) Group education (baseline n = 66, end-point n = 16) 0.18 (0.10) Behavioural education (baseline n = 56, end-point n = 27) 0.06 (0.08)		NS (all pairwise contrasts)

continued

TABLE 9 *Lipid characteristics (cholesterol and triglyceride) in studies of self-management education in adults with Type 2 diabetes. In studies where concentrations were reported in mg/dl, these were converted to mmol/l (1 mg/dl = 0.0555 mmol/l). The studies are ordered by type (RCT, CCT) and size (largest first) (cont'd)*

Outcome	Study and design	Time-point	Mean (SD) (unless stated)		Difference between groups
			Intervention	Control	
	Trento *et al.* 2001;[53] 2002;[54] 2004[55] RCT	Baseline	1.2 (0.3) (n = 56)	1.3 (0.3) (n = 56)	–
		2 years	1.4 (0.4) (n = 43)	1.3 (0.3) (n = 47)	$p < 0.05$
		5 years	1.39 (0.33) (n = 42)	1.42 (0.31) (n = 42)	–
		Change 0–5 years[b]	0.14	0.10	NS
	Raz *et al.*, 1988[62] RCT	Baseline	2.6 (0.2) (n = 25)	2.5 (0.2) (n = 26)	–
		1 year	2.7 (0.2) (n = 23)	2.5 (0.2) (n = 26)	NS
LDL cholesterol (mmol/l)	**[AIC data removed]**				
	Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline	2.7 (0.9) (n = 157)	2.7 (0.8) (n = 157)	NS[a]
		14 months	2.7 (0.9) (n = 150)	2.7 (0.8) (n = 141)	$p = 0.1$
Triglyceride (mmol/l)	**[AIC data removed]**				
	Brown *et al.*, 2002[49,50] RCT	Baseline	11.9 (7.2) (n = 128)	10.8 (6.6) (n = 128)	–
		1 year	11.9 (10.8) (n = 113)	11.0 (8.2) (n = 113)	NS
	Deakin *et al.*, 2003;[47,48] 2006[46] RCT		Geometric mean (95% CI)		Ratio of means:
		Baseline	2.2 (2.0 to 2.4) (n = 157)	2.0 (1.9 to 2.2) (n = 157)	NS[a]
		14 months	1.8 (1.6 to 2.0) (n = 141)	1.8 (1.6 to 1.9) (n = 141)	NS[a]
	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline	2.6 (95% CI 0.7 to 11.5) (n = 56)	1.7 (0.5 to 5.2) (n = 56)	–
		2 years	2.1 (95% CI 0.7 to 6.9) (n = 43)	1.7 (0.6 to 3.9) (n = 47)	$p = 0.053$
		5 years	2.17 (SD 2.30) (n = 42)	1.52 (0.75) (n = 42)	–
		Change 0–5 years[b]	–0.48 (95% CI –1.15 to 0.20)	–0.28 (–0.60 to 0.03)	NS
	Raz *et al.*, 1988[62] RCT	Baseline	12.8 (1.8) (n = 25)	11.7 (1.9) (n = 26)	–
		1 year	11.8 (1.3) (n = 23)	11.3 (1.7) (n = 26)	NS

NS, not statistically significant.
[a] Based on 95% CI ($p > 0.05$ if CI for a difference includes zero, or if CI for a ratio includes 1).
[b] Based on baseline values for those participants followed up to end-point.

for the control group. Analysis of the 5-year data in a secondary publication[55] showed no statistically significant differences between groups on either HDL cholesterol or triglycerides. In the trial by Deakin and colleagues,[46,47] the change in total cholesterol was reported to be statistically significantly different ($p = 0.01$) after 14 months in favour of the intervention group. However, neither HDL nor low-density lipoprotein (LDL) cholesterol at end-point were statistically significantly different between the intervention group and the control group. **[AIC data removed]**.

Oral hypoglycaemic treatment

Stopping OHA therapy was an explicit objective of the programme in two studies.[63,64] Both reported significant differences in the use of medication between the intervention and control groups. In the Kronsbein and colleagues study,[63] the proportion of patients not using glucose-lowering medications in the intervention group rose from 32% to 62% between baseline and evaluation whereas it remained at 39% in the control group. In the Domenech and colleagues study,[64] intervention patients had reduced their average daily intake of OHAs (–1.4 tablets) whereas the control group had increased intake (+0.9 tablets), but units of the variance (±0.2 in each case) were not stated. This outcome would need to be interpreted along with the outcome on measures of glycaemic control, which in this study showed a difference between groups but this difference was not statistically significant.

Interestingly, these studies were both CCTs rather than RCTs. In the Kronsbein and colleagues study,[63] the intervention patients came from practices in which their physician chose to participate immediately in the programme. Although the physicians of both intervention and control patients had attended a training session, it is possible that those physicians who chose to start the programme immediately were more motivated to change the treatment of their patients. In the Domenech and colleagues study,[64] the intervention and control patients were treated by the same physicians; however, there was no blinding as to which patients were in which group. These two interventions were also the most brief, consisting of only 6–8 hours of education over 4 weeks.

In the Trento and colleagues trial,[53–55] data were presented on the numbers of participants being treated on diet alone, OHAs and insulin. No statistically significant differences were observed between the intervention group or the comparator group after 2 years of follow-up. The data were not presented as changes from baseline values, and no data were presented at the 5-year follow-up. In the Cooper and colleagues trial,[56–58] changes in drug treatment were assessed as either moving from diet treatment to oral drug treatment, or from oral drug treatment to insulin treatment. Data showed that more patients in the intervention group had treatment increased or decreased relative to baseline but this was not statistically significantly different from changes in the control group. **[AIC data removed]**.

Outcomes reflecting diabetic end-points

Very few of the studies included complications as outcomes, usually because the follow-up in these studies was too short. It is acknowledged that for the most part it is not feasible for studies to be of long enough duration to assess these longer-term end-points. However, those that were reported are shown in *Table 10*.

There were no statistically significant differences between the intervention and control groups for any of these outcomes. In the study by Ko and colleagues,[45] the median frequency of hospital admissions due to any diabetic complications over 4 years was reported to differ significantly between the treatments ($p = 0.005$). However, to which treatment group the data presented by Ko and colleagues refers, for this outcome, is unclear as the tabulated and narrative descriptions of the findings do not concur.

Outcomes reflecting quality of life and cognitive measures

It is possible that interventions may affect the QoL of patients either in conjunction with or instead of effects on physiological or behavioural measures. However, few studies included measures of QoL or knowledge using validated instruments. Reported effects on QoL and diabetes knowledge that were assessed using validated instruments are given in *Table 11*; details of the instruments are given in Appendix 7.

Two published trials[46,47,53] reported on QoL using a validated scale. In the Trento and colleagues study,[53] the Diabetes Quality of Life (DQOL) scale was used. This scale used questions that were to be answered on a Likert scale such that lower overall scores reflect higher satisfaction. This study reported results from 2 years follow-up from inception; however, educational sessions were conducted every 3 months throughout the 2-year period. At 2 years the intervention did statistically significantly improve patients' QoL compared with that in the control group, which had deteriorated. In a follow-up study at 5 years, this trend continued, where the mean change in DQOL was –23.7 in the intervention group compared with 19.2 in the control group. When interpreting this analysis, it is important to note the level of drop-outs in the samples, although this was at a similar rate in each comparison arm of the trial. In the trial by Deakin and colleagues,[46,47] no statistically significant difference in QoL as measured by the Audit of Diabetes-Dependent Quality of life (ADDQoL) was observed between the treatment group and control group after 14 months,

TABLE 10 *Diabetic end-points from studies of self-management education in adults with Type 2 diabetes*

Outcome	Study and design	Time-point	Intervention	Control	Differences between groups
Diabetic retinopathy (none/mild/more severe)	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years	42/8/6 (n = 56) 35/5/3 (n = 43)	38/13/5 (n = 56) 33/7/7 (n = 47)	– NS
Foot ulcers (never/past/active)	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years	54/0/2 (n = 56) 42/1/0 (n = 43)	53/2/1 (n = 56) 45/1/1 (n = 47)	– NS
Mean (SD) creatinine (μmol/l)	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years 5 years Change 0–5 years	91.94 (14.14) (n = 56) 88.8 (16.5) (n = 43) 75.14 (25.63) (n = 42) –16.79 (95% CI –25.63 to –10.60)	91.05 (14.14) (n = 56) 87.8 (17.2) (n = 47) 78.67 (47.73) (n = 42) –12.37 (–26.52 to 2.65)	– NS – NS
Proportion consulting ophthalmology (%)	Campbell *et al.*, 1996[51] RCT	(No baseline data) 1 year	Individual education (n = 57, end-point n = 38) 97 Group education (n = 66, end-point n = 37) 95 Behavioural education (n = 56, end-point n = 47) 89		NS (all pairwise contrasts)
Proportion consulting podiatry (%)	Campbell *et al.*, 1996[51] RCT	(No baseline data) 1 year	Individual education (n = 57, end-point n = 31) 55 Group education (n = 66, end-point n = 30) 73 Behavioural education (n = 56, end-point n = 42) 74		NS (all pairwise contrasts)

NS, not statistically significant.

although it would appear that the change in mean scores was greater in the treatment group than the control group. In this study, the intervention–evaluation interval was much larger as participants had a 6-week intervention and then were followed up at 14 months. Speculatively, this may account for the difference in findings between the two studies. **[AIC data removed]**.

Three of four studies[46,47,53,63] reporting results for knowledge measures demonstrated that intervention patients had a statistically significantly higher knowledge of diabetes than the control patients and this continued for up to 5 years in the Trento and colleagues study.[53] Patients who are more knowledgeable are better able to communicate with their physicians and likely to feel in better control of their own health. However, it is unclear whether knowledge of diabetes alone has any effect on metabolic control (see, e.g., Glasgow and Osteen[66]).

Cooper and colleagues[56] reported significantly better attitudes to diabetes and its treatment in the intervention group at 12 months on the Diabetes Integration Questionnaire {baseline 72.8 [standard deviation (SD) 13.2], 12 months 75.1 (SD 11.0)} than the control group [baseline 76.7 (SD 14.2), 12 months 70.5 (SD 11.0), $p < 0.01$]. The test measured the integration of diabetes and

TABLE 11 *QoL and knowledge from studies of self-management education in adults with Type 2 diabetes*

Outcome (scale)	Study and design	Time-point	Mean (SD) (unless stated) of outcome		Differences between groups
			Intervention	Control	
[AIC data removed]					
[AIC data removed]					
QoL (ADDQoL: –9 to +9)	Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline 14 months	–2.2 (2.2) (n = 157) –1.4 (1.7) (n = 100)	–1.9 (2.2) (n = 157) –1.7 (2.1) (n = 91)	NS[a] NS
QoL (Modified DQOL: 39 questions: each 1 to 5)	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years 5 years Change 0–5 years	67.6 (19) (n = 56) 55.6 (15.9) (n = 43) 43.7 (7.2) (n = 42) –23.7 (95% CI –30.0 to –17.3)	66.7 (25) (n = 56) 80.8 (31.5) (n = 47) 89.2 (30.1) (n = 42) 19.2 (95% CI 8.4 to 29.9)	– $p < 0.01$ – $p < 0.001$ –
Knowledge (0–14)	Deakin *et al.*, 2003;[47,48] 2006[46] RCT	Baseline 14 months	7.5 (3.5) (n = 157) 9.3 (3.1) (n = 100)	7.0 (3.1) (n = 157) 7.8 (2.7) (n = 91)	NS[a] $p < 0.001$
Knowledge (DKNA)	Campbell *et al.*, 1996[51] RCT	Mean (SEM) change from baseline	Individual education (baseline n = 57, end-point n = 29) 4.4 (0.6) Group education (baseline n = 66, end-point n = 26) 4.2 (0.5) Behavioural education (baseline n = 56, end-point n = 35) 5.6 (0.6)		NS (all pairwise contrasts)
Knowledge (GISED: 0 to 38)	Trento *et al.*, 2001;[53] 2002;[54] 2004[55] RCT	Baseline 2 years 5 years Change 0–5 years	14.9 (7.9) (n = 56) 24 (6.6) (n = 43) 27.9 (5.7) (n = 42) 12.4 (95% CI 9.7 to 15.2)	20.2 (7.4) (n = 56) 17.4 (8.6) (n = 47) 18.0 (8.5) (n = 42) –3.4 95% (CI: –1.1 to –5.7)	– $p < 0.01$ – $p < 0.001$
Knowledge (based on NIDDM questionnaire)	Kronsbein *et al.*, 1988[63] CCT	Baseline 1 year	9 (3) (n = 65) 13 (4) (n = 50)	9 (3) (n = 62) 10 (4) (n = 49)	– $p < 0.01$

ADDQoL, Audit of Diabetes-Dependent Quality of Life; DKNA, Diabetes Knowledge scale – form A; DQOL, Diabetes Quality of Life measure; GISED, Group of the Italian Society for Diabetes.
[a] Based on 95% CI ($p > 0.05$ if CI for a difference includes zero).

its treatment into the lifestyle and personality of the patient. Higher scores indicate better psychological adjustment to diabetes.

The QoL and knowledge results suggest that some of these programmes may affect the psychological well-being of patients with diabetes, although these effects are by no means universal.

Interim summary

Of the studies designed to instruct patients about multiple components of self-management for Type 2 diabetes, the majority compared a single intervention with a usual care control group over 12 months. One study followed up patients for 5 years and another for 4 years.

Some effects of education on diabetic control, as measured by HbA_{1c}, were demonstrated in some studies. These were mostly attributable to longer-term interventions that had a shorter interval between the intervention's conclusion and the follow-up. There may also be an effect of having a multi-professional team delivering the

educational programme. There was little effect on weight loss or BMI shown. Two studies reported reduced usage of OHAs in the intervention groups.

Very few studies were of long enough duration to report outcomes relating to diabetic end-points. Where these were reported, no significant effects were demonstrated.

Patients' QoL was assessed with a validated measure in only two published trials **[AIC data removed]**. QoL was better in the intervention group than the control group in one published trial but no difference was demonstrated between groups in the second published study. **[AIC data removed]**. Diabetes knowledge scores were found to be significantly higher amongst participants in the intervention groups in three studies.

Trials of focused self-management interventions

Rather than educating patients on all aspects of diabetes self-care as in the studies just discussed, the following studies attempted to address specific, limited topics in diabetes self-management.

Quantity and quality of evidence

Eight studies (seven RCTs, one CCT) comparing focused self-management education for patients with Type 2 diabetes met the inclusion criteria for the review and are reported in *Table 12* and Appendix 5. These interventions focused on diet and exercise (four studies[67–69,74]), diet,[70] exercise,[72] weight versus self-regulation[73] or weight versus self-monitoring of blood glucose (SMBG).[71] Study sample sizes were generally small, varying from 20[73] to 104.[74] Three of the included studies compared education in more than two groups of patients.[67,70,74] All trials that reported the study setting carried out the trial in primary care. Two trials did not report the setting.[67,73] Duration of diabetes was not widely reported. In the four trials that reported duration it ranged from newly diagnosed[68] to 13 years.[69] The majority of trials followed up their participants for 12 months from inception; the follow-up was 18 and 24 months in the trials by Kaplan and colleagues[67] and Uusitupa and colleagues,[68] respectively.

The quality of reporting and methodology of the included studies was poor by today's standards (*Tables 13* and *14*). No details of an adequate method of randomisation, or concealment of allocation were reported in any of the included trials. The similarity of groups at baseline and the eligibility criteria were reported in all seven included RCTs. No trial reported analysis by ITT.

Description of interventions

These interventions, due to their focused nature, are more self-explanatory than those that included a range of diabetes-related topics. However, as in the previous group of interventions, it is often difficult to describe the exact nature of the interventions as published reports were vague or incomplete. Some assumptions as to the interventions have been made by the reviewers based on the reported outcomes used or vague descriptions (see below). An overview of the different interventions is provided here; further details can be found in the relevant sections in Appendix 5.

Interventions for diet and exercise

Four studies focused on diet and exercise.[67–69,74] Detailed dietary education was provided in each of these studies and two of the four[68,69] used individualised dietary programmes. Another[67] used the American Diabetes Association (ADA) exchange diet. Little detail of the nature of the dietary education was reported in the fourth study.[74]

Exercise programmes were individualised in two of the studies[67,69] and in one other study[68] exercise was recommended at a particular intensity and frequency for all. Little detail of the nature of the exercise programme was reported in the fourth study.[74] Three of these interventions used behaviour modification principles to greater or lesser extents. One study[67] required a monetary deposit that was returned with the meeting of goals and meeting attendance. One used contracts[69] and the other[68] used food records. All of these studies involved at least some group work.

Providers of the interventions varied but generally involved teams of specialists such as dieticians, nutritionists, DSNs and physicians. In the Gilliland and colleagues study,[74] a trained community mentor provided the intervention. Only two studies mentioned that they trained educators, but no further detail was given.[69,74]

The duration and intensity of the interventions varied. Two interventions involved approximately 9 hours of contact.[68,69] One of these involved six monthly sessions, the other was six sessions

TABLE 12 *Included studies of focused self-management education for Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)]*

Reference and design	Intervention	No. of participants	Duration of intervention	Timing of evaluation[a]
Kaplan *et al.*, 1987[67] RCT	Four groups 1. Group diet education. Dietician delivered. 20 contact hours 2. Group exercise education. Contact hours not given 3. Group diet and exercise education over 5 weeks, no details contact time 4. Control education in group with team – each gave a lecture. ~14 contact hours	87	10 weeks	18 months
Uusitupa *et al.*, 1992–6[68] RCT	Two groups 1. Diet and exercise education. Provided by a team. Contact = 6 clinic visits (duration not given) 2. Usual care control. Local health centre visits every 2–3 months + outpatient clinics Both groups given basic diabetes education	86	12 months	24 months
Ridgeway *et al.*, 1999[69] RCT	Two groups: 1. Group diet and exercise education. Nurse and dietician delivered. 9 contact hours 2. Usual care control. No details	56	6 months	12 months
Wing *et al.*, 1985[70] RCT	Three groups: 1. Diet – behaviour modification 2. Nutrition education 3. Usual care (with nutrition education) Groups 1 and 2 = group education provided by psychologist and nutritionist. Contact = 16 weekly sessions Group 3 = content identical with group 2 but only 4 monthly meetings	53	16 weeks	16 months
Wing *et al.*, 1986[71] RCT	Two groups: 1. Diet – weight control. Contact time not given 2. Diet – SMBG. Contact time ~ 20 meetings	50	12 months	62 weeks
Samaras *et al.*, 1997[72] RCT	Two groups: 1. Exercise education. Group sessions provided by a team. Contact time ~6 hours 2. Usual care. routine clinic visits + 3 assessment visits (no details of duration)	26	6 months	12 months
Wing *et al.*, 1988[73] RCT	Two groups: 1. SMBG with education on meaning of SMBG ('self-regulation'), 13 sessions 2. SMBG ('self-monitoring'). Contact time not given	20	10 months	68 weeks
Gilliland *et al.*, 2002[74] CCT	Three groups: 1. Friends and family. Group culturally appropriate diet and exercise education with support. 5 sessions, one every 6 weeks, for ~2 hours 2. One-on-one. Individual culturally appropriate diet and exercise education. 5 sessions, once every 6 weeks for ~45 minutes 3. Usual care control (some education but not culturally appropriate and no details given)	104 (Mexican-American)	10 months	12 months

[a] Based on the start of the intervention.

TABLE 13 *Quality assessment of RCTs of focused education for Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)]*

Study	Randomisation	Concealment of allocation	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values
Kaplan *et al.*, 1987[67]	Unknown	Unknown	Reported	Yes	Unknown	Inadequate	Unknown	Reported
Uusitipa *et al.*, 1992–6[68]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Inadequate	Unknown
Ridgeway *et al.*, 1999[69]	Unknown	Unknown	Reported	Yes	Unknown	Inadequate	Inadequate	Adequate
Wing *et al.*, 1985[70]	Unknown	Unknown	Reported	Yes	Unknown	Partial	Unknown	Partial
Wing *et al.*, 1986[71]	Unknown	Unknown	Reported	Yes	Adequate	Partial	Unknown	Reported
Samaras *et al.*, 1997[72]	Unknown	Unknown	Reported	Yes	Unknown	Partial	Unknown	Unknown
Wing *et al.*, 1988[73]	Unknown	Unknown	Reported	Yes	Not applicable	Partial	Inadequate	Partial

TABLE 14 *Quality assessment of CCT of focused education for Type 2 diabetes*

Study	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values	Representativeness
Gilliland *et al.*, 2002[74]	Reported	Yes	Unknown	Adequate	Inadequate	Partial	No

bimonthly. Another[67] involved 20 hours of contact in 10 2-hour meetings over 10 weeks. The group intervention in the Gilliland and colleagues study[74] involved approximately 12 contact hours over 10 months, and the individual intervention approximately 4 hours over the same period.

In studies with a control group, participants underwent usual care, most often provided by their physicians or local clinics, and received clinic appointments as necessary.

Other focused interventions

Four other studies involved focused interventions that were each unique.

One study[72] used an exercise intervention. This intervention was theoretically motivated using the 'proceed–precede' health promotion model which is built on the notion that health and health risks are determined by multiple factors.[75] The intervention involved group sessions focusing on barriers to exercise, diabetes and exercise, self-esteem, goal-setting, etc. Education sessions were followed by group aerobic exercise sessions. The intervention formally involved 6 months of sessions, but exercise sessions were also available after 6 months.

One study[70] compared a diet intervention with a weight loss-focused intervention. This study only reported within-group differences and is not discussed further.

One study[71] compared a group who focused on the relation between weight loss and BG control with a group who focused on weight control. This study used behaviour modification for weight control with self-monitoring of calories by diaries. Patients gave a deposit which was returned on the basis of meeting goals and attendance. There were 12 weeks of weekly meetings followed by monthly meetings for the next 6 months and follow-up sessions at 9 and 12 months.

Another study[73] was similar to the previous one using a behavioural weight control programme and use of participants' monetary deposits. The two groups in this study differed in what they were taught about SMBG. One group (self-regulation) was taught how to use SMBG information to regulate behaviour using behaviour modification principles. The other group (self-monitoring) was taught how to do SMBG but not how to use the information. The intervention involved 13 sessions in 16 weeks with follow-up education sessions lasting until 10 months.

Assessment of effectiveness

Outcomes reflecting diabetic control

Table 15 shows the results for GHb for the included studies that considered focused interventions.

The Kaplan and colleagues intervention involving combined diet and exercise[67] produced significantly lower HbA_{1c} than in a control group who received only didactic education. The diet plus exercise intervention produced a sizeable reduction in HbA_{1c} (–1.48%), whereas the drop was small in the diet group (–0.46%) and HbA_{1c} increased from baseline in the exercise group (+1.3%) and education group (+0.36%). The diet plus exercise intervention was the most intensive intervention involving 20 hours of contact, but it lasted only 10 weeks. Therefore, this effect was reasonably long-lasting as the outcome was measured at 18 months.

In the Uusitupa and colleagues study,[68] mean levels of HbA_{1c} did not differ between the intervention and control groups (although there was a marginal difference at 12 months), but the proportion of patients with HbA_{1c} $\leqslant$7.0% was greater in the intervention group. This was true at both the 12- and 24-month evaluations. Again, this was a long-lasting effect as the intervention ceased at 12 months. In the Gilliland and colleagues CCT,[74] all groups saw an increase in HbA_{1c} but the two intervention groups combined showed a significantly smaller rise than the control group.

The Samaras and colleagues exercise study[72] reported no overall significant differences in HbA_{1c} between intervention and control patients. However, HbA_{1c} levels among patients who were treated with metformin or diet alone rose less in intervention patients (change +0.4) than in control patients (+1.5%), $p < 0.05$.

The remaining four studies did not report any differences in measures of GHb between intervention and control groups (Ridgeway and colleagues' study[69]) or between different interventions (Wing and colleagues' studies[70,71,73]).

Blood pressure

Only two studies[68,74] reported BP results. There were no significant differences between the intervention and control groups in the Uusitupa and colleagues study.[68] There was a significant difference in diastolic BP between the two intervention groups combined [Friends and family –6.5 (±2.0), One-to-one –0.4 (±1.7)] and the

TABLE 15 *Glycated haemoglobin (%) findings from studies of focused education in adults with Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)]*

Study and design	Outcome	Time-point	(Mean ± SD) (unless stated)		Differences between groups
			Intervention	Control	
Diet and exercise interventions					
Kaplan *et al.*, 1987[67] RCT	HbA_1 (%)		Diet		Overall difference between groups, $p < 0.10$; diet + exercise differs from education, $p < 0.05$
		Baseline	8.97 (2.82) (group *n* values not reported)		
		18 months	8.51 (group *n* values not reported)		
			Exercise		
		Baseline	8.16 (3.44) (group *n* values not reported)		
		18 months	9.46 (group *n* values not reported)		
			Diet + exercise		
		Baseline	9.18 (2.46) (group *n* values not reported)		
		18 months	7.70 (group *n* values not reported)		
			Education		
		Baseline	8.21 (1.54) (group *n* values not reported)		
		18 months	8.57 (group *n* values not reported)		
Uusitupa *et al.*, 1992–6[68] RCT	HbA_{1c} (%)	Baseline	7.1 (1.8) ($n = 40$)	7.8 (2.0) ($n = 46$)	$p = 0.06$
		12 months	6.6 (1.6) (*n* not reported)	7.5 (1.7) (*n* not reported)	NS
		24 months	7.2 (1.9) ($n = 38$)	8.0 (1.6) ($n = 44$)	
Uusitupa *et al.*, 1992–6[68] RCT	HbA_{1c} (% adjusted)	Baseline	7.4 ($n = 40$)	7.8 ($n = 46$)	NS
		12 months	6.7 (*n* not reported)	7.3 (*n* not reported)	NS
		24 months	7.4 ($n = 38$)	7.9 ($n = 44$)	
Uusitupa *et al.*, 1992–6[68] RCT	HbA_{1c} (% patients with ⩾7.0%)	Baseline	Not reported (NR) ($n = 40$)	NR ($n = 46$)	
		12 months	74.4% (*n* not reported)	47.8% (*n* not reported)	$p < 0.01$
		24 months	55.3% ($n = 38$)	31.8% ($n = 44$)	$p < 0.05$
Ridgeway *et al.*, 1999[69] RCT	GHb	Baseline	12.3 (2.2) ($n = 28$)	12.3 (SD3.0) ($n = 28$)	NS
		12 months	11.52 ($n = 18$)	11.64 ($n = 20$)	
Gilliland *et al.*, 2002[74] CCT	HbA_{1c} (% adjusted)	Reported values are changes from baseline	*Friends and family*	*One-to-one*	Between 3 groups, $p < 0.05$ Between Friends family and One-to-one combined and control, $p < 0.05$
			+0.5 (0.3) (baseline $n = 32$, end-point $n = 32$)	+0.2 (0.3) (baseline $n = 39$, end-point $n = 39$)	+1.2 (0.4) (baseline $n = 33$, end-point $n = 33$)
Other focused interventions					
Wing *et al.*, 1986[71] RCT Weight vs SMBG	HbA_1		Weight control		
		Baseline	10.86 (2.0) ($n = 25$)		
		12 months	10.44 (2.16) ($n = 22$)		
			Glucose monitoring		
		Baseline	10.19 (2.51) ($n = 25$)		
		12 months	10.19 (2.29) ($n = 23$)		

continued

TABLE 15 *Glycated haemoglobin (%) findings from studies of focused education in adults with Type 2 diabetes [ordered by type (RCT, CCT) and size (largest first)] (cont'd)*

Study and design	Outcome	Time-point	(Mean ± SD) (unless stated)		Differences between groups
			Intervention	Control	
Samaras *et al.*, 1997[72] RCT Exercise	HbA_{1c} (reported values are changes from baseline)	12 months	+ 0.86 (SEM 0.29) (baseline n = 13, end-point n = 13)	+ 0.86 (SEM 0.27) (baseline n = 13, end-point n = 13)	NS
Wing *et al.*, 1988[73] RCT self-regulation vs self-monitoring	HbA_1	 Baseline 12 months Baseline 12 months	Self-regulation 10.57 (SEM 0.44) (n = 10) 10.8 (SEM 0.8) (n = 9) Self-monitoring 10.54 (SEM 0.55) (n = 10) 9.71 (SEM 0.78) (n = 8)		NS

control group [–0.3 (±2.1)] in the Gilliland and colleagues CCT.[74]

BMI or weight

Five studies reported either BMI or weight.[68,69,72–74] In none of these studies was there a significant difference between the intervention and control groups. In one study[74] there was a significant difference in weight between the two intervention groups combined [Friends and family –2.0 (±1.5), One-to-one –1.8 (±1.5)] compared with the control group [+1.7 (±1.8)]. Any effect on BMI or weight may be attributed to more motivated participants remaining in the intervention arms of this study.

Cholesterol and triglycerides

Four studies reported cholesterol and triglyceride levels.[68,69,72,74] There were no reported differences between the intervention and control groups for total cholesterol, HDL cholesterol, LDL cholesterol or triglycerides in these studies.

Treatment intensity

Uusitupa and colleagues[68] reported the percentage of patients taking glucose-lowering drugs. At 24 months, 12.5% of intervention patients and 34.8% of control patients were taking drugs ($p < 0.01$). Wing and colleagues[71] reported no significant differences in medication decreases between patients trained in weight control and those trained in glucose self-monitoring.

Outcomes reflecting quality of life and cognitive measures

One study[67] considered QoL effects using a validated measure (see Appendix 7). In this study, QoL was significantly better in the diet (+0.03) and diet plus exercise groups (+0.06) than in a didactic education control group (–0.04). The differences are small, but placed on an overall scale of 0 to 1.0 they may be meaningful to patients.

Summary of clinical effectiveness

A wide variety of interventions have been designed to impact on self-management of diabetes in patients with Type 2 diabetes. Many have attempted to instruct patients about the multiple facets of self-care required whereas others have focused on changing major lifestyle characteristics that have a negative impact on BG control (e.g. diet and/or exercise). There have also been limited attempts to tailor interventions to particular cultural subgroups of the population (e.g. Mexican-Americans).

In general, the impact on outcomes that are relevant to patients (e.g. HbA_{1c}, QoL, or long-term complications) has been limited in these programmes.

On measures of diabetic control (mostly using measures of glycaemic control), it appears from the evidence that in general the educational programmes that affected diabetic control were those delivered over longer intervals and/or those that provided more frequent contact between the participants and the educators. However, there were some interventions that did result in long-lasting effects on GHb despite longer intervals between the last point of contact with the educators and the point of outcome measurement.

Reductions in the need for OHAs may also be an important measure of the success of an intervention. This may be particularly true if glycaemic control levels are already relatively low in patients. Two multifaceted interventions demonstrated reduced use of OHAs,[63,64] as did one focused intervention.[68] From the results of these studies, it is difficult to say what characteristics of an educationally based intervention may be crucial to successful metabolic control in Type 2 diabetes. The two multifaceted interventions that reduced the use of OHAs were based on the same basic programme. Surprisingly, these interventions were limited in contact (6–8 hours).

Most studies were far too short to allow for the measurement of diabetic complications. None of the studies of short-term complications reported any significant effects.

Few studies measured QoL using a validated measurement scale. One published study of a multifaceted intervention reported a significant improvement in QoL, whereas another did not. **[AIC data removed]**. The published study which demonstrated an improvement in QoL between the two groups was an intervention that involved multiple sessions spaced over most of the entire evaluation period and may therefore reflect the effects of continual contact.

Three studies reported significant improvements in patients' knowledge of diabetes. It is not surprising that educational programmes should affect knowledge. If anything, it is perhaps surprising that more studies did not report such effects. Some studies did not test for knowledge changes or did not use a validated measure to do so. Improved knowledge is desirable, but its relation to metabolic control is unclear.[66]

Most of the interventions aimed at Type 2 diabetes were group interventions. The study designs included in this review do not allow for any strong conclusions about the merits of group versus individual interventions. However, generally those studies that reported significant results used group interventions. Groups have the advantages that patients can serve as support for one another and may form a sort of behaviour modification milieu even if the intervention itself is not formally oriented towards behaviour modification. In addition, group interventions are generally less costly and allow staff to use the time they devote to patient education more efficiently.

Chapter 4

Evidence from systematic reviews

Reviews of educational interventions in diabetes were identified and checked for methodological rigour. Those that did not use systematic methods are excluded from further discussion.

The systematic reviews did not use the same inclusion criteria as those set out for the current review. In particular, most did not impose any requirement for a long-term follow-up. In addition, many allowed a wider range of study designs including single-group, pre-test, post-test, designs. Due to these differences, the reviews have not been data extracted and will not be discussed in detail. Instead, the bibliographies of these reviews have been used as sources of studies that meet our inclusion criteria. Five systematic reviews of educational interventions in Type 2 diabetes were located[76–80] and brief summaries are provided below.

In a review by Norris and colleagues,[76] 72 studies of self-management training were included. They reported short-term positive effects (<6 months) for knowledge, frequency and accuracy of SMBG, self-reported dietary habits and glycaemic control. "With longer follow-up, interventions that used regular reinforcement throughout follow-up were sometimes effective in improving glycaemic control" (p. 561). This review concluded that self-management training in Type 2 diabetes is effective in the short term, but that further research is needed.

A second review by Norris and colleagues[77] was based on the search strategy of the previous review and discussed a subset of the same trials included in the above review. Studies with follow-up periods shorter than 1 year were included. Thirty-one studies were assessed to evaluate the effects of self-management education on glycaemic control. The findings were similar to those reported above. "Self-management education improved GHb levels at immediate follow-up, and increased contact time increases the effect. The benefit declines 1–3 months after the intervention ceases, however, suggesting that learned behaviours change over time." (p. 1159). Improvements in GHb averaged only 0.26% in studies with follow-up of ≥4 months, suggesting that it is difficult to maintain improvements in glycaemic control without maintenance of educational or other supportive contact.

Norris and colleagues[78] also reviewed the effectiveness and economic efficiency of self-management interventions for people with Type 2 diabetes in community settings. Thirty trials met the inclusion criteria and evaluated a variety of outcomes, over a range of follow-up periods. Self-management education was demonstrated to be effective in community gathering places (e.g. community centres, libraries) in terms of glycaemic control at 6 months. Evidence was insufficient for outcomes such as dietary intake, physical activity and blood pressure and was also inadequate to assess the effects of interventions in the workplace or at home.

A systematic review was also conducted by the Alberta Heritage Foundation for Medical Research.[79] This review stated that reliable conclusions could not be made as to which types of programmes or components are most effective in improving self-management in Type 2 diabetes or which category of patients might benefit most. "There is no consistent pattern of effect across outcomes based on type of intervention, length of educational intervention, core team composition or type of educational setting; and there is no standard method to describe formal patient diabetes education programmes and interventions, thus making it difficult to replicate studies." (p. ii).

Deakin and colleagues[80] conducted a systematic review to investigate group-based training for self-management of Type 2 diabetes. They included RCTs and CCTs in which group-based education was compared with routine treatment, a waiting list control or no intervention. They excluded studies for which follow-up was less than 6 months and/or group size was less than six patients. Eleven studies (eight RCTs and three CCTs) comprising 1532 patients met these inclusion criteria (of which six studies are included above in the current review). Overall, at 12–14 months follow-up, the intervention group had a significantly lower weighted mean HbA_{1c} (%) (seven trials), and a significantly higher weighted mean diabetes knowledge score (three trials).

A significantly larger number of patients in the intervention group reduced their use of diabetes medication over 12–14 months (five trials). The significant treatment effect on HbA_{1c} was also supported at 24 months' follow-up (two trials). The overall conclusion from these findings was that group-based education in self-management strategies improves clinical and lifestyle outcomes in patients with Type 2 diabetes.

These systematic reviews had some differences in their aims and therefore some differences in their inclusion criteria. In addition, the systematic reviews were undertaken at different points in time. Overall, the reviews seem to concur with many of the findings of the present review.

Chapter 5

Research in progress

Porta and Trento[81] reported preliminary results of an Italian 4-year multi-centre study (ROMEO: Rethink Organization to iMprove Education and Outcomes) that is comparing group care versus individual care in 812 patients with Type 2 diabetes. At the time of censoring searches for the present review, results of this study were restricted to a description of the baseline characteristics of the patient populations.

Samuel-Hodge and colleagues[82] reported preliminary findings from a 1-year church-based intervention for diabetes self-management in North Carolina, USA (DAWN: Diabetes AWareness Network). The study was aimed at African-Americans with Type 2 diabetes and involved 24 churches and a total of 201 participants. Although the study was completed in 2003, only outcome data for baseline (pre-intervention) populations are available at the time of writing (January 2007).

The DESMOND study, an RCT of a structured group education programme for people with newly diagnosed Type 2 diabetes is ongoing at the time of writing. This multi-centre practice based trial aims to recruit 1000 participants and will compare structured education with control groups receiving structured care. The intervention arm will have a structured group education programme providing 6 hours of contact time between patients and healthcare professionals. Outcomes will include HbA_{1c}, lipid profiles, QoL and psychosocial outcomes and will be assessed at 12 months.

The effectiveness of patient self-managed structured education for Type 2 diabetes (The Diabetes Manual), a multi-centre cluster RCT, is ongoing at the time of writing. This is a 24-month study which aims to examine the effectiveness of a patient self-managed structured education programme, called the Diabetes Manual, for Type 2 diabetes in primary care. Outcomes include measures of glycaemic control, psychological distress, QoL and self-efficacy at 6 months and maintenance of effect at 12 months. The study aims to recruit 424 eligible patients and GP practices will be randomised into intervention or 6-month waiting list control groups.

A multi-centre RCT, 'Does the chronic disease self-management programme (Xpert Patient Programme) improve metabolic control of diabetes?' is in progress and is expected to complete in 2008. The study aims to recruit 255 participants. The nature of the educational intervention is not described on the National Research Register.

A Phase II trial of an Internet-based group diabetes self-management education programme is ongoing in the USA. Participants with Type 2 diabetes are randomised to participate in the Internet programme or serve as controls continuing with usual care. Participants will participate in a structured 6-week interactive web-based online class with 20–24 other participants and two trained peer moderators. This study is funded by the Robert Wood Johnson Foundation and expects to complete in June 2008 (ClinicalTrials.gov [NCT00372463]).

Cochrane Review protocols are available for two systematic reviews that will investigate the effectiveness of educational or education-related interventions for patients with Type 2 diabetes (The Cochrane Library, 2006, Issue 4). Colagiuri and colleagues[83] aim to evaluate interventions for individual patient education, whereas Armour and colleagues[84] intend to evaluate interventions for maintaining physical activity in diabetic patients, which could include educational strategies.

Chapter 6
Discussion

Statement of principal findings

Across the studies whose interventions aimed to teach multiple aspects of diabetes self-management, the effects on measures of diabetic control, such as HbA_{1c}, BMI or cholesterol, were variable. Whereas some studies showed a statistically significant effect of education on HbA_{1c}, others did not. In the case of reduction in HbA_{1c}, statistically significant effects were in the region of a 1% change in many of the studies, which may reflect a clinically significant effect. A number of studies showed significant effects of education on weight loss but less showed significant effects on BMI. Very few studies showed significant effects of education on lipid concentrations. On measures of diabetic complications (e.g. retinopathy) or outcomes which may be considered as possible indicators of diabetic complications (e.g. consultations with ophthalmologists), very few studies had a long enough follow-up duration to measure these but, where they did, no significant effects were seen. QoL (using a validated scale) was only measured by two published studies **[AIC data removed]** and the results were conflicting, but knowledge was shown to have been influenced by education. Some effects of education on measures of diabetic control were demonstrated in studies focusing on diet or exercise alone. Although the effects were not large, those that were present did appear to be relatively long-lasting. Overall, inconsistent effects of educational interventions aimed at patients with Type 2 diabetes make the results difficult to interpret; there were positive effects of interventions in each of the types of outcomes considered, but also studies reporting few or no significant effects of the educational interventions.

Interventions which were more frequent and extended over a longer period did appear to improve outcomes more than less frequent, shorter duration interventions, but this observation has not been tested in a scientific way. As education for people with Type 2 diabetes is already provided, and because there is likely to be little negative effect of education on participants, it should continue. However, there is little evidence to suggest whether and how educational programmes might currently be directed to achieve maximal benefit for patients with Type 2 diabetes.

In the PEWG structured education report,[32] four key criteria were noted for education programmes: they should have a structured, written curriculum; have trained educators; be quality assured; and be audited. The present review includes only studies with a reasonable amount of information about the intervention, the topics covered, the provider and the sessions. Although not expressed as such in the publications, it is our view that in the most part these included studies would have had a structured, written curriculum to some extent or other. However, only five of the 21 published studies **[AIC data removed]** reported that they provided training for the diabetes educators and only three of these gave any details. Data on quality assurance or audit was not extracted from the studies in the present review.

Other considerations

Complexity of the interventions

Patient education is an example of a complex intervention as it is a package of care that has several interconnecting components. This presents a number of problems for evaluation and also for the interpretation of any demonstrated effects. It is difficult to establish with any precision what the 'active ingredient' causing any such effect is. It may be, for example, that knowledge of one key topic is responsible for the effect; on the other hand, it may be that it is a subtle combination of factors that may thereafter be difficult to reproduce, beyond the setting in which the education was undertaken, or with the providers of the education.

Not only are educational interventions complex in themselves, but they exist in a complex environment of management of a chronic disease. Educational interventions will interact with factors such as the medical management of diabetes, the overall healthcare setting in which patients are routinely seen and patient lifestyles. These factors may affect the effectiveness of an intervention or may have indirect impacts through other factors, such as compliance. Ideally, these complexities

would be considered in modelling exercises and pilot studies prior to conducting an RCT as recommended by the Medical Research Council (MRC) framework for the development and evaluation of RCTs for complex interventions.[85] Few of the interventions seem to have been developed in a way such that the crucial components of interventions can be teased apart from those aspects that may be less important.

The MRC framework describes the need to establish the theoretical basis of why the intervention should have the anticipated effect. This is seen as the first phase of any study design. Given the poor quality of reporting, it is unclear whether certain characteristics of studies have simply not been reported or whether they were not incorporated into the studies. Primary among these is a theoretical foundation to the intervention under study. Although health psychology is well established and a great number of findings suggest that there are particular methods of health promotion that are more effective than others, very little of this research seems to have been incorporated into studies of diabetes education. This is a disappointing finding as an integrated, theoretically motivated, approach may improve the effects of the intervention.

Confounding

There is likely to be confounding in some studies of this nature, for instance, personal factors such as the personality types of participants who volunteer for a research trial and who are able to remain throughout the duration of the trial. In some studies, the participants were to a greater or lesser extent self-selected. When people volunteer to participate in programmes it is always a concern that they may be more motivated or otherwise differ from those who have not volunteered and this may affect the generalisability of results. Similarly, results of self-report measures may be compromised as some participants may try to anticipate the desired effect or to give socially desirable answers; these are reasons for ensuring that self-report measures are validated instruments which may reduce some confounding and/or bias in patients' outcomes.

Quality of study design

The designs of several studies were flawed. A few that claimed to be randomised were only randomised in the broadest sense, for instance randomly choosing the order in which interventions would be implemented in consecutive groups of patients. These studies have been classed as CCTs in this report.

Several studies also had fairly small sample sizes and therefore are likely to have been underpowered, particularly when multiple interventions were tested. Very few studies mentioned performing prior power calculations in order to determine an appropriate size for the study.

Quality of reporting

The quality of reporting of important design issues was mostly poor. The method of randomisation was usually not described and most studies made no mention of any efforts to conceal the allocation of patients to treatment groups. This is a major shortcoming that can produce significant bias.

Although a prerequisite for including trials in this review was a good level of detail about the interventions, in terms of the topics covered, the providers and the number and nature of the sessions, many of the included studies still did not include enough detail about interventions to allow them to be replicated. This shortcoming is important, not only scientifically, but practically. If studies have shown that an intervention has been effective, then sufficient detail should have been provided to allow that intervention to be implemented, and tested, in other settings.

Another problem that relates to the poor quality of reporting is uncertainty about the nature of the control group in many of the studies. Several studies stated that the control group was receiving 'usual care'. However, in many cases what this consists of is unclear. As a result, the extent to which the interventions actually differed from the controls is sometimes unclear. The lack of a clear boundary between interventions and controls can obscure the determination of what component of the intervention may be effective and it may influence the size of effect that is shown for an intervention (either an over- or underestimate). Generality of studies is difficult to determine if it is not clear to what extent a study resembles the practice setting where the intervention might be implemented.

These issues might in part reflect word length limits in peer-reviewed publications; however, some studies were able to provide more detail than others. Ideally, complex studies or those necessitating lengthy descriptions should be supported in the literature by online material or by cross-referencing between publications to ensure that all the important methodological details can be presented.

Length of follow-up

Because diabetes is a chronic disease with a natural history of worsening metabolic control and the development of very serious long-term complications, it is critical to demonstrate that interventions can have lasting effects. Ideally, trials should report on interventions evaluated after a reasonably long follow-up in which no further intervention was conducted. However, there are very few such studies in the diabetes education literature.

Clearly, studies that report results immediately following an intervention or those with very brief follow-up are not useful in this context. Such studies were excluded, unless outcomes were evaluated at least 12 months following the introduction of an intervention. A few of these studies involved relatively short interventions with long follow-ups, but many used relatively lengthy interventions with additional educational sessions at intervals throughout almost all of the study follow-up period. With such a mix of designs, it is difficult to draw any conclusions about whether there are time-limited interventions in diabetes education that are effective. It is therefore difficult to draw any conclusions as to the optimum length of an intervention. Of the included studies, 14 reported results at interim time-points and, although these are not reported in the present review, it is worth pointing out that nine of these showed a significant effect of diabetes education on HbA_{1c} at earlier analyses ($\leqslant$12 months) than the end-point analysis. Only three of these also demonstrated significant effects of the intervention on HbA_{1c} at end-point analysis ($\geqslant$12 months).

Although long-term studies are desirable, care is needed to ensure that bias is not caused by the introduction of other interventions, or by changing the initial interventions, in response to changes in the participants' circumstances.

Attrition

Many included studies had fairly high levels of drop-out between initial recruitment and reporting of results. This is problematic for a number of reasons. Only one study reported that an ITT analysis was carried out; the other studies tested for differences between intervention and control groups on the basis of patients who remained in each group at the time of evaluation. When there is considerable attrition this can produce misleading results, particularly if there is differential attrition between groups. If, for instance, the most motivated patients remain in an intervention while those who are less motivated drop out, then the estimate of effectiveness for an unselected group of patients would be overestimated. Even testing for (or statistically adjusting for) differences in baseline characteristics will not adjust for effects such as motivational differences that are not captured in baseline evaluations. If attrition is greater in the control group than the intervention group, this could reduce the estimate of the effectiveness of the intervention (for example, if the patients who are least motivated toward self-management and who are most ill are those most likely to leave the study).

High attrition rates affect the validity of study results, but they are also of practical concern. If an intervention results in very high attrition rates, then it is questionable as to whether large numbers of patients would attend such an intervention once it is implemented in a healthcare setting.

Transferability

Of the 21 studies, only three were carried out in the UK,[46,56,59] all of which addressed complete self-management interventions. The remaining trials were carried out in the USA (eight studies), Australia (two studies), and Argentina, Finland, Germany, Israel, Italy, Korea, Sweden and The Netherlands (one study each). It is unclear to what extent educational interventions delivered in other countries are transferable to the UK and it is important to consider this within the context of these interventions. Cultural issues, not only of ethnicity, but also of traditions and customs, may have an impact upon outcomes. Patient health beliefs and attitudes are likely to differ from one country to another, and the healthcare context (private/state provision) may also affect outcomes. Generality of results may be reduced if participants are not adequately representative of the population groups likely to suffer from the condition. For example, diabetes is more prevalent in socially isolated individuals and within groups known to have health inequalities, but trials have tended either not to include participants with these backgrounds or, when such groups have been included, they have not been analysed separately from other groups.

Strengths and limitations of the assessment

The systematic review has the following strengths:

- It is independent of vested interest.
- The systematic review brings together the evidence on the effectiveness of diabetes

education models for Type 2 diabetes applying consistent methods of critical appraisal and presentation.
- A broad and thorough systematic search of the literature has identified English-language RCTs and has highlighted gaps in the literature and areas for further research.
- The work was guided by the best practice principles for undertaking a systematic review.
- Before undertaking the review, the methods were set out in a research protocol (Appendix 1), which was commented on by an advisory group. The protocol defined the research question, inclusion criteria, quality criteria, data extraction process and methods employed to undertake the different stages of the review.
- An advisory group has informed the review from its initiation, through the development of the research protocol and completion of the report.

In contrast, there were certain limitations:

- Owing to time constraints, there was a lack of follow-up with authors of the primary studies to clarify methodological details and results. However, it is unlikely that further details from the authors would have changed our overall conclusions.
- Inclusion was limited to English language due to time constraints.
- Synthesis of the included studies was through narrative analysis with no quantitative meta-analysis because of the many differences in the interventions, the designs, and the outcome measures described in the included studies.

This update review does not substantially alter the conclusions of the previous systematic review; for each outcome (HbA_{1C}, weight, BMI, cholesterol and lipids, complications, QoL and diabetes knowledge) the proportion of studies that demonstrated significant effects of education was similar.

Chapter 7
Conclusions

Implications for service provision

National policy initiatives support the role of self-management education programmes in improving health in Type 2 diabetes and recommendations and guidance have been issued for establishing high-quality patient-education programmes. Based on the evidence reviewed in this report, it would seem that education delivered by a team of educators, with some degree of reinforcement of that education made at additional points of contact, may provide the best opportunity for improvements in patient outcomes. This remains in line with the conclusions of the previous systematic review. The implications of this for service provision would be the need for educators to have time and resources to fulfil the needs of any structured educational programme, and for there to be a clear programme for the education. These issues are currently set out in national strategy (see current service provision) and it is expected that there should not be barriers to their implementation if resources are made available as part of these policy recommendations. The evidence reviewed provided little information on the training of trainers and as such a key question remains as to whether the level of training of educators could affect the success of the education. From the evidence reported, it is unclear how much resource would need to be directed at the educators themselves to ensure that they can deliver programmes successfully.

There is no evidence at present to suggest that locally implemented interventions that meet the recommendations and guidance for practice issued by national policy would be better, or worse, placed to achieve the goals of self-management education compared with nationally implemented interventions.

Suggested research priorities

Despite being based upon the best available empirical evidence, this review has only been able to give limited guidance about the effectiveness of educational interventions for Type 2 diabetes. This reflects the complex and heterogeneous multi-component nature of the interventions, which has not been helped by poor reporting in some cases. Several areas would benefit from further clarification (see below). When thinking about these, it is important for researchers to consider patient education as a complex intervention. Research methodologies are required that allow an understanding of the processes involved so that outcomes can be interpreted correctly. Education should be considered in the context of overall diabetes management and future evaluations should be considered in the broader context of understanding theory, testing intervention interactions and longer-term surveillance after testing effectiveness. The MRC framework provides useful recommendations for developing evaluations of complex interventions.

- Long-term studies of the effectiveness of diabetes education are desirable because the natural progression of diabetes is to worsen over time, and because diabetes self-management behaviour may decline through time if not reinforced. Future long-term RCTs of diabetes education interventions face challenges because a non-intervention control arm may be difficult to justify as practitioners are set targets to achieve optimal glycaemic and BP control. The design of any future study looking at diabetes education would therefore require creativity around the nature of the control group and to minimise attrition bias, which was a particular problem in the studies reviewed. Currently, there is insufficient evidence to determine whether newly diagnosed and previously diagnosed patients should receive similar educational interventions and researchers may wish to consider these subgroups in any future research.
- Realistically, long-term monitoring of clinical effects and complications of diabetes is unlikely to happen in all but a minority of trials. Therefore, the pace at which diabetes education programmes are implemented is likely to exceed the rate of generation of supporting evidence. Accordingly, procedures should be available, or developed, to monitor closely the performance of education programmes once implemented. This will require careful consideration about methodology, in order to provide meaningful information in the absence of randomisation and control populations.

- Information is needed to clarify the sensitivity of diabetes education programmes to the performance of the diabetes educators, in order to ensure success and cost-effectiveness of education programmes.
- The generality of diabetes education programmes is very difficult to establish from the available literature, partly because trials have been carried out in specific clinical or cultural settings, and partly because reporting has been of a poor standard. Future studies could benefit by more explicitly evaluating the generality of their findings, in order to maximise possible uptake and wider relevance of the work.
- Research should also address the issues around the methodologies of systematic reviews of complex interventions and particularly issues around quantitative meta-analysis of data from such studies.

Acknowledgements

We would like to thank members of the advisory group panel who provided expert advice and comments on the protocol and/or a draft of this report: Dr Helen Cooper, Lecturer in Health Care Education, University of Liverpool; Dr Simon Heller, Reader in Medicine, University of Sheffield; Linda Carter, Community Dietitian, Somerset PCT, on behalf of the Diabetes Management and Education Group (DMEG) of the British Dietetic Association (BDA); and Professor Norman Waugh, Professor of Public Health, University of Aberdeen.

We are also grateful to Alison Price and Liz Hodson, of the information resource centre, WIHRD, University of Southampton, for running searches and retrieving references, respectively, and Dr Andrea Takeda, Senior Research Fellow, SHTAC, for reviewing a draft of this report.

This report was commissioned by the NHS R&D HTA Programme. The views expressed in this report are those of the authors and not necessarily those of the NHS R&D HTA Programme. Any errors are the responsibility of the authors.

Contribution of authors

Emma Loveman (Senior Research Fellow) was the project coordinator for this review, developed the protocol, drafted the background, undertook the inclusion screening, critical appraisal and data extraction and drafted the final report. Geoff Frampton (Research Fellow) drafted the background, undertook the inclusion screening, critical appraisal and data extraction and drafted the final report. Andy Clegg (Director of SHTAC) developed the protocol and drafted the background and the final report.

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Appendix 1

Protocol methods

Full title of research question

Clinical effectiveness of models for educating people with Type 2 diabetes mellitus in diabetes self-management.

Clarification of research question and scope

- This research updates a previous systematic review on self-management interventions for diabetes. It was commissioned to inform the NICE Type 2 diabetes guideline update.
- The primary question for this review is whether current models of diabetes self-management education are clinically effective.
- Self-management in diabetes refers to achieving and maintaining BG control through diet, exercise, oral medications and insulins.
- The potential clinical benefit of an effective programme of education would be better self-management. This may be measured in the long term by a reduced level of diabetes-related complications and in the short term by maintenance of recommended levels of BG control, as reflected by GHb levels and hypoglycaemic episodes. Other potential benefits would be greater flexibility of lifestyle, and hence better QoL.
- The main comparator for this review will be usual care in clinics or primary care. This will vary amongst clinics and general practices, but will include informal education and unevaluated, locally developed education packages.
- Self-management interventions are generally complex, often including education in addition to changes in the intensity of medical treatment. This type of data may provide limited information about the educational interventions *per se* (without confounding with intensity of treatment).

Report methods

- The review will be undertaken as systematically as time allows following the general principles outlined in NHS CRD Report 4.

Search strategy

- We will search the following databases: Cochrane Systematic Reviews Database, Cochrane Central Register of Controlled Trials, NHS CRD (University of York) databases (including DARE, NHS EED and HTA database), MEDLINE (Ovid), MEDLINE In Process (Ovid), EMBASE (Ovid), PsycINFO (Ovid), CINAHL (Ovid), ERIC, Science Citation Index, Biosis Previews, ISI Proceedings (Web of Knowledge), National Research Register, Clinical Trials.gov and Current Controlled Trials.
- Searches will include RCTs, CCTs, systematic reviews and meta-analyses for evidence of efficacy. Searches will include terms relating to learning mechanisms, so as to exclude trials that appraise the effectiveness of self-management alone, since the focus of the review is on how to facilitate self-management, rather than whether self-management in itself is valuable.
- Searches will be limited to the years from 2002 to the present and will also be limited to English language. Reports published only as meeting abstracts will be excluded. Unpublished Masters dissertations and theses will be excluded.
- All studies will be collated and filtered on retrieval of the abstracts and full papers. Bibliographies of included studies and other relevant papers will be assessed for relevant studies.
- Expert advisers will be asked to comment on the comprehensiveness of our searches.

Inclusion and exclusion criteria

- Systematic reviews and meta-analyses of RCTs and CCTs and also individual RCTs and CCTs will be included.

Design

- RCTs and CCTs that compare a specific educational programme with usual care or with another educational programme will be included. Because diabetes care is constantly evolving, CCTs must have a concurrent control group.
- RCTs or CCTs that compare models of group education with individual education will be included.

Intervention

- The review will be limited to educational interventions, that is, the dissemination of knowledge and skills brought about using a number of approaches, which can be carried out with the normal range of personnel available in diabetes care. Trials that evaluate specific, specialised psychological interventions such as cognitive/behavioural or psychoanalytic therapy or counselling alone will be excluded. Educational interventions that include a psychological component will be included.
- Studies of education solely about specific complications (e.g. foot care) will not be included.
- Studies of case management interventions will not be included.

Reporting

1. In order potentially to inform practice, included studies must be reported with sufficient detail to be reproducible. They must describe the main components of the educational programme, such as:
   (a) what the intervention is with some description of the topics covered
   (b) who provides instruction (e.g. post and qualification)
   (c) how education is delivered (e.g. in person, by computer)
   (d) group or individual
   (e) length of intervention (length and number of sessions)
   (f) target audience (e.g. Type 2; newly diagnosed)
   (g) didactic or interactive instruction
   (h) training for the educators.

Educational interventions that are not described in sufficient detail to replicate will not be included.

Participants

- Participants should be diagnosed with Type 2 diabetes using the standard diagnostic criteria in effect at the inception of the study. Both newly diagnosed and participants with established diabetes will be included. Studies which include a mixed group of Type 1 and Type 2 participants, or that do not clearly define the type of diabetes as being Type 2, will be excluded.
- Participants should be described as 'adults' or a minimum of 80% of participants should be 18 years of age or older.

Outcomes

- Diabetes is a chronic condition and complications may not appear for years after diagnosis. Many 'lifestyle' interventions do not have lasting effects. Therefore, included studies must report results from a minimum of 1 year after the beginning of the intervention.
- To be included, studies must report at least one of the primary outcomes: long-term blood glucose levels (HbA_{1c}), severe hypoglycaemic episodes, diabetes-related complications or QoL [as assessed by validated measures, e.g. Short Form with 36 Items (SF-36)].
- Additional outcomes that will be reported if available within trials that meet the other inclusion criteria will include: BP, hospital admissions, relief of distress or anxiety, uptake of screening (e.g. eye screening or BP checks), patient knowledge, patient satisfaction, achievement of individual treatment goals and resource use/costs. Any psychological measures must be evaluated with validated psychometric instruments.
- Results that address individual preferred learning styles or meeting the needs of ethnic minorities or others with specific needs will be included if they are reported in studies that meet the inclusion criteria set out above.
- Inclusion and exclusion criteria will be applied by one reviewer and checked by a second. Any disagreement will be resolved by discussion.

Data extraction strategy

- Data concerning details of the study population, the intervention and outcomes will be extracted by one person and checked by a second. Any disagreements will be resolved through discussion. A draft data extraction sheet is attached, but is subject to change.

Quality assessment strategy

- The quality of included systematic reviews will be assessed using the NHS CRD (University of York) six criteria.
- Quality assessment for RCTs will be done in accordance with Chapter II.5 of CRD Report 4 (2nd Edition). The criteria for blinding patients and care providers are not achievable for this intervention and will not be included.
- Quality assessment for CCTs will focus on comparability of groups and the assessment of outcomes.
- Criteria will be applied by one reviewer and checked by a second with any disagreements resolved through discussion.

- If sufficient numbers allow, the reporting of results may be subject to a sensitivity analysis based on the quality of included studies. Where the quality of any included studies is assessed to be particularly poor, the reporting of these studies within the review may be restricted.

Methods of analysis/synthesis

- Clinical effectiveness will be synthesised through a narrative review with tabulation of results of included studies.
- Data will be combined statistically if of sufficient quantity and quality and if sufficiently similar by meta-analysis using Review Manager software.

Research in progress

- Research in progress will be sought by searching protocols on the Cochrane Database of Systematic Reviews, the National Research Register, Current Controlled Trials and the MRC Trials database, plus personal communication with the review advisors.

External advisory group

The review will be informed by an external advisory group made up of a number of experts drawn from relevant disciplines. These experts will be chosen according to academic seniority and content expertise. The advisory group will also include a methodological advisor. External advisors will see a complete and near final draft of the review and will understand that their role is part of external quality assurance. Advisors will be required to sign a copy of the NCCHTA Confidentiality Acknowledgement and Undertaking form and be asked to alert us of any potential conflicts of interest.

Appendix 2

Literature search strategies

The databases described in Appendix 1 were searched for published studies, and recently completed and ongoing research. All searches were limited to English language only. Update searches were undertaken in January 2007.

Search strategies for the main databases are described below.

Cochrane Library Issue 3 (2006)

#1 MeSH descriptor Diabetes Mellitus, Type 2 explode all trees
#2 ((typ* 2 or type ii or type two) NEAR/5 diabet*)
#3 NIDDM:ti
#4 (#1 OR #2 OR #3)
#5 MeSH descriptor Patient Education explode all trees
#6 MeSH descriptor Models, Educational explode all trees
#7 MeSH descriptor Self Care explode all trees
#8 ((educat* or train* or learn* or teach*) NEAR/3 (patient* or self* or program* or model* or system*))
#9 MeSH descriptor Self Efficacy explode all trees
#10 (#5 OR #6 OR #7 OR #8 OR #9)
#11 (#4 AND #10)
#12 (#11), from 2002 to 2006
#13 (random* or control* near (study or group or trial or usual care))
#14 (#12 AND #13)

Ovid MEDLINE 1966 to September Week 4 2006

1 ((typ$ 2 or type ii or type two) adj5 diabet$).ti. (832)
2 ((adult-onset or "adult onset" or matur$ or late or slow or stable) adj4 diabet$).ti. (13)
3 (NIDDM or (("non insulin" or non-insulin or noninsulin) adj5 diabet$)).ti. (29)
4 1 or 2 or 3 (868)
5 ((educat$ or train$ or learn$ or teach$) adj3 (patient$ or self$ or program$ or model$ or system$)).ti,ab. (2160)
6 (self$ adj3 (care$ or monitor$ or regulat$ or manage$)).ti,ab. (547)
7 (self regulat$ or self manage$ or self care or self monitor$).ti,ab. (457)
8 (blood glucose adj4 (monitor$ or regulat$ or manage$ or control$)).ti,ab. (158)
9 (patient$ adj3 (empower$ or control$ or manage$ or regulat$)).ti,ab. (4092)
10 5 or 6 or 7 or 8 or 9 (6577)
11 10 and 4 (108)
12 limit 29 to english language (83)
13 randomized controlled trial.pt. (286)
14 controlled clinical trial.pt. (20)
15 clinical trial.pt. (312)
16 (clin$ adj5 trial$).mp. [mp=title, original title, abstract, name of substance word] (3982)
17 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 (4269)
18 ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw. (1665)
19 placebo$.tw. (2287)
20 random$.tw. (16773)
21 or/13-20 (20459)
22 21 and 12 (26)
23 (review or review-tutorial or review-academic).pt. (499)
24 meta-analysis.pt. (2)
25 (meta-analys$ or meta analys$ or metaanalys$).mp. [mp=title, original title, abstract, name of substance word] (910)
26 (systematic$ adj9 review$).mp. [mp=title, original title, abstract, name of substance word] (992)
27 (systematic$ adj9 overview$).mp. [mp=title, original title, abstract, name of substance word] (18)
28 (quantitativ$ adj9 review$).mp. (77)
29 (quantitativ$ adj9 overview$).mp. [mp=title, original title, abstract, name of substance word] (6)
30 (quantitativ$ adj9 synthesis$).mp. (41)
31 (methodologic$ adj9 review$).mp. (112)
32 (methodologic$ adj9 overview$).mp. (9)
33 (integrative research review$ or research integration).mp. (1)
34 or/23-33 (1898)
35 34 and 12 (3)
36 35 not 22 (1)

PsycINFO (Ovid) including Psyc ARTICLES 2000–present

1 exp Diabetes Mellitus, Type 2/ (0)
2 ((typ$ 2 or type ii or type two) adj5 diabet$).ti. (287)

3 ((adult-onset or "adult onset" or matur$ or late or slow or stable) adj4 diabet$).ti. (1)
4 (NIDDM or (("non insulin" or non-insulin or noninsulin) adj5 diabet$)).ti. (12)
5 1 or 2 or 3 or 4 (299)
6 exp Patient Education/ (622)
7 exp models, educational/ (0)
8 exp Learning/ (28168)
9 ((educat$ or train$ or learn$ or teach$) adj3 (patient$ or self$ or program$ or model$ or system$)).ti. (3143)
10 (self$ adj3 (care$ or monitor$ or regulat$ or manage$)).ti,ab. (6453)
11 exp Self Care/ (529)
12 self administration/ or self medication/ (378)
13 self efficacy/ (3427)
14 (self regulat$ or self manage$ or self care or self monitor$).ti,ab. (5206)
15 (patient$ adj3 (empower$ or control$ or manage$ or regulat$)).ti,ab. (5737)
16 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 (45548)
17 letter.pt. (0)
18 editorial.pt. (0)
19 17 or 18 (0)
20 (5 and 16) not 19 (88)
21 limit 20 to (human and english language and yr="2002 – 2006") (64)
22 controlled study/ (0)
23 single blind procedure/ (0)
24 double blind procedure/ (0)
25 clinical trial/ (878)
26 crossover procedure/ (0)
27 randomized controlled trial/ (0)
28 (trial or random$).ti,ab. (33665)
29 22 or 23 or 24 or 25 or 26 or 27 or 28 (33945)
30 21 and 29 (9)
31 (meta analy$ or metaanaly$ or systematic review or systematic overview$).mp. [mp=title, abstract, heading word, table of contents, key concepts] (4749)
32 21 and 31 (1)

National Research Register – Searched 31 October 2006

#1. (diabet* and (model* or (self next care) or (self next manage*))) 421
#2. (diabet* and (patient and education)) 208
#3. (#1 or #2) 568
#3 Limited to 2002–2006 317

In addition, handsearching of the bibliographies of included studies was undertaken.

A flow chart of identification of studies is presented in *Figure 2*.

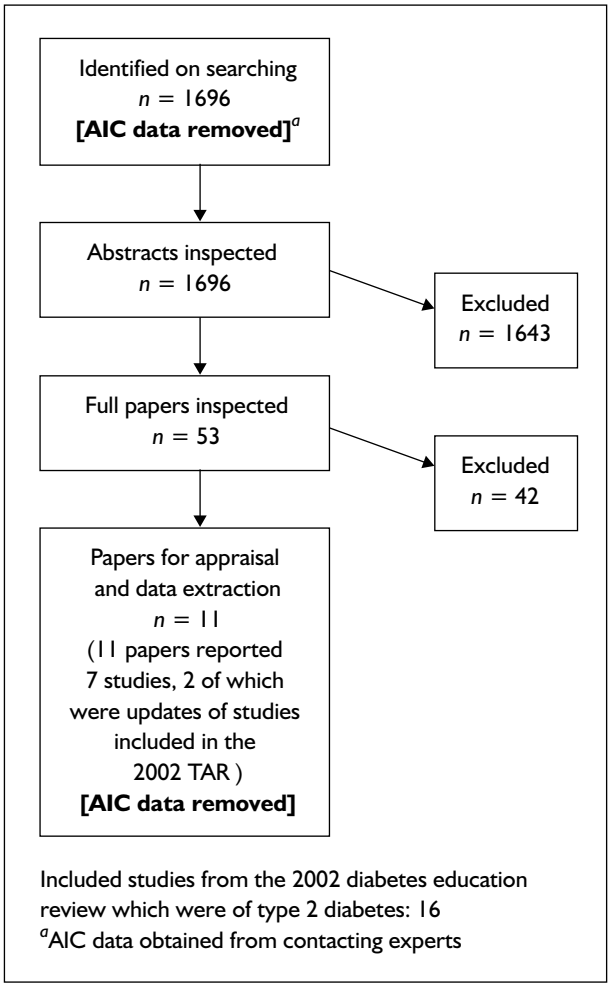

FIGURE 2 *Flow chart of identification of studies (RCTs, CCTs and systematic reviews) for clinical effectiveness systematic review (update review searches only presented)*

Appendix 3

Inclusion criteria worksheet

Trial name or number:				**Comments**
Patients with Type 2 diabetes? *NB exclude gestational diabetes*	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	
Patients described as '**adults**' or <20% under 18 years old?	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	
RCT or CCT or Sys review/MA *NB CCT must have concurrent control*	Yes ↓ next question	Unclear ↓ next question	No ↓ EXCLUDE	
Education programme? *NB exclude purely psychological/counselling interventions*	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	
Education for **self-management** of diabetes? *NB exclude education for prevention/treatment of specific complications (e.g. foot ulcer)*	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	
Comparator: Educational programme vs usual care OR another ed. programme? OR Group programme vs individual programme?	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	
Is description of intervention sufficient to **reproduce?** *NB must include topics (or content obtainable). Other characteristics: provider, length & no. of sessions, target audience, mode of delivery (in person or distance), group or individual, didactic/interactive, changes in treatment*	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	
Follow-up from inception ⩾1 year?	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	Length of follow-up?
Report one or more of **primary outcomes**: HbA_{1c} OR severe hypos OR diabetic complications OR QoL? *NB other outcomes will also be included if primary outcomes reported.*	Yes ↓ next question	Unclear ↓ next question	No → EXCLUDE	Costs reported?
Final Decision	**INCLUDE**	**UNCLEAR (Discuss)**	**EXCLUDE**	**Results of Discussion:**

1. Individual aspects of self-management, such as diet, exercise education alone to be included if there is a taught component (and meet other criteria). Where only a diet is prescribed or where fitness training occurs with no taught component, exclude.
2. Self-monitoring of diabetes – include any education programme directed at training in self-monitoring.
3. Exclude case management systems which are prompts for clinics, self-care behaviours, etc., which may or may not include some aspects of education.
4. Include education about intensifying treatment even though the effect may be due to the intensification – this can be discussed in the narrative.

Appendix 4

Quality assessment criteria

Quality criteria for assessment of experimental studies

1. Was the assignment to the treatment groups really random?	
2. Was the treatment allocation concealed?	
3. Were the groups similar at baseline in terms of prognostic factors?	
4. Were the eligibility criteria specified?	
5. Were outcome assessors blinded to the treatment allocation?	
6. Was the care provider blinded?	Not applicable
7. Was the patient blinded?	Not applicable
8. Were the point estimates and measure of variability presented for the primary outcome measure?	
9. Did the analyses include an ITT analysis?	
10. Were withdrawals and drop-outs completely described?	

Some instructions for using a checklist for RCTs

Quality item	Coding	Explanation
1. Was the assignment to the treatment groups really random?		
Random sequence generation	Adequate Partial Inadequate Unknown	Adequate: random numbers table or computer and central office or coded packages Partial: (sealed) envelopes without further description or serially numbered opaque, sealed envelopes Inadequate: alternation, case record number, birth date or similar procedures Unknown: just the term 'randomised' or 'randomly allocated', etc.
2. Was the treatment allocation concealed?		
Concealment of randomisation The person(s) who decide on eligibility should not be able to know or be able to predict with reasonable accuracy to which treatment group a patient will be allocated. In trials that use good placebos this should normally be the case; however, different modes or timing of drug administration in combination with the use of small block sizes of known size may present opportunities for clinicians who are also involved in the inclusion procedure to make accurate guesses and selectively exclude eligible patients in the light of their most likely treatment allocation; in centres with very low inclusion frequencies combined with very brief follow-up times this may also present a potential problem because the outcome of the previous patient may serve as a predictor of the next likely allocation	Adequate Inadequate Unknown	Adequate: when a paper convinces you that allocation cannot be predicted (separate persons, placebo really indistinguishable, clever use of block sizes (large or variable). Adequate approaches might include centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system with a randomisation sequence that is not readable until allocation, and other approaches with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients Inadequate: this option is often difficult. You have to visualise the procedure and think how people might be able to circumvent it. Inadequate approaches might include use of alternation, case record numbers, birth dates or week days, open random numbers lists, serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation) and any other measures that cannot prevent foreknowledge of group allocation Unknown: no details in text. Disagreements or lack of clarity should be discussed in the review team

continued

Quality item	Coding	Explanation
3. Were the groups similar at baseline regarding the prognostic factors?		
Baseline characteristics Main aim is to enable the reviewer to see which patients were actually recruited. It enables one to get a rough idea on prognostic comparability. A real check on comparability requires multi-variable stratification (seldom shown)	Reported Unknown	Consult the list of prognostic factors or baseline characteristics (not included in this appendix) Reviewer decides
4. Were the eligibility criteria specified?		
Prestratification Consult the list of prognostic factors or baseline characteristics (not included in this Appendix)	Adequate Partial Inadequate Unknown	Single-centre study Adequate: prestratification on at least one factor from the list or no prestratification if the number of patients exceeds a prespecified number. Partial: leave judgement to reviewer Inadequate: stratification on a factor(s) not on our list or no stratification whereas the number of patients is less than the prespecified number Unknown: no details in text and no way to deduce the procedure from the tables. Multi-centre study Adequate: must prestratify on centre. Within each centre the criteria for single-centre studies also apply Partial: impossible option Inadequate: no prestratification on centre or violating the criteria for single-centre studies (see above) Unknown: no details in text and no way to deduce the procedure from the tables
5. Were outcome assessors blinded to the treatment allocation?		
Blinding of assessors The assessor may be the patient (self-report), the clinician (clinical scale, BP…) or, ideally, a third person or a panel. Very important in judgement of cause of death but unimportant in judgement of death	Adequate Inadequate Unknown	Adequate: independent person or panel or (self) assessments in watertight double-blind conditions Inadequate: clinician is assessor in trial on drugs with clear side-effects or a different influence on laboratory results, ECGs, etc. Unknown: no statements on procedures and not deducible
6. Was the care provider blinded?		
Blinding of care givers Look out for good placebos (see, hear, taste, feel, smell), tricky unmasking side-effects accounting for the subjectivity of the outcome measurements and the accessibility of co-interventions by the care givers	Adequate Partial Inadequate Unknown	Adequate: placebo described as 'indistinguishable' and procedures watertight (use your imagination with the 'cheat' in mind; e.g. statement that sensitive/unmasking laboratory results were kept separate from ward personnel) Partial: just 'double blind' in text and no further description of procedures or nature of the placebo Inadequate: wrong placebo (e.g. fructose in trial on ascorbic acid) Unknown: no details in text
Co-interventions Register when they may have an impact on any of the outcome phenomena. Consult the list of cointerventions (not included in this Appendix)	Adequate Partial Inadequate Unknown	Adequate: percentages of all relevant interventions in all groups Partial: one or more interventions omitted or omission of percentages in each group Inadequate: not deducible Unknown: no statements

continued

Quality item	Coding	Explanation
7. Was the patient blinded?		
Blinding of patients This item is hard to define. Just the statement 'double blind' in the paper is really insufficient if the procedure to accomplish this is not described or reasonably deducible by the reviewer. Good placebos (see, hear, taste, feel, smell), tricky unmasking side-effects accounting for the subjectivity of the outcome measurements and the accessibility of co-interventions by the patient are required	Adequate Partial Inadequate Unknown	Adequate: placebo described as 'indistinguishable' and procedures watertight Partial: just 'double blind' in text and no further description of procedures or nature of the placebo Inadequate: wrong placebo Unknown: no details in text
Compliance Dosing errors and timing errors	Adequate Partial Inadequate Unknown	Adequate: Medication Event Monitoring System (MEMS or eDEM) Partial: blood samples, urine samples (use of indicator substances) Inadequate: pill count or self-report Unknown: not mentioned
Check on blinding Questionnaire for patients, care givers, assessors and analysis of the results; the (early) timing is critical because the treatment effect may be the cause of unblinding, in which case it may be used as an outcome measure	Reported Unknown	Reviewer decides
8. Were the point estimates and measure of variability presented for the primary outcome measure?		
Results for the primary outcome measure	Adequate Partial Inadequate Unknown	Adequate: mean outcome in each group together with mean difference and its standard error (SE) or standard deviation (SD) or any CI around it or the possibility to calculate those from the paper. Survival curve with log-rank test and patient numbers at later time-points Partial: partially reported Inadequate: no SE or SD or SD without *N* (SE = SD/*N*) Unknown: very unlikely
9. Did the analysis include an ITT analysis?		
ITT analysis Early drop-out can make this very difficult. Strictest requirement is sensitivity analysis including early drop-outs	Adequate Inadequate	Reviewers should not just look for the term ITT but assure themselves that the calculations were according to the ITT principle
Dealing with missing values The percentage missing values on potential confounders and outcome measurements (seldom given) is a rough estimate of a trial's quality. One can carry them forward, perform sensitivity analysis assuming the worst and best case scenarios, use statistical imputation techniques, etc. Note that the default option (deletion) assumes that the value is randomly missing, which seems seldom justified	Adequate Partial Inadequate Unknown	Adequate: percentage of missing values and distribution over the groups and procedure of handling this stated Partial: some statement on numbers or percentages Inadequate: wrong procedure (a matter of great debate) Unknown: no mention at all of missing and not deducible from tables

continued

Quality item	Coding	Explanation
Loss to follow-up This item examines both numbers and reasons; typically an item that needs checking in the methods section and the marginal totals in the tables. Note that it may differ for different outcome phenomena or time-points. Some reasons may be reasons given by the patient when asked and may not be the true reason. There is no satisfactory solution for this	Adequate Partial Inadequate Unknown	Adequate: number randomised must be stated. Number(s) lost to follow-up (dropped out) stated or deducible (from tables) for each group and reasons summarised for each group Partial: numbers, but not the reasons (or vice versa) Inadequate: numbers randomised not stated or not specified for each group Unknown: no details in text

Quality criteria for assessment of CCTs – CRD Report 4

Were the groups similar at baseline in terms of prognostic factors?
Were the eligibility criteria specified?
Were outcome assessors blinded to the treatment allocation?
Were the point estimates and measure of variability presented for the primary outcome measure?
Did the analyses include an ITT analysis?
Were withdrawals and drop-outs completely described?
Were participants likely to be representative of the intended population?

Appendix 5

Data extraction forms

Interventions of multifaceted self-management education (RCTs in alphabetical order, followed by CCTs)

Reference and design	Intervention	Participants	Outcome measures
Study: Brown *et al.*, 2002[49,50] **Source:** Journal article **Country:** USA **Setting:** Community **Language:** English **Trial design:** RCT	**Treatment intervention**: Culturally referenced diabetes self-management group education intervention using didactic and interactive approach, delivered in person. 4 cohorts over 1 year *Topics:* nutrition, self-monitoring, exercise, hygiene, illness days, foot care, complications (short and long term). Promotion behaviour changes through problem-solving, food preparation demonstrations and social support *Provider:* Mexican-American nurses, dieticians and community workers *Sessions:* 52 contact hours (3 months of weekly 2-h sessions, 6 months of biweekly + 3 months of monthly 2-h support group sessions) *Theory:* based on results of four meta-analytic reviews and 6 years of development and piloting of intervention *Delivery:* groups with each participant bringing a 'support' person *Treatment changes:* *Training trainers*: 4 nurses and 4 dieticians attended seminars on diabetes education and participated in supervised clinical practicum with outpatients. 8 community workers with Type 2 diabetes participated in an 8-week programme on diabetes self-management *Mode:* written materials limited due to low literacy rates. Language predominantly Spanish with a blend of English and each participant nominated a family member as a support person. Ref. 16 in trial gives more details of intervention plus Table 1, p. 261 **Control intervention:** Usual care by physicians or local clinics (wait-list controls) **Duration of intervention:** 12 months	**Eligibility/exclusion criteria**: *Inclusion:* Type 2 diabetes (defined p. 260) diagnosed after 35 years of age, aged between 35 and 70 years, willing to participate *Exclusion*: if pregnant or if had medical conditions for which diet and exercise changes would be contraindicated **How selected**: randomly selected from rosters of previous research studies (none intervention studies, all blood sampling). Grouped by area of county in which they lived **Numbers involved**: 256 [128 intervention (int.), 128 control (con.)] **Numbers on insulin**: int. 25; con. 26 *Tablets*: int. 83; con. 86 *Diet alone*: int. 10; con. 7 *Oral and insulin*: int. 8; con. 7 **Type of diabetes?**: Type 2 **Mean duration of diabetes**: int. 7.6 (SD 5.8) years; con. 8.1 (SD 6.9) years **Baseline measurements of outcome parameter (mean ± SD)**: HbA_{1c} int. 11.81% ± 3; con. 11.8% ± 3.02 *BMI:* int. 32.33 ± 5.97; con. 32.12 ± 6.35 *Cholesterol:* int. 211.83 ± 45.34; con. 203.57 ± 48.82 *Triglycerides:* int. 215.35 ± 130.07; con. 195.58 ± 118.95 **Gender (M/F):** int. 51/75; con. 40/86 **Mean age**: int. 54.7 (SD 8.2) years; con. 53.3 (SD 8.3) years **Ethnic groups**: all Mexican-Americans **Losses to follow-up**: not reported. Baseline data on 126 int. and 126 con. patients, 12 months data based on 112 int. and 112 con. patients **Compliance**: attendance at first session was 79%. At end of 12 months it was 50%. Dropped to 40% at 13 weeks when focus changed from education to support group sessions	**Primary outcomes used**: HbA_{1c} **Secondary outcomes used**: diabetes-related knowledge, fasting BG, BP, total cholesterol, HDL and LDL cholesterol, triglycerides, health beliefs, home glucose monitoring, BMI, costs **Individual preferred learning style addressed?**: no **Any subgroups**: age and gender **Normal range(s) for outcomes**: none reported **How outcomes assessed?**: no details reported **Validated?**: physiological measures yes, knowledge and health beliefs unclear **Timing of outcomes same for both groups**: yes **Length of follow-up**: 12 months from inception

continued

Outcome (mean ± SD)	Intervention	Control	Difference between groups
HbA_{1c} (n = 112)	10.89% (2.56), adjusted 10.87%*	11.64% (2.85), adjusted 11.66%	*$p < 0.05$
FBG (n = int. 114; con. 113)	194.95 (63.27)*	210.51 (66.55)	*$p < 0.05$
Cholesterol (n = int. 112; con. 113)	189.88 (36.35)	187.64 (42.66)	
Triglycerides (n = 113)	214.43 (194.93)	198.65 (148.38)	
BMI (n = int. 113; con. 114)	32.17 (6.45)	32.28 (6.52)	
Knowledge/beliefs not reported as not a validated measure. 3 and 6 months data reported Costs: total for eight subjects/group = US$3070. Total per person US$384			

Methodological comments
Allocation to treatment groups: reports that individuals allocated to groups and then later that groups were randomly assigned to experimental or control conditions. In 'data analysis' section also states random assignment but no method described
Blinding of outcome assessors?: not reported
Allocation concealment?: not reported
Analysis by ITT?: see Method of data analysis
Comparability of treatment groups: reported to be no significant differences only any baseline variables
Method of data analysis: multi-level modelling (within subjects and between subjects analysis) which estimates for a given subject from available data and thus doesn't eliminate those with missing data. SD reported, no CIs
Sample size/power calculation: not reported
Attrition/drop-outs: not reported except numbers in results tables

General comments
Generalisability: high HbA_{1c} at baseline, culturally referenced to Mexican-Americans, different cohorts over time
Conflict of interests: funded by National Institute for Diabetes and Digestive and Kidney Diseases and the Office of Research on Minority Health
Other:

FBG, fasting blood glucose.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Adequate
8. Were withdrawals and drop-outs completely described?	Partial

Reference and design	Intervention	Participants	Outcome measures
Study: Brown *et al.*, 2005[52] **Source**: Journal article **Country**: USA **Setting**: Community (schools, churches, day care centres, health clinics) **Language**: English **Trial design**: RCT	**Treatment intervention:** Some data (*in italics*) here taken from previous publication.[49] *Topics*: nutrition, home glucose monitoring, physical activity, other self-management topics [*Hygiene, illness days, foot care, complications (short and long term)*]. Promotion of behaviour changes through problem solving and goal setting *Provider*: bilingual Mexican-American nurses, dietitians and community workers *Sessions*: 52 contact hours over 12 months: 12 weekly 2-h sessions, followed by 14 2-h support group sessions *Audience*: group based with family member support *Delivery*: didactic and interactive approach *Treatment changes*: Not reported *Training trainers*: 4 nurses and 4 dieticians attended seminars on diabetes education and participated in supervised clinical practicum with outpatients. 8 community workers with Type 2 diabetes participated in an 8-week programme on diabetes self-management *Theory*: based on results of four meta-analytic reviews and 6 years of development and piloting of intervention *Mode*: written materials limited due to low literacy rates. Language predominantly Spanish with a blend of English **Control intervention**: Culturally referenced compressed (shorter) educational intervention which was informed by focus groups from a previous publication. NB: some data (*in italics*) here taken from previous publication[49] *Topics*: nutrition, home glucose monitoring, physical activity, other self-management topics. Hygiene, illness days, foot care, complications (short and long term). Promotion of behaviour changes through problem-solving and goal setting *Provider*: bilingual Mexican-American nurses, dietitians, community workers *Sessions*: 22 contact hours over 12 months: 8 weekly 2-h sessions	**Eligibility/exclusion criteria:** *Inclusion*: age 35–70 years, diagnosed with Type 2 diabetes (two verifiable FBG results $\geqslant$140 mg/dl or taking or having taken insulin or hypoglycaemic agents for $\geqslant$1 year). *Exclusion*: pregnant or had medical conditions for which changes in diet and walking were contraindicated (e.g renal failure or previous amputation) **How selected:** selected from rosters of ongoing genetic studies. Six cohorts were recruited and individuals assigned to groups organised within a specific area of the county and then randomly assigned to either condition. Four groups of eight participants (and support people) constituted each cohort, two groups were randomly assigned to each intervention. The same process occurred every 3 months until 23 groups were enrolled **Numbers involved**: 216 participants selected. 114 to 'compressed' groups and 102 to 'extended' groups **Losses to follow-up**: attendance at data collection sessions averaged 82%, only 10 participants were considered by the authors as true drop-outs as they did not return to any data collection sessions **Numbers on insulin**: 6.3% extended, 5.3% compressed *Tablets*: 81.1% extended, 78.0% compressed *No medication (diet alone)*: 10.5% extended, 10.6% compressed **Duration of diabetes**: not reported **Gender (F/M)**: extended 61/41, compressed 69/45 **Age (mean ± SD)**: extended 49.6 ± 8.2 years, compressed 49.6 ± 7.6 years **Ethnic groups**: Mexican-Americans **Compliance**: attendance at data collection sessions averaged 82%; however, this does not measure compliance with the intervention **Baseline measurements of outcome parameters (mean ± SD)**: *Age at diagnosis*: extended 44.6 ± 9.2 years, compressed 44.4 ± 8.3 years *BMI (kg/m^2)*: extended 32.9 ± 8.3, compressed 32.2 ± 5.8 *HbA_{1c}*: extended 11.5 ± 3.5, compressed 11.8 ± 3.4 *FBG*: extended 190.5 ± 68.3, compressed 192.1 ± 64.4	**Primary outcomes used**: HbA_{1c}; FBG **Secondary outcomes used**: diabetes knowledge (data not extracted as the outcome was not validated). Also BP, BMI, cholesterol, triglycerides (data not presented in publication). Others not reported here as do not fit the protocol for this review **Individual preferred learning style addressed?**: no **Subgroups**: high and low attendance, gender (not data extracted) **Normal range(s) for outcomes**: not reported **How outcomes were assessed**: HbA_{1c} by Glyc-Affin GHb) **Validation of outcomes**: not reported; knowledge instrument was from an unpublished thesis – not validated **Timing of outcomes the same for both groups?**: intervention groups began immediately after baseline data collection and data were collected as

continued

Reference and design	Intervention	Participants	Outcome measures
	followed by 3 support sessions at 3, 6 and 12 months *Audience*: group based with family member support *Delivery*: didactic and interactive approach *Treatment changes*: not reported *Training of trainers*: as above *Theory*: as above Both interventions also received usual care **Duration of intervention**: 12 months **Were the care programmes identical?** Unknown		each cohort reached 3, 6, 12, 24 and 36 months **Length of follow-up**: 36 months. Data only presented for 3 and 12 months (3-month data not extracted)

Results

Outcome	Extended group, *n* = 114	Compressed group, *n* = 102	Comparisons between groups
Mean HbA_{1c} change from baseline at 12 months	*n* = 89 –1.0%	*n* = 96 –0.7%	Not significant (*p*-values of differences between groups not given).
HbA_{1c} end-point value (12 months), mean ± SD	*n* = 89 10.5 ± 3.0	*n* = 96 11.1 ± 3.2	Not reported
FBG change from baseline at 12 months	*n* = 89 –16.7	*n* = 97 –12.4	Not reported
FBG end-point value (12 months), mean ± SD	*n* = 89 173.8 ± 63.6	*n* = 97 179.7 ± 61.6	Not reported

Methodological comments
Allocation to treatment groups: no details reported
Blinding of outcome assessors: not reported
Allocation concealment: not reported
Analysis by ITT: method of data analysis suggests that all participants with missing data were incorporated into the analysis; however, the numbers presented in the table of results suggest that missing data were not used
Comparability of treatment groups: reports no statistically significant differences between groups for any baseline measure
Method of data analysis: prospective repeated measure ANOVA. To handle missing data, hierarchical linear models were applied by which non-randomly missing data were handled by including indicators of missing data patterns. States all analyses were adjusted for baseline differences but no detail of which were included as statement made reporting no differences in baseline noted
Sample size/power calculation: based on previous studies estimated that a total of 170 participants (85 in each intervention group) provided power of 80% for detecting a medium between-group effect size on HbA_{1c} (reference given). They oversampled by 30% to help account for attrition
Attrition/drop-out: numbers reported but no reasons given

General comments
Generalisability: high HbA_{1c} at baseline, culturally referenced to Mexican-Americans
Conflict of interests: unknown: funded by research award from National Institute for Research Awards

ANOVA, analysis of variance.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Inadequate

Reference and design	Intervention	Participants	Outcome measures
Study: Campbell *et al.*, 1996[51] **Source**: Journal article **Country**: Australia **Setting**: Unclear **Language**: English **Trial design**: RCT	**Treatment intervention:** 4 programmes: minimal instruction (1), individual education (2), group education (3), behavioural programme (4). All encouraged to bring a support person *Provider*: programmes 1, 2 and 3 were delivered by staff in the diabetes education service, including 5 nurse educators and 3 dieticians. A single nurse delivered the programme 4 *Treatment intervention 1 (apparently individual) = minimal education*: *Sessions*: two 1-h sessions within 2 weeks of referral *Topics*: (same topics but less detail than others); the portion exchange dietary system, exercise, use of oral hypoglycaemics, practical instruction in urine testing, foot care and recommendations to consult an ophthalmologist and podiatrist *Treatment intervention 2 = individual education*: *Sessions*: 2 sessions for 1 h within 2 weeks of referral, then 30-minute sessions approximately monthly until 12 months *Topics*: same but more detail than for intervention 1 and included information on the causes, symptoms, mechanisms and complications of diabetes *Treatment intervention 3 = group education*: *Sessions*: at least 2 individual sessions and a 3-day small group education course. (Individual monthly sessions were continued until a course could be scheduled) *Mode*: Course involved lectures, small group exercises, practical sessions	**Eligibility/exclusion criteria**: *Inclusion*: <80 years, Type 2 for <5 years, speak and write English, had received no previous formal instruction, not taking >75% of the maximum dose OHAs, had no terminal illness **How selected**: patients referred by GP **Numbers involved**: total *N* = 238; group (1) 59, (2) 57, (3) 66, (4) 56 **Numbers on insulin**: none **Tablets**: group (1) 19, (2) 22, (3) 24, (4) 23 **Diet alone**: group (1) 40, (2) 35, (3) 42, (4) 33 **Type of diabetes?**: Type 2 **Duration of diabetes (mean years + SE)**: group (1) 0.5 (0.1), (2) 0.9 (0.2), (3) 0.4 (0.1), (4) 0.36 (0.1) **Baseline measurements of outcome parameter:** *HbA_1*: group (1) 11.9% (SE 0.6), (2) 12.2% (0.5), (3) 12.1% (0.6), (4) 13.3% (0.6) *Knowledge*: group (1) 5.7 (0.4), (2) 5.3 (0.4), (3) 5.5 (0.4), (4) 4.6 (0.5) *Systolic BP*: group (1) 136.9 (2.4), (2) 135.5 (3.0), (3) 137.5 (2.7), (4) 145.8 (3.3) *Diastolic BP*: group (1) 80.7 (1.3), (2) 81.6 (1.2), (3) 81.7 (1.4), (4) 91.7 (1.7) *Gender (M/F)*: group (1) 22/37, (2) 33/24, (3) 35/31, (4) 24/32 *Mean age*: group (1) 58.2 (1.3), (2) 56.8 (1.5), (3) 58.4 (1.4), (4) 60.9 (1.4) years *Ethnic groups*: not reported *Losses to follow-up*: group (2) 40% attrition, (3) 42%, (4) 9% *Compliance*:	**Primary outcomes used**: HbA_1 **Secondary outcomes used**: BP, knowledge, satisfaction, uptake podiatry, ophthalmology, hospitalisations, BMI **Individual preferred learning style addressed?**: no **Any subgroups**: no **Normal range(s) for outcomes**: HbA_1 <8.5%, knowledge? **How outcomes assessed?**: HbA_1 laboratory, knowledge, satisfaction, hospitalisations self-report, BP unclear **Validated?**: HbA_1, knowledge (DKNA) yes, satisfaction reported to have shown good internal consistency and reliability **Timing of outcomes**: same for both groups

continued

Reference and design	Intervention	Participants	Outcome measures
	Topics: same topics as the other programme. 2-h follow-ups were scheduled at 3 and 9 months *Treatment intervention 4 = behavioural*: *Sessions*: series of individual visits, 3 in first month, after which differed depending on patient's needs with a minimal schedule of 3, 6 and 13 months supplemented with telephone calls *Topics*: same topics as other groups *Mode*: Sessions in patient's home *All groups*: *Treatment changes*: no details *Training trainers*: no details *Theory*: no details except for group 4: based on cognitive–behavioural strategies Participants in groups 2 and 3 also had opportunity to attend a 2-h lecture on diet (group) **Duration of intervention**: Up to 12 months		**Length of follow-up**: 12 months (minimal instruction only 6 months) from inception

Outcomes (mean change ± SE unless otherwise noted)	Group 1 (minimal education)	Group 2 (individual education)	Group 3 (group education)	Group 4 (behavioural)	Difference between groups
HbA_1 (%): *n* = ?/25/19/39	No follow-up	–3.3 (0.9)	–3.0 (1.1)	–4.8 (0.7)	
Knowledge: *n* = ?/29/26/35	No follow-up	4.4 (0.6)	4.2 (0.5)	5.6 (0.6)	
Systolic BP (mgHg): *n* = ?/16/11/37	No follow-up	–6.8 (5.8)	–12.4 (6.8)	–16.9 (3.8)	
Diastolic BP (mgHg): *n* = ?/16/11/374	No follow-up	–5.3 (3.0)*	–5.0 (4.0)*	–7.9 (2.6)	*Significant from group 4, $p < 0.05$
BMI: *n* = ?/30/25/41	No follow-up	–2.0 (0.4)	–1.4 (0.5)	–2.6 (0.5)	
Cholesterol (mmol/l): *n* = ?/23/19/34	No follow-up	0.12 (0.20)	0.16 (0.16)	–0.33 (0.15)	
HDL cholesterol (mmol/l): *n* = ?/21/16/27	No follow-up	0.02 (0.04)	0.18 (0.10)	0.06 (0.08)	
Cholesterol risk ratio (total/HDL): *n* = ?/21/15/25	No follow-up	–0.25 (0.03)	–0.35 (0.46)	–0.59 (0.20)	
Treatment intensity: *n* = ?/29/27/42	No follow-up	% unchanged: 75 % decreased: 17 % increased: 7	% unchanged: 70 % decreased: 22 % increased: 8	% unchanged: 74 % decreased: 17 % increased: 10	
Satisfaction (actual score + SE): *n* = ?/25/25/30	No follow-up	74.8 (2.2)	77.9 (2.0)	77.0 (2.3)	

continued

Outcomes (mean change ± SE unless otherwise noted)	Group 1 (minimal education)	Group 2 (individual education)	Group 3 (group education)	Group 4 (behavioural)	Difference between groups
Proportion consulting ophthalmology (%): *n* = ?/38/37/47	No follow-up	97	95	89	
Proportion consulting podiatry (%): *n* = ?/31/30/42	No follow-up	55	73	74	

(3- and 6-month data reported)
Methodological comments
Allocation to treatment groups: not described
Blinding of outcome assessors?: not described
Allocation concealment?: not described
Analysis by ITT?: no
Comparability of treatment groups: significant differences in levels of education, duration since diagnosis, diastolic BP, smoking
Method of data analysis: continuous data – change scores were calculated and compared by ANCOVA with *t*-tests as *post hoc* tests; categorical data – χ^2 and pair-wise comparisons, mean and SE given
Sample size/power calculation: no
Attrition/drop-outs: percentages reported but no reasons given

General comments
Generalisability: 94% patients asked to participate consented, high HbA_{1c} at baseline
Conflict of interests: funding support not mentioned
Other:

ANCOVA, analysis of covariance; SE, standard error.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Partially
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Partial

Reference and design	Intervention	Participants	Outcome measures
Study: Cooper *et al.*, 2002;[56] 2003[57,58a] **Source**: Published and unpublished **Country**: UK **Setting**: Multi-centre: 2 hospitals and 1 health centre **Language**: English **Trial design**: RCT (waiting list design)	**Treatment intervention**: Diabetes Look After Yourself (DLAY) course (for further details of constituent patient groups, see the next column) *Topics*: self-management [nutrition, physical activity, relaxation, screening, management of complications, foot care, sick-day rules (personal communication author)] exploration of feelings, how to make best use of health service) *Provider*: specialist diabetes nurses (supported by dieticians – personal communication by author) *Sessions*: 8 weekly sessions of approximately 2 h each. Delivered at staggered intervals over 14 months *Delivery*: largely interactive, small and plenary group discussions, problem-based learning, goal setting, exercise, relaxation and practice of skills in 3 centres (see first column) *Treatment changes*: proportionally more people (46%) in the intervention group had their diabetes drug treatment changed compared with the control group (30%) but the difference was not significant (χ^2, $p = 0.16$). Four people (2 in each group) were changed to insulin therapy during the course of the trial *Training of trainers*: nurse trainers trained together and were provided with a teaching manual *Theory*: grounded in educational and behavioural theories associated with adult experiential learning and health protective behaviour, which produced a framework of variables including cognitive factors, and social–environmental factors. Central to the philosophy was an empowerment approach to health education **Control group**: randomised but on a waiting list for 12 months **Duration of intervention**: 8 weeks	**Eligibility/exclusion criteria**: *Inclusion*: Type 2 diabetes diagnosed for at least 1 year, able to give written consent, undergoing regular diabetes screening *Exclusion*: if <21 or >75 years old, persistent defaulters, with alcohol problem, language problem or a physical handicap which precluded participation in the activity/exercise programme (more details provided) **How selected**: not reported **Allocation to treatments**: staggered over a 14-month period with five trial courses running over 1 year Participants were allocated to the 8-week intervention directly (at 0 months) (short-term trial group; $n = 30$) or after a 6-month wait-list control period (short-term control group; $n = 23$). These groups were then combined to form a long-term (12-month) trial group which was compared with a long-term (12-month) control group (patients on a waiting list; $n = 36$). The longer-term trial groups are reported here **Numbers involved**: intervention $n = 53$; control $n = 36$; total $n = 89$ (represented only 40% of the total number of people asked to take part – characteristics of those not recruited were not different from those recruited in terms of age, ethnicity or gender) **Numbers on diabetes treatment**: insulin: none Tablets: intervention 75%; control 66% Diet alone: intervention 25%; control 34% **Mean (range) duration of diabetes since diagnosis**: intervention 6 (1–28) years; control 6 (1–30) years **Mean ± SD baseline measurements of relevant parameters**: *HbA_{1c}*: intervention 7.9 ± 1.7% (range 4.5–11.0); control 7.0 ± 1.6% (range 4.6–10.6) *BMI*: intervention 32.5 ± 6.7 kg/m^2; control 32.1 ± 6.1 kg/m^2 *Self-monitoring*: intervention 67%; control 47% *Attitudes (scale 0–100%)*: intervention 73.1 ± 11.9; control 74.6 ± 11.0 *Exercise (scale 0–100)*: intervention 50.8 ± 25.5; control 48.8 ± 31.6 *Diet (scale 0–100%)*: intervention 71.6 ± 18.2; control 69.6 (15.5) *Treatment effectiveness (Likert scale 0–5)*: intervention 4.4; control 4.0 **Gender (M/F)**: intervention 57/43%; control 58/42%	**Primary outcomes used**: HbA_{1c} **Secondary outcomes used**: summary of Diabetes Self-Care Activities Questionnaire. Diabetes Integration Questionnaire (attitudes to diabetes and its treatment) Personal Models of Diabetes Questionnaire (treatment effectiveness) (qualitative outcomes on patient's perspectives based on focus group interviews not reported here) **Individual preferred learning style addressed**: no **Subgroups**: none reported **Normal range(s) for outcomes**: HbA_{1c}: 4–6% **How outcomes were assessed**: HbA_{1c} by lab, others by self-report **Validation of outcomes**: yes. Quantitative measures were validated **Timing of outcomes same for both groups**: yes (if allowing for staggered design)

continued

Reference and design	Intervention	Participants	Outcome measures
		Mean (range) age: Intervention 58 (30–70) years; control 58 (35–73) years **Ethnic groups**: other than caucasian: intervention 1 (2%); control 0% **Losses to follow-up**: stated in the original work[56] that overall $n = 11$ (12%) lost to follow-up, comprising 5 deaths (3 in intervention, 2 in control) and 6 drop-outs (3 in intervention, 4 in control) (note discrepancy: $n \neq 11$). Information from author: drop-outs (2 in intervention and 4 in control) **Compliance**: 76% attended 7 or more sessions (a significant correlation between attendance rates and reductions in HbA_{1c} at 12 months)	**Length of follow-up**: 12 months from inception

	Mean ± SD (unless stated) of outcome at 12 months		
	Intervention ($n = 48$)	**Control ($n \approx 30$)**	**Difference between intervention and control**
HbA_{1c} (%)	7.9 ± 2.1	7.2 ± 1.6	$p = 0.84$
Attitudes (scale 0–100%, ↑ = better)	75.1 ± 11.0	70.5 ± 11.0	$p = 0.01$
Treatment effectiveness (median on Likert scale 0–5, ↑ = better)	4.5	4.1	NS
BMI (kg/m^2)	31.3 ± 5.7	30.5 ± 3.9	NS
Diet (scale: 0–100%, ↑ = better)	76.5 ± 12.2	68.0 ± 17.8	NS
Exercise (scale: 0–100%, ↑ = better)	62.5 ± 25.3	55.9 ± 25.0	NS
Self-monitoring (% blood testing)	92	63	$p = 0.002$

Methodological comments

Allocation to treatment groups: stated that patients were blindly and randomly assigned to the intervention using random number generator

Blinding of outcome assessors: not reported

Allocation concealment: information from author that patients were randomly allocated to the intervention by a statistician who was blind to the patients involved in the trial

Analysis by ITT: not reported

Comparability of treatment groups: higher mean HbA_{1c} level in the intervention group compared with control after attrition (7.9 vs 7.0%) – adjusted for in the analysis. Overall, groups were comparable in relation to demographic, medical and social characteristics. Significant differences were encountered for co-morbidities only

Method of data analysis: used both quantitative and qualitative analysis. Means, SDs and *p*-values were reported. Regression analysis was used in the calculation of changes in baseline HbA_{1c} levels, to account for differences in baseline data for the intervention and control groups

Sample size/power calculation: yes. Calculated that 48 patients would be needed to detect a 1% change in HbA_{1c}. This would give 95% power with significance at the 5% level

Attrition/drop-outs: 12% (details above). Reasons for drop-outs not reported

General comments

Generalisability: only about 40% of the patients asked to take part were recruited. Those refusing to take part showed no difference in age and sex compared with those who participated. HbA_{1c} levels were relatively good at baseline. Patients might have been better at self-management than typical from the outset

Conflict of interests: funded by Diabetes UK

Other: possible ceiling effects in treatment effectiveness evaluation

[a] Cooper *et al.*, 2002[65] was also screened but duplicated existing information.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Adequate
2. Was the treatment allocation concealed?	Adequate
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Partia

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Reference and design	Intervention	Participants	Outcome measures
Study: Deakin *et al*., 2006;[46] also 2003[47,48] **Source**: Journal article **Country**: UK **Setting**: Community **Language**: English **Trial design**: RCT	**Treatment intervention**: X-PERT programme (reference available) *Topics*: education and self-management, including weight, diet, exercise, complications (risk, prevention, treatment and monitoring), goal setting and self-monitoring *Provider*: delivered by diabetes research dietician (author) using X-PERT programme (no further details) *Sessions*: one 2-h session per week for 6 weeks *Audience*: on average 16 subjects plus 4–8 carers in each community venue (number of venues not stated) *Delivery*: X-PERT programme involving didactic and interactive delivery to groups, with supermarket visits, group games, discussion sessions and provision of an information manual. Separate sessions for Urdu-speaking South Asian participants with a translator *Treatment changes*: none reported *Training of trainers*: not reported	**Eligibility/exclusion criteria**: *Inclusion*: no criteria reported *Excluded*: housebound patients and those with reduced cognitive ability **How selected**: patients identified from practice records of 16 GP clinics and invited by letter to participate. Focused on socio-economic deprived neighbourhoods **Numbers involved**: intervention $n = 157$; control $n = 157$; total randomised $n = 314$ (22 additional subjects were eligible but did not participate due to work or holiday commitments, or for other unreported reasons) **Losses to follow-up**: intervention $n = 7$ (4.5%); control: $n = 16$ (10.2%) **Numbers on insulin**: 53 (17%) *Tablets*: $n = 178$ (57%) *Diet alone*: $n = 83$ (26%) **Mean ± SD duration of diabetes**: intervention 6.7 ± 6.4 years; control 6.7 ± 6.7 years; mean difference 0.0; 95% CI of difference –1.4 to 1.5 **Gender (for overall group only):** Male: $n = 162$ (52%) Female: $n = 152$ (48%) **Mean ± SD age**: intervention: 61.3 ± 9.7 years; control: 61.8 ± 11.0 years; mean difference: 0.5 years; 95% CI of difference: –1.8 to 2.8 **Ethnic groups**: South Asian and white caucasian but numbers of each not	**Primary outcome used:** HbA_{1c} **Secondary outcomes used**: BP (systolic and diastolic) Lipids (total cholesterol, HDL, LDL) Triglycerides Body weight BMI Body fat[a], waist size[a] Lifestyle outcomes: perceived frequency of hyper/hypoglycaemia[a], diabetes knowledge, self-care activity[a] (exercise, foot care, blood testing), diet[a], nutritional intake[a], treatment satisfaction[a], diabetes empowerment[a], QoL **Individual preferred learning style addressed?**: no (group interventions) **Subgroups**: none reported **Normal range(s) for outcomes**: stated that acceptable ranges of blood lipids and BP

continued

Reference and design	Intervention	Participants	Outcome measures
	Theory: empowerment and discovery learning (reference cited) **Control intervention**: Routine care plus diabetes education and individual review with a dietician (30 minutes), practice nurse (15 minutes) and GP (10 minutes) **Duration of intervention**: 6 weeks **Were the care programmes identical?**: Not reported	reported. Noted (see first column) that Urdu-speaking South Asian subjects received separate sessions **Compliance**: not reported; no inclusion criteria were stated. If a participant failed to attend one session, a telephone reminder was given; if they failed to attend two sessions, no further contact was made (the numbers of subjects in these categories were not reported) **Mean ± SD baseline measurements of relevant parameters in the intervention (int.) and control (con.) and the difference in means (diff., 95% CI in parentheses):** *HbA_{1c}*: int. 7.7 ± 1.6 %; con. 7.7 ± 1.6%; diff. 0.0 (–0.3 to 0.4 %) *Systolic BP*: int. 147.5 ± 19.8 mmHg; con. 147.8 ± 23.7 mmHg; diff. 0.3 (–4.6 to 5.1 mmHg) *Diastolic BP*: int. 82.6 ± 11.0 mmHg; con. 82.2 ± 12.2 mmHg; diff. –0.4 (–3.0 to 2.2 mmHg) *Total cholesterol*: int. 5.1 ± 1.1 mmol/l; con. 4.9 ± 1.0 mmol/l; diff. –0.2 (–0.4 to 0.1 mmHg) *HDL cholesterol*: int. 1.3 ± 0.3 mmol/l; con. 1.3 ± 0.4 mmol/l; diff. 0.0 (–0.1 to 0.1 mmol/l) *LDL cholesterol:* int. 2.7 ± 0.9 mmol/l; con. 2.7 ± 0.8 mmol/l; diff. 0.0 (–0.2 to 0.2 mmol/l) *Triglycerides: geometric means (95% CI)*: int. 2.2 (2.0 to 2.4) mmol/l; con. 2.0 (1.9 to 2.2) mmol/l; ratio of means 0.9 (0.8 to 1.0) *Body weight*: int. 83.2 ± 14.5; con. 82.8 ± 17.6 kg; diff. –0.4 (–4.0 to 3.2) kg *BMI*: int. 30.8 ± 5.3 kg/m^2; con. 30.6 ± 5.7 kg/m^2; diff. –0.3 (–1.5 to 1.0) kg/m^2 *Diabetes knowledge score (0–14)*: int. 7.5 ± 3.5; con. 7.0 ± 3.1; diff. –0.5 (–1.3 to 0.3) *Overall ADDQoL score*: int. –2.2 ± 2.2; con. –1.9 ± 2.2; diff. 0.3 (–0.3 to 0.8) *Perceived frequency of hypoglycaemia (score 0–6)*: int. 1.2 ± 1.7; con. 0.9 ± 1.5; diff. –0.3 (–0.7 to 0.1) *Perceived frequency of hyperglycaemia (score 0–6)*: int. 2.8 ± 1.9; con. 2.1 ± 1.8; diff. –0.7 (–1.2 to –0.3)	were obtained from recent guidance reports (data not provided) **How outcomes were assessed**: *HbA_{1c}*: measured using a Diabetes Control and Complications Trial (DCCT) aligned method (reference cited) *BP*: measured conforming to 'accepted' methods (reference cited) *Height (for BMI)*: measured with a portable sonic device *Body weight*: measured with calibrated electronic scales *Diabetes knowledge*: assessed using a validated questionnaire with 14 multiple-choice questions (reference cited) *QoL*: assessed using validated scale (ADDQoL: audit of Diabetes Dependent Quality of Life; reference cited) rated from –9 (negative impact) to +9 (positive impact) *Perceived frequency of hypo- and hyperglycaemia*: assessed using a validated psychosocial questionnaire (reference cited) **Validation of outcomes**: yes: used validated lifestyle, psychosocial and QoL questionnaires; clinical outcomes used standard methods (above) **Timing of outcomes the same for both groups?**: yes **Length of follow-up**: 14 months

continued

Results

Outcome (14 months)	Intervention group Mean ± SD (*n*)	Control group Mean ± SD (*n*)	Comparisons between groups: mean difference (95% CI) and significance of overall change
HbA_{1c} (%)	7.1 ± 1.1 (150)	7.8 ± 1.6 (141)	0.7 (0.3 to 1.0) ($p < 0.001$)
Change from baseline in HbA_{1c} (%)	–0.6	0.1	$p < 0.001$
Systolic BP (mmHg)	141.3 ± 16.8 (150)	144.4 ± 23.5 (141)	3.1 (–1.6 to 7.9) ($p = 0.1$)
Diastolic BP (mmHg)	78.4 ± 9.6 (150)	80.2 ± 10.9 (141)	1.7 (–0.6 to 4.1) ($p = 0.1$)
Total cholesterol (mmol/l)	4.8 ± 1.1 (150)	4.7 ± 1.0 (141)	–0.1 (–0.3 to 0.1) ($p = 0.01$)
Change from baseline in total cholesterol (mmol/l)	–0.3	–0.2	$p = 0.01$
HDL cholesterol (mmol/l)	1.1 ± 0.4 (150)	1.1 ± 0.4 (141)	0.0 (–0.1 to 0.1) ($p = 0.3$)
LDL cholesterol (mmol/l)	2.7 ± 0.9 (150)	2.7 ± 0.8 (141)	0.0 (–0.3 to 0.1) ($p = 0.1$)
Triglycerides (geometric mean, 95% CI) (mmol/l)	1.8 (1.6 to 2.0)[b] (150)	1.8 (1.6 to 1.9)[b] (141)	Ratio of means: 1.0 (0.9 to1.1) ($p = 0.3$)
Body weight (kg)	82.7 ± 14.8 (150)	83.9 ± 18.8 (141)	1.2 (–2.7 to 5.2) ($p < 0.001$)
Change from baseline in body weight (kg)	–0.5	1.1	$p < 0.00$
BMI (kg/m^2)	30.6 ± 5.5 (150)	31.0 ± 6.4 (141)	0.4 (–1.0 to 1.7) ($p < 0.001$)
Change from baseline in BMI (kg/m^2)	–0.2	0.4	$p < 0.001$
Diabetes knowledge score (0–14 scale; multiple-choice question)	9.3 ± 3.1 (100)	7.8 ± 2.7 (91)	–1.5 (–2.3 to –0.7) ($p < 0.001$)
Overall ADDQoL score	–1.4 ± 1.7 (100)	–1.7 ± 2.1 (91)	–0.3 (–0.8 to 0.3) ($p = 0.2$)

Methodological comments

Allocation to treatment groups: random permuted blocks (details not specified) and sealed opaque envelopes were used to randomise participants to the intervention or control group. Patients were told that the objective was to compare the effectiveness of an individual versus group approach, to reduce their likelihood of identifying whether they were in the intervention or control group

Blinding of outcome assessors?: yes: carried out by a community nurse and healthcare assistant blinded to treatment assignment (details of the blinding procedure were not given)

Allocation concealment?: yes: using opaque envelopes

Analysis by ITT?: no: the authors stated that ITT populations were analysed where possible but the outcomes presented exclude those participants who were lost to follow-up

Comparability of treatment groups: the study reports there were no statistically significant differences between groups for demographic or outcome variables. However, the perceived frequency of hyperglycaemia (based on a scoring system of 0–6 from questionnaires but not obviously linked to actual BG) was significantly higher in intervention than control subjects at baseline (95% CI of the mean difference did not include zero). All other outcomes did not differ significantly between the treatment groups at baseline

Method of data analysis: repeated measures ANOVA was used to test the effect of interaction between treatment group and time (change from baseline), with HbA_{1c} as the primary outcome variable. Other outcomes were interpreted as hypothesis-generating variables (no details were given of how the analysis was adjusted for this purpose). Means, SDs and 95% CIs were provided for all outcomes at baseline and end-point. The authors reported that they adhered to the CONSORT statement where possible (reference cited)

Sample size/power calculation: yes: 64 patients per group required for 80% power to detect a 1% difference in HbA_{1c} with $\alpha = 0.05$ and assuming an SD of 2%; 157 patients per group were recruited to allow for attrition

Attrition/drop-outs: yes. Intervention: $n = 7$ (4.5%): 2 died, 2 refused (1 because too ill), 1 in Pakistan, 1 lost contact, 1 moved out of area. Control: $n = 16$ (10.2%): 5 died, 1 terminally ill, 4 refused (1 because too ill), 1 severe psychiatric illness, 1 in Pakistan, 2 lost contact, 2 moved out of area

General comments

Generalisability: Northern England population focusing on socio-economic deprived neighbourhoods but generality of the findings is unknown because the inclusion and exclusion criteria were not specified

Conflict of interests: None evident (funding support stated; research foundations)

Other: The paper by Deakin *et al*. (2003)[47] only presents results for <1 year

[a] Data not extracted for these.

[b] The value for the intervention only (not the control) is indicated by the authors to be a geometric mean.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Partial
2. Was the treatment allocation concealed?	Adequate
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	No
5. Were outcome assessors blinded to the treatment allocation?	Adequate
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Adequate

Reference and design	Intervention	Participants	Outcome measures
Study: Goudswaard *et al.*, 2004[61] **Source**: Journal article **Country**: The Netherlands **Setting**: Community **Language**: English **Trial design**: RCT	**Treatment intervention**: Described as a 'collaborative, mixed, education intervention' *Topics*: general diabetes information; reinforcement of medication compliance; self-monitoring and self-management of exercise, weight, diet, nutrition, and BG (BG meters and reagents were provided) *Provider*: two diabetes nurses *Sessions*: six sessions at intervals of 3–6 weeks during a 6-month period. Each session 15–45 minutes, giving a total contact time of ~2.5 *Audience*: one-to-one sessions between participants and diabetes nurses *Delivery*: assume mainly didactic (no interactive component reported). Location of the sessions was not stated (probably GP practice or diabetes clinic) *Treatment changes*: there were no changes in medication for diabetes in either group, except for two participants in the control group who were referred to secondary care before the end of the intervention period (for symptomatic hyperglycaemia and co-morbidity) *Training of trainers*: not reported. *Theory*: not stated **Control group**: Usual GP care according to the Dutch Guideline on Type 2 diabetes, which recommends 3-monthly reviews, focusing on diabetic symptoms and measurement of	**Eligibility/exclusion criteria**: *Inclusion*: patients receiving primary care only, age <76 years and with HbA_{1c} ⩾ 7.0% were eligible if, after optimisation of oral medication, their HbA_{1c} remained ⩾7.0% while taking the maximum feasible doses of two different OHAs (mostly sulfonylurea and metformin) *Exclusion*: severe co-morbidity, inability to follow instructions spoken in Dutch or short-term insulin requirement for severe hyperglycaemic symptoms **How selected**: medical records of 1810 patients who were receiving only primary care were obtained from 57 general practices (78 GPs) and screened against the inclusion/exclusion criteria by two research assistants **Numbers involved**: intervention $n = 28$; control $n = 30$; total randomised $n = 58$ [18 additional eligible patients were excluded due to refused consent ($n = 6$), severe co-morbidity ($n = 7$) or short-term insulin requirement ($n = 5$)]. The authors stated (without data) that the included and excluded patient groups had similar baseline characteristics **Losses to follow-up**: intervention $n = 4$ (14.3%); control $n = 4$ (13.3%) **Diabetes treatment (in the full population; *n* = 1810)**: insulin 12%; tablets 66%; diet alone 22% **Mean ± SD duration of diabetes**: intervention 7.3 ± 5.0 years; control: 7.6 ± 3.8 years **Gender**: intervention 52% male; control: 44% male **Mean ± SD age**: intervention 62.6 ± 9.0 years; control 58.7 ± 11.4 years **Ethnic groups**: not reported	**Primary outcomes used**: HbA_{1c} at end-point; HbA_{1c} change from baseline **Secondary outcomes used**: body weight (measured only at 6 months after inception; not reported here) **Individual preferred learning style addressed?**: not reported. **Subgroups**: none reported **Normal range(s) for outcomes**: HbA_{1c} 4–6% **How outcomes were assessed**: HbA_{1c} was measured by turbidimetric inhibition assay (reference cited) **Validation of outcomes**: yes (standard outcomes used) **Timing of outcomes the same for both groups?**: yes (except for an HbA_{1c} measurement at 3 months after inception, which was only carried out in the intervention group) **Length of follow-up**: 18 months (following the 6-month intervention, both

continued

Reference and design	Intervention	Participants	Outcome measures
	fasting BG, with education being given during normal medical appointments. The GP was instructed not to refer the subject to a diabetes nurse or (except for severe hyperglycaemic symptoms) to alter their medication **Duration of intervention**: 6 months **Were the care programmes identical?**: Unknown: not stated, other than the details above	**Compliance**: intervention $n = 25/28$ (89.3%) due to 3 refusals to take part after randomisation; control $n = 29/30$ (96.7%) due to 1 inaccurate inclusion **Baseline measurements of relevant parameters**: *Mean ± SD HbA_{1c}*: intervention 8.2 ± 1.1%; control 8.8 ± 1.5 *Mean ± SD BMI*: intervention 30.2 ± 4.4 kg/m^2; control 29.8 ± 5.5 kg/m^2	groups received usual care until end-point)

Results

Outcome	Intervention group	Control group	Comparisons between groups: (control – intervention)
Mean ± SD HbA_{1c} at end-point (18 months) (%)	7.8 ± 0.9	8.2 ± 1.4	No statistics were reported for this comparison at end-point
HbA_{1c} change from baseline to end-point (18 months) (%)[a,b]	–0.4	–0.6 %	Mean difference (95% CI): 0.2% (–0.7 to 0.4%) (*p* not significant)
Patients with HbA_{1c} <7.0% at end-point (18 months) (%)	17	15	Reported as not statistically significant (no *p*-value given)
Patients on insulin therapy at end-point (18 months)	6 (25%)	10 (38%)	Reported as not statistically significant (no *p*-value given)

Methodological comments

Allocation to treatment groups: the authors stated that randomisation was done by a telephone call to an independent trial centre, which used a computer-generated random assignment with blocks of eight at a time (blocks were not defined)
Blinding of outcome assessors?: not reported
Allocation concealment?: computer-generated assignment off-site
Analysis by ITT?: no: the authors stated that their analysis was by ITT using the last observation carried forward, but the numbers of patients involved in calculating the reported statistics are not given; ineligible patients mistakenly randomised, and patients who withdrew before the start of the intervention were excluded from analysis
Comparability of treatment groups: these were similar at baseline in terms of age, gender and educational level, but no statistical assessment was made. (Data for duration of diabetes, BMI and HbA_{1c} for the two groups at baseline are given above)
Method of data analysis: comparison of HbA_{1c} and body weight between the two groups was carried out using ANCOVA to adjust for baseline values. Logistic regression was used to assess the proportions of patients who had $HbA_{1c} < 7.0\%$ and the proportions of those who were treated with insulin. Other statistical techniques (not described here) were used in comparisons of outcomes in the short term (<1 year)
Sample size/power calculation: yes: to detect a difference in HbA1c of at least 0.8%, which was considered clinically relevant for the patient groups, 26 patients were needed per group, based on SD = 1.0, $\alpha = 0.05$ and power 80%
Attrition/drop-outs: yes. intervention: $n = 4$ (14.3%), comprising three withdrawals before the first session (refusal) and one death between intervention and end-point. Control: $n = 4$ (13.3%), comprising one withdrawal due to inaccurate inclusion, two deaths and one hospital admission

General comments

Generalisability: unknown due to lack of information on ethnicity. The tightly defined inclusion criteria might limit the generality of the findings
Conflict of interests: unknown. The study was supported by a research grant from a diabetes device company
Other: This study provides limited data on outcomes at 18 months and focuses in more detail on the short-term outcomes (<1 year)

[a] The authors reported a significantly larger decrease (by 0.7%) of HbA_{1c} in the intervention compared with the control group at 7.5 months after inception (95% CI 0.1 to 1.4; $p = 0.025$).
[b] Adjusted for baseline values in an ANCOVA model.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Adequate
2. Was the treatment allocation concealed?	Adequate
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Adequate

Reference and design	Intervention	Participants	Outcome measures
Study: Heller *et al.*, 1988[59] **Source**: Journal article **Country**: UK **Setting**: Hospital **Language**: English **Trial design**: RCT	**Treatment intervention**: Group weight loss intervention of 4–6 patients with a spouse or friend. Each given a target weight *Topics*: aim was to lose weight, what foods to eat and those to avoid, aetiology of diabetes, self-monitoring, self-care, diabetic complications, the importance of eye examinations and foot care. Self-monitoring of urine taught (twice per day). *Provider*: one of two diabetes nurses and one dietician *Sessions*: 3 × 90-minute sessions at weekly intervals with follow-up visits (90 minutes) at 3 and 6 months *Materials*: video which explained foods to eat, etc., a board for plotting weights so the group could see progress and a book on diabetes for patients *Delivery*: group education *Treatment changes*: *Training of trainers*: *Theory*: *Mode*: Persistent symptoms glycosuria or random blood glucose >15 mmol/l were withdrawn At 3 months patients visited for 90 minutes and lunched with nurse and dietician followed by a group discussion with critical discussion of food choice. At 6-month visit a general review undertaken and watched video again Patients could contact nurses within following 6 months **Control intervention**: Usual clinic care, seen by doctor and then referred to dietician, seen individually. Clinic appointments as necessary and mandatory at 3,6,12 months. Any patients started on OHAs in first year were withdrawn. **Duration of intervention**: 6 months	**Eligibility criteria**: *Included*: all newly diagnosed Type 2 patients (defined), overweight (BMI >27 kg/m^2), aged 30–75 years) *Excluded*: patients with ketonuria, those in whom diagnosis was made as an inpatient (e.g. at time of surgery), judged too infirm, or with major language difficulties **How selected:** from patients referred to clinic over 18-month period **Numbers involved**: total *N* = 87, intervention (int.) 40; control (cont.) 47 **Numbers on insulin**: none *Tablets*: none *Diet alone*: assume all **Type of diabetes?**: Type 2 **Duration of diabetes**: newly diagnosed **Baseline measurements of outcome parameter**: HbA_1 (mean + 95% CI): int. 12.3% (11.4 to 13.2); con. 12.7% (11.9 to 13.5) **Gender (M/F)**: int. 20/16; con. 16/23 **Age ranges (mean + 95% CI)**: int. 56.6 (55 to 58) years; con. 56.4 (53 to 59.9) years **Ethnic groups**: not reported **Losses to follow-up**: int. 4; con. 8 (reasons given) **Compliance**: 1 con. + 2 int. did not attend 3-month follow-up, 1 int. did not attend at 6 months	**Primary outcomes used**: HbA_1 **Secondary outcomes used**: knowledge, fasting BG, weight **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: HbA_1 5.0–7.5%; knowledge (max. score 36) **How outcomes assessed?**: knowledge self-report, laboratory for HbA_1 **Validated?**: HbA_1 yes; knowledge no details of validation **Timing of outcomes same for both groups**: yes **Length of follow-up**: 12 months from inception

continued

Outcome (mean + 95% CI)	Intervention (n = 36)	Control (n = 39)	Differences between groups
HbA_1	9.0% (8.2 to 9.8)	9.9% (8.9 to 10.9)	
Proportion of patients HbA_1 <7.5% (%)	36	28	
FBG (mmol/l)	9.1 (7.9 to 10.3)	10.3 (8.8 to 11.8)	
Weight loss (kg)	–5.5 (4 to 6.5)	–3 (2 to 4)	$p < 0.05$

Knowledge – not reported as not validated. 3- and 6-month data reported

Methodological comments
Allocation to treatment groups: not reported. Correspondence from author: randomisation using computerised random numbers
Blinding of outcome assessors?: not reported. Correspondence from author: HbA_{1c} values were measured in the laboratory by people unaware of assignment; weight was measured by co-investigators
Allocation concealment?: not reported. Correspondence from author: process was sealed opaque envelopes
Analysis by ITT?: not reported
Comparability of treatment groups: no differences reported, no statistical analysis reported
Method of data analysis: mean or median with 95% CIs. *t*-Tests, Mann–Whitney and χ^2 tests used
Sample size/power calculation: no
Attrition/drop-outs: drop-outs reported and reasons given

General comments
Generalisability: overweight population. All newly diagnosed
Conflict of interests: Boehringer acknowledged for donation of urine testing equipment. British Diabetic Association supported 2 authors
Other:

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Adequate
2. Was the treatment allocation concealed?	Adequate
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Partial
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Adequate

Reference and design	Intervention	Participants	Outcome measures
Study: Ko *et al.*, 2007[45] **Source**: Journal article **Country**: Korea **Setting**: Secondary care (inpatient clinic with patients hospitalised by diabetes-related illnesses) **Language**: English **Trial design**: RCT	**Treatment intervention**: Structured Intensive Diabetes Education Programme (SIDEP) based on Bucharest–Dusseldorf study and Diabetes Prevention Programme (DPP) (references available) *Topics*: diabetes knowledge, diabetes self-management skills, self-monitoring, injection techniques, sick-day care, diet and nutrition, physical activity, foot inspection, hypoglycaemia management *Provider*: delivered by 8 professional diabetes health providers: diabetologist, certified diabetes educator (nurse or dietician), ophthalmologist, rehabilitation therapist, pharmacist, psychologist, family doctor, rehabilitation medicine doctor *Sessions*: 6 h per day for 5 days during hospitalisation (total 30 h), with free physical activity under supervision, plus one 3-h reinforcement outpatient session per year *Audience*: group education with 5–10 patients per group *Delivery*: didactic and interactive inpatient sessions to which patients' family members were also invited (curriculum timetable reported) *Treatment changes*: at annual reinforcement sessions physician assessed and adjusted glucose-lowering agents *Training of trainers*: stated only that trainers were professional health providers in the field of diabetes *Theory*: cognitive-behavioural therapy (references cited) **Control intervention**: Patients received the same first 4 h of group education as the intervention group. Control patients were offered 30 minutes of diet and also nutritional advice and also introductory education and introductions to insulin injection, physical activity, self-monitoring and diabetes management (but unclear if these were within or additional to the initial 4-h session). Follow-up was at 3-month intervals without education reinforcement (focus on BG monitoring and drug adjustment only)	**Eligibility/exclusion criteria**: *Inclusion*: hospital inpatients with Type 2 diabetes who had been admitted with symptoms related to poor glycaemic control and who had no previous experience of systematic diabetes education *Exclusion*: patients who were aged >70 years, mentally ill, unable to undertake recommended physical activity or had any severe illness (e.g. sepsis, severe infection, hypoglycaemia or shock). **How selected**: consecutive recruitment of inpatients in a hospital-based university-affiliated diabetes centre **Numbers involved**: intervention $n = 219$; control $n = 218$; total randomised $n = 437$ (64 additional subjects were eligible but of these 48 refused to participate and 16 did not participate for other, unspecified, reasons) **Losses to follow-up: intervention/control:** *In total*: $n = 59$ (27%)/$n = 70$ (32%) *By individual year*: Year 1: $n = 26$ (11.9%)/$n = 30$ (13.8%) Year 2: $n = 17$ (7.8%)/$n = 19$ (8.7%) Year 3: $n = 7$ (3.2%)/$n = 19$ (8.7%) Year 4: $n = 9$ (4.1%)/$n = 2$ (0.9%) **Numbers on insulin**: intervention $n = 36$ (16.4%); control $n = 31$ (14.2%) (difference $p = 0.520$) *Numbers on tablets*: intervention $n = 111$ (50.7%); control $n = 127$ (58.3%) (difference $p = 0.112$) *Numbers on tablets + insulin*: intervention $n = 72$ (32.9%); control $n = 60$ (27.5%) (difference $p = 0.223$) *Numbers on diet alone*: none **Mean ± SD duration of diabetes**: intervention 6.0 ± 6.0 years; control 6.2 ± 5.5 years (difference $p = 0.838$) **Gender (M/F)**: intervention $n = 92/127$ (44/56%); control $n = 100/118$ (46/54%) (difference, $p = 0.665$) **Mean ± SD age**: intervention 53.3 ± 9.3 years; control 54.1 ± 7.4 years (difference $p = 0.307$) **Ethnic groups**: none stated; due to location assumed most or all patients were Korean **Compliance**: not reported	**Primary outcome used**: mean value of HbA_{1c} and changes in HbA_{1c} during follow-up **Secondary outcomes used**: Diet[a] SMBG[a] Physical activity[a] Frequency of admissions related to diabetic complications (BMI, FBG and BP were also monitored but no data provided for follow-up) **Individual preferred learning style addressed?**: no (group interventions) **Subgroups**: two subgroups were analysed retrospectively, according to the mean of all HbA_{1c} values over the 4-year follow-up period: group 1, $HbA_{1c} < 7.0$ (well-controlled); group 2, $HbA_{1c} > 7.9\%$ (not well controlled) (data not extracted) **Normal range(s) for outcomes**: not stated, but reference range for HbA_{1c} given (see below) **How outcomes were assessed**: HbA_{1c} measured using HPLC (laboratory name reported) with reference range 4.6–6.4%. Diet, exercise and

continued

Reference and design	Intervention	Participants	Outcome measures
	Duration of intervention: 30 h over 5 days followed by annual 3-h reinforcement sessions **Were the care programmes identical?**: Not reported	**Mean ± SD baseline measurements of relevant parameters (95% CI in parentheses)**: *HbA_{1c}*: intervention: 9.4 ± 2.0 % (n = 219); control: 9.2 ± 1.9 % (n = 211); difference –0.24 (–0.62 to 0.14 %) (p = 0.213) *BMI*: intervention 25.5 ± 3.5 kg/m^2; control 25.3 ± 3.2 kg/m^2 difference p = 0.650 *Fasting plasma glucose*: intervention 9.8 ± 3.8 mmol/l; control 9.9 ± 3.6 mmol/l; difference p = 0.712 *Total cholesterol*: intervention 4.9 ± 1.1 mmol/l; control 4.9 ± 1.0 mmol/l; difference p = 0.752 *Triglycerides*: intervention 1.96 ± 1.4 mmol/l; control 1.91 ± 1.5 mmol/l; difference p = 0.726 *HDL cholesterol*: intervention 1.16 ± 0.3 mmol/l; control 1.18 ± 0.4 mmol/l; difference p = 0.558 *Smoking*: intervention n = 50 (22.9%); control n = 57 (26.0%); difference p = 0.452 *Alcohol*: intervention n = 62 (28.3%); control n = 53 (24.3%); difference p = 0.343 *Numbers hypertensive (⩾140 mmHg systolic, ⩾90 mmHg diastolic, or on treatment)*: intervention n = 81 (37%); control n = 94 (43.1); difference p = 0.191 *Diabetes family history*: intervention n = 64 (29.2%); control n = 58 (26.6%); difference p = 0.542	SMBG were monitored by annual questionnaires and scored on a 5-point scale **Validation of outcomes**: unclear if the questionnaires for diet, exercise and SMBG (data not extracted) were validated, but references cited **Timing of outcomes the same for both groups?**: yes **Length of follow up**: data presented for 6, 12, 24, 36 and 48 months, but actual follow-up in intervention group was 51.7 ± 7.4 months (2 weeks after discharge then every 3 months thereafter when diabetes nurse checked adherence to lifestyle modifications)

Results

	SIDEP group Mean ± SD (n = 219)[b]	Control group Mean ± SD (n = 218)[b]	Comparison between groups
Mean (± SD) HbA_{1c} (%) at 12 months	n = 174 7.9 ± 1.7	n = 187 8.1 ± 1.5	Mean difference (95% CI) 0.14 (–0.20 to 0.47), p = 0.420
Mean (±S D) HbA_{1c} (%) at 24 months	n = 168 7.9 ± 1.5	n = 169 8.2 ± 1.5	Mean difference (95% CI) 0.28 (–0.04 to 0.61), p = 0.089
Mean (± SD) HbA_{1c} (%) at 36 months	n = 167 7.8 ± 1.5	n = 148 8.4 ± 1.6	Mean difference (95% CI) 0.51 (0.17 to 0.85), p = 0.004
Mean (± SD) HbA_{1c} (%) at 48 months	n = 161 7.9 ± 1.2	n = 147 8.7 ± 1.6	Mean difference (95% CI) 0.8 (0.49 to 1.12), p < 0.0001
Median frequency per patient of admissions due to any diabetic complications over 4 years	n = 160 1.0 (range 0–4)	n = 148 0.8 (range 0–3)	p = 0.005[c]

continued

Methodological comments
Allocation to treatment groups: randomisation using a random number table
Blinding of outcome assessors: yes
Allocation concealment: used sealed, sequentially numbered envelopes given to participants. Unclear if the allocation within these envelopes was concealed from the investigator
Analysis by ITT?: not reported
Comparability of treatment groups: there were no significant differences in baseline characteristics of the two groups
Method of data analysis: unpaired *t*-tests with 0.05 significance level. Subgroup analysis of the intervention group to determine any differences in glycaemic control (data not extracted)
Sample size/power calculation: yes: sample size was determined to be large enough to detect a difference of 0.6% in HbA_{1c} between SIDEP and control groups with 80% power at the two-tailed significance level $\alpha = 0.05$, assuming 20% loss to follow-up
Attrition/drop-outs: number given but no reasons reported

General comments
Generalisability: Korean population of people admitted to hospital with complications of diabetes and HbA_{1c} in the region of 9%
Conflict of interests: none declared or evident
Other:

[a] Data not extracted for this review.
[b] The mean HbA_{1c} dropped after 6 months in the intervention group and the control group. The intervention group change from baseline was statistically significantly different compared with the control group (SIDEP $n = 205$, 7.1 ± 1.5; control group $n = 187$, 7.9 ± 1.4 [mean difference 0.87 (95% CI 0.58 to 1.16), $p < 0.0001$].
[c] Text reports that frequency was significantly lower in the intervention group than the control group; however, data are presented showing the control group significantly lower than the intervention group. Possible error in the data presented. The most common cause of hospitalisation in both groups was infection.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Adequate
2. Was the treatment allocation concealed?	Inadequate
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Adequate
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Partial

Reference and design	Intervention	Participants	Outcome measures
Study: Raz *et al.*, 1988[62] **Source**: Journal article **Country**: Israel **Setting**: Hospital **Language**: English **Trial design**: RCT after stratification by pre- and post-prandial glucose and HbA_{1c}	**Treatment intervention**: *Topics*: explanation of the disease, the main mode of treatment, explanation and demonstration of self-care and treatment techniques, the logic and practice of diet, and home exercise *Provider*: physicians, a nurse, dietician and physical therapist each providing different topics *Sessions*: three lessons within 3 weeks, repeated every 4 months. Patients were encouraged to interact between the sessions and were also individually followed in the diabetic clinic every 2 months *Delivery*: assume didactic, group education *Treatment changes*: diet and exercise could be manipulated, but drug therapy unchanged *Training of trainers*: *Theory*: **Control intervention**: Control group were followed up every 2 months **Duration of intervention**: 12 months	**Eligibility/exclusion criteria**: *Inclusion*: Type 2 diabetes, aged 30–65 years, ⩾1 year since diagnosis, clinic record of uncontrolled diabetes (defined) in last 12 months, no late diabetic complications or concurrent psychiatric or terminal illnesses **How selected**: states patients were selected from the clinic, no details. **Numbers involved**: total $N = 51$, int 25; cont. 26 **Numbers on insulin**: none *Tablets*: 20 *Diet alone*: 31 **Type of diabetes**: Type 2 NB: baseline characteristics based on those completing study **Duration of diabetes**: (intervention) (int.) 9.0 years (SD 4.5); (control) (con.) 9.2 years (SD 5.3) **Baseline measurements of outcome parameter (mean ± SD)**: *HbA_{1c}*: int. 10.0% ± 2.7; con. 9.6% ± 2.6 *Fasting glucose*: int. 200.1 ± 55.1; con. 200.8 ± 59.9 *Postprandial glucose*: int. 234.3 ± 68.6; con. 238.5 ± 69.3 *Cholesterol*: int. 226.1 ± 42.6; con. 220.3 ± 55.4 *Triglyceride*: int. 232 ± 32; con. 211 ± 34 *HDL cholesterol*: int. 47.0 ± 4.2; con. 45.8 ± 4.5 *Weight*: int. 75.4 ± 11.7 kg; con. 73.4 ± 11.5 kg **Gender (M/F)**: int 7/16; con. 10/16 **Age ranges**: int. 51.1 (SD 8.1) years; con. 53.7 (SD 12.8) years **Ethnic groups (Israel/Asia + Africa/Europe + America)**: int. 8/7/8; con. 3/10/13 **Losses to follow-up**: 2 int. patients did not participate in the education programme or keep appointments **Compliance**: 23 patients participated in the first meetings, 21 in the second and 18 in the third and fourth	**Primary outcomes used**: HbA_{1c} **Secondary outcomes used**: knowledge (not reported here), BP, weight (kg – not reported here), pre- and postprandial blood glucose (not reported here), blood cholesterol, HDL cholesterol blood triglyceride **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: not reported **How outcomes assessed?**: HbA_{1c} laboratory, knowledge by self-report **Validated?**: knowledge not validated (prepared for this study) **Timing of outcomes same for both groups**: yes **Length of follow-up**: 12 months from inception

continued

Outcomes (many approximations from figure)	Intervention (n = 23)	Control (n = 26)	Difference between groups
HbA_{1c} (%) (from Figure 3)	8.25	9.6	Interaction between intervention and time, $p < 0.05$[a]
Preprandial BG (mg/dl) (from Figure 1)	162	210	Interaction between intervention and time, $p < 0.01$[a]
Postprandial BG (mg/dl) (from Figure 2)	190	225	Interaction between intervention and time, $p < 0.05$[a]
BP	Not reported		
Mean blood cholesterol (mg/dl)	213.8 ± 37.7	226.1 ± 60.8	NS
Blood triglycerides (mg/dl)	214 ± 24	204 ± 31	NS
HDL cholesterol (mg/dl)	49.6 ± 4.3	45.2 ± 4.4	NS
Weight (kg) (from Figure 4)	73	73	Interaction between intervention and time, $p < 0.05$[a]

Methodological comments
Allocation to treatment groups: patients stratified according to mean values of pre- and postprandial glucose and HbA_{1c} and randomised. No detail of method
Blinding of outcome assessors?: laboratories unaware
Allocation concealment?: not reported
Analysis by ITT?: not reported
Comparability of treatment groups: no differences reported in baseline characteristics
Method of data analysis: ANOVA for repeated measures (over time) and *t*-tests and χ^2 between groups. No point estimates given or CIs
Sample size/power calculation: not given
Attrition/drop-outs: drop-outs reported and reasons given

General comments
Generalisability:
Conflict of interests: funding support not mentioned
Other:

NS, not significant.
[a] This interaction represents the difference between groups in the change from baseline to end-point.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Adequate
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Inadequate
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Adequate

Reference and design	Intervention	Participants	Outcome measures
Study: Sarkadi and Rosenqvist, 2004[60] **Source**: Journal article **Country**: Sweden **Setting**: Pharmacies **Language**: English **Trial design**: RCT	**Treatment intervention**: *Topics*: self-management, including diet, exercise and other lifestyle changes, complications and self-monitoring BG (not reported in detail) *Provider*: specially trained pharmacists, initially also with a diabetes nurse specialist (numbers and allocation among groups and pharmacies not stated) *Sessions*: once monthly (length not stated) *Audience*: groups (size, composition and allocation among pharmacies and pharmacists not stated) *Delivery*: pilot-tested programme (reference available) comprising interactive and didactic education: a diabetes education video and booklet, interactive group game, diabetes management booklet and continuous back-up support from pharmacists *Treatment changes*: subjects were referred to a medical team if glucose control was unsatisfactory *Training of trainers*: pharmacists trained by one of the authors in a 3-day intensive course *Theory*: experience-based learning with a pedagogical principle that any questions raised should be solved by the group, not by the group leader **Control group**: Patients assigned to 2-year waiting list (no other details reported) **Duration of intervention**: 1 year **Were the care programmes identical?**: Not reported	**Eligibility/exclusion criteria**: *Inclusion*: diagnosed with Type 2 diabetes and, if treated with insulin, for $\leqslant$2 years *Exclusion*: insulin use >2 years, or did not provide an initial HbA_{1c} measurement or did not complete an initial questionnaire **How selected**: self-referrals responding to advertisements in local newspapers, GP clinics and office of Stockholm Diabetes Association **Numbers involved (excluding losses to follow-up)**: intervention $n = 39$; control $n = 38$; total randomised $n = 77$ (7 additional subjects eligible but not randomised as no baseline HbA1c and/or questionnaire – see Exclusion criteria) **Losses to follow-up**: intervention $n = 6$; control $n = 7$ **Diabetes treatment**: numbers on insulin, tablets, or diet only: not reported **Duration of diabetes (mean ± SD)**: intervention 5.9 ± 5.8 years; control 2.6 ± 2.2 years (significance of this difference stated, without explanation, as a range: $p = 0.007$ to $p = 5.6$) **Gender**: not reported **Age (mean ± SD)**: intervention 66.4 ± 7.9 years; control: 66.5 ± 10.7 years **Ethnic groups**: not reported **Compliance**: not reported **Baseline measurements of relevant parameters**: HbA_{1c} estimated from Figure 2 by reviewer: intervention and control both close to 6.5%; the difference between them not statistically significant (no *p*-value provided) *Mean ± SD BMI*: intervention 27.2 ± 3.6; control 28.6 ± 5.8 (units not stated; assumed kg/m^2)	**Primary outcomes used**: HbA_{1c} at end-point; HbA_{1c} changes from baseline **Secondary outcomes used**: none reported **Individual preferred learning style addressed?**: no (group education) **Subgroups**: none reported **Normal range(s) for outcomes**: not reported **How outcomes were assessed**: not reported **Validation of outcomes**: not reported **Timing of outcomes the same for both groups?**: yes **Length of follow up**: 2 years

Results

Outcomes	Intervention ($n = 39$)	Control ($n = 38$)	Differences between groups
Mean (95% CI) HbA_{1c} (%) at 1 year (intervention end)	6.2 (5.7 to 6.7)[a]	6.4 (5.8 to 7.0)[a]	Not significant (no *p*-value provided)
Mean (95% CI) HbA_{1c} (%) at 2 years (follow-up end)	6.1 (5.5 to 6.7)[a]	6.6 (6.0 to 7.2)[a]	$p < 0.01$

continued

Methodological comments:
Allocation to treatment groups: unmarked envelopes containing patient information were drawn randomly from a box then assigned to the two groups (inadequate details provided) by an assistant who was witnessed by another assistant, with the latter deciding which of the groups would be the intervention and the control
Blinding of outcome assessors?: none stated
Allocation concealment?: envelopes were unmarked but it was not reported whether they were opaque
Analysis by ITT?: no (but unclear): numbers analysed were not stated but appear to exclude losses to follow-up
Comparability of treatment groups: the control group had a lower duration of diabetes; this difference between groups may have been statistically significant, but this is unclear due to ambiguous reporting. Four participants were missing from the control group on this measure (randomised $n = 31$; actual $n = 27$)
Method of data analysis: the authors report that one-way ANOVA was used but no data are presented, only *p*-values and a chart (Figure 2). They also used regression models to enable the analyses to be adjusted for baseline differences in diabetes duration and HbA_{1c}. However, the models are poorly and ambiguously reported. Accordingly, the adjusted outcomes are excluded from this data extraction
Sample size/power calculation: yes: the authors reported that 18 subjects per group would be needed to detect a 1% decrease in HbA_{1c} with $\alpha = 0.05$ and $\beta = 0.1$. The authors recruited additional patients to allow for 20% drop-out and for testing of other variables. However, the reported calculation provides only 10% power with 18 subjects per group, whereas no power calculation is given for >18 subjects per group
Attrition/drop-outs: yes: intervention $n = 6$ (15%); control $n = 7$ (18%)

General comments
Generalisability: unknown: the populations were not described (no indication given of ethnicity, gender, etc.)
Conflict of interests: none evident (funding support stated; research foundations)
Other: overall, the poor standard of reporting and lack of empirical data limit data extraction

[a] Estimated from chart (Figure 2) by reviewer; an assumption is made that the bars shown in the chart each represent half of a symmetrical CI.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Partial
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Partial
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Partial

Reference and design	Intervention	Participants	Outcome measures
Study: Trento *et al.*, 2001;[53] 2002;[54] 2004[55] **Source**: Journal articles **Country**: Italy **Setting**: University clinic **Language**: English **Trial design**: RCT	**Treatment intervention**: *Topics*: observation phase, educational diagnosis, definition of goals and development of plan including methods and setting in which to deliver. Data collected on patient baseline education, health beliefs, undesirability of being overweight, meal planning, improving and checking metabolic control and preventing complications (more detail provided). Homework diaries for weight and food intake were given out at the end of each meeting, and discussed at the beginning of the next *Provider*: 1 or 2 physicians and an educationalist. Also GP, 2 postgraduate medical students, clinical psychologist and psychometrist helped design the programme *Sessions*: 4 sessions, over 1 h each, repeated every 3 months in years 1 and 2. Then spread over 7 sessions in years 3 and 4. Patients in need/wishing to have clinical attention were seen on a one-to-one basis at the end *Audience*: 6 groups of 9–10 patients *Delivery*: Both didactic and interactive (hands-on activities, group work, problem-solving activities, real-life simulations and role play) *Treatment changes*: none reported *Training of trainers*: not reported *Theory*: not reported **Control group**: Traditional consultations every 3 months in the diabetes clinic, unless intercurrent problems. Seen by same physicians as intervention who were unaware that patients were in the control group. Also had weekly diaries of body weight and nutrition. Individual education sessions from same educationalist, with special	**Eligibility/exclusion criteria**: *Inclusion*: Type 2 diabetes treated with either diet alone or diet and OHAs, who had attended clinic for at least 1 year and aged <80 years **How selected**: not reported **Numbers involved**: total 112 (56 intervention; 56 control) **Numbers on diabetes treatment**: insulin none; tablets 50 intervention, 46 control; diet alone 6 intervention, 10 control **Mean (range) duration of diabetes**: intervention 9.4 (1–23) years; control 9.8 (1–39) years **Gender M/F**: intervention 27/29; control 34/22 **Mean (range) age**: intervention 62 (35–80) years, control 61 (43–78) years **Ethnic groups**: not reported **Mean ± SD baseline measurements of relevant parameters:** **1. Reported by Trento *et al.*[53] in their comparison with 2-year follow-up:** *HbA_{1c}*: Intervention (int.) 7.4% ± 1.4; control (con.) 7.4% ± 1.4 *QoL (DQOL)*: int. 67.6 ± 19; con. 66.7 ± 25 *Retinopathy (none/mild/more severe)*: int. 42/8/6; con. 38/13/5 *Knowledge*: int. 14.9 ± 7.9; con. 20.2 ± 7.4 *BMI*: int. 29.7 ± 4.5; con. 27.8 ± 4.1 *No. hypertensive*: int. 34; con. 25 *Weight (kg)*: int. 77.4 ± 13.1; con. 78.2 ± 14.6 *Fasting BG (mmol/l)*: int. 9.8 ± 2.6; con. 10.0 ± 3.1 *Total cholesterol (mmol/l)*: int. 5.8 ± 1.1; con. 5.5 ± 0.9 *HDL cholesterol (mmol/l)*: int. 1.2 ± 0.3; con. 1.3 ± 0.3 *Triglyceride (mmol/l)*: int. 2.6 (0.7–11.5); con. 1.7 (0.5–5.2) *Creatinine (μmol/l)*: int. 91.6 ± 14.2; con. 90.0 ± 14.0 *Albuminuria (none/micro or macro)*: int. 32/24; con. 37/19 *Foot ulcers (never/past/active)*: int. 54/0/2; con. 53/2/1 *Hypoglycaemic treatment (int./cont.)*: diet only 6/10, sulfonylureas 27/21, metformin 5/6, sulfonylureas + metformin 18/19, insulin 0/0	**Primary outcomes used:** body weight, fasting BG[a], HbA_{1c}, diabetic retinopathy, blood lipids, knowledge of diabetes, health behaviour (Contact and Disorder Rating)[a], QoL (DQOL) **Secondary outcomes used**: hypoglycaemic medication[a], microalbuminuria, systolic and diastolic BP **Individual preferred learning style addressed?**: no (group interventions) **Subgroups**: none reported. **Normal range(s) for outcomes**: not reported **How outcomes were assessed**: not reported **Validation of outcomes**: HbA_{1c} yes. QoL with Diabetes Quality of Life (DQOL) (slightly modified with 6 qualities omitted from the worry, social/vocational section as pertinent to young Type 1 patients). Retinopathy: yes. Knowledge by education study group of the Italian Society of Diabetes (reported to be valid); Health Conduct assessed by CdR validated

continued

Reference and design	Intervention	Participants	Outcome measures
	reference to eating habits, home monitoring of glucose and prevention of complications **Duration of intervention**: Varied among patients; up to 5 years	**2. Reported by Trento *et al.*[54] in their comparison with 4-year follow-up:** *HbA_{1c}*: int. 7.4% ± 1.4; con. 7.4% ± 1.4 *QoL (DQOL)*: int. 67.6 ± 19; con. 70.5 ± 21.7 *Retinopathy (none/mild/more severe)*: int. 33/12/0; con. 28/14/0 *Knowledge*: int. 14.9 ± 7.9; con. 20.4 ± 7.8 *BMI*: int: 29.8 ± 4.5; con. 27.9 ± 4.5 *Weight (kg)*: int 77.8 ± 13.6; con. 77.8 ± 15.0 *Fasting BG (mmol/l)*: int. 9.8 ± 2.6; con. 10.2 ± 3.2 *Total cholesterol (mmol/l)*: int. 5.84 ± 1.11; con. 5.46 ± 0.93 *HDL cholesterol (mmol/l)*: int. 1.27 ± 0.31; con. 1.32 ± 0.31 *Triglyceride (mmol/l)*: int. 2.54 (0.66–11.49); con. 1.81 (0.51–5.22) *Creatinine (μmol/l)*: int. 91.94 ± 14.14; con. 91.05 ± 14.14 *Microalbuminuria*: int. 31.79; con. 4.96 *Hypoglycaemic treatment (int./con.)*: diet only: 6/10; OHAs: 0/46 *Systolic BP (mmHg)*: int. 160 ± 26; con. 151 ± 19 *Diastolic BP (mmHg)*: int. 95 ± 11; con. 92 ± 10 **3. Reported by Trento *et al.*[55] in their comparison with 5-year follow-up:** *HbA_{1c}*: int. 7.4% ± 1.4; con. 7.4% ± 1.4 *QoL (DQOL)*: int. 67.4 ± 19; con. 70.0 ± 21.4 *Knowledge*: int. 15.5 ± 7.9; con. 21.4 ± 7.2 *BMI*: int. 30.0 ± 4.7; con. 27.7 ± 4.6 *Weight (kg)*: int. 79.6 ± 13.7; con. 77.5 ± 16.0 *Fasting BG (mmol/l)*: int. 9.8 ± 2.6; con. 9.9 ± 3.2 *Total cholesterol (mmol/l)*: int. 5.84 ± 1.11; con. 5.46 ± 0.93 *HDL cholesterol (mmol/l)*: int. 1.27 ± 0.31; con. 1.32 ± 0.31 *Triglyceride (mmol/l)*: int. 2.54 (0.66–11.49); con. 1.81 (0.51-5.22) *Creatinine (μmol/l)*: int. 91.94 ± 14.14; con. 91.05 ± 14.14 **Losses to follow-up**: *At 2 years*: int. 13 (3 deaths, 10 moved); con. 9 (1 death, 5 moved, 3 lost to follow-up) *At 4 years*: int. 11 [3 deaths, 8 moved (2 moved in year 1 and returned in year 3)], con. 11 [2 deaths, 17 moved (10 returned for year 4 assessment), 2 lost to follow-up] *At 5 years*: int. 14 (3 deaths, 10 moved, 1 not traced), con. 14 (3 deaths, 9 moved, 2 not traced)	**Timing of outcomes the same for both groups**: yes **Length of follow-up**: 5 years from inception, with reporting at 2, 4 and 5 years

continued

	Mean ± SD of outcomes at 2-year follow-up		
	Intervention (n = 43)	**Control (n = 47)**	**Differences between groups**
HbA_{1c} (%)	7.5% ± 1.4	8.3% ± 1.8	$p < 0.002$
DQOL score	55.6 ± 15.9	80.8 ± 31.5	$p < 0.001$
Diabetic retinopathy (none/mild/more severe)	35/5/3	33/7/7	NS
GISED (knowledge) score	24 ± 6.6	17.4 ± 8.6	$p < 0.001$
BMI (kg/m^2)	29.0 ± 4.4	27.6 ± 4.2	$p = 0.06$
Number hypertensive	26	22	NS
Weight (kg)	76.0 ± 13.4	77.1 ± 14.7	NS
Fasting BG (mmol/l)	9.9 ± 2.6	9.2 ± 2.9	NS
Total cholesterol (mmol/l)	5.7 ± 1.2	5.6 ± 1.2	NS
HDL cholesterol (mmol/l)	1.4 ± 0.4	1.3 ± 0.3	$p < 0.05$
Triglycerides (mmol/l) (range)	2.1 (0.7–6.9)	1.7 (0.6–3.9)	$p = 0.53$
Creatinine (μmol/l)	88.8 ± 16.5	87.8 ± 17.2	NS
Albuminuria (none/micro or macro)	20/21	19/22	NS
Number with foot ulcers (never/past/active)	42/1/0	45/1/1	NS
SMBG	10	14	NS
Hypoglycaemic treatment:			
Diet only	2	5	NS
Sulphonylureas	18	13	NS
Metformin	3	6	NS
Sulfonylureas + metformin	18	25	NS
Insulin	2	5	NS

	Mean ± SD of outcomes and mean changes from baseline at 4 years follow-up			
	Intervention (n = 45)		**Control (n = 45)**	
	At 4 years	**Change from baseline**	**At 4 years**	**Change from baseline**
HbA_{1c} (%)	7.0 ± 1.1	–0.3 (NS)	8.6 ± 2.1	1.3 ($p < 0.001$)
DQOL score	44.0 ± 7.5	–23.6 ($p < 0.001$)	89.8 ± 28.1	19.2 ($p < 0.001$)
Diabetic retinopathy (none/mild/more severe)	35/10/0		19/20/3	
GISED (knowledge) score	27.1 ± 6.6	12.2 ($p < 0.001$)	17.2 ± 8.7	–3.2 ($p < 0.05$)
BMI (kg/m^2)	28.7 ± 4.0	–1.0 ($p < 0.001$)	27.6 ± 4.7	–0.3 (NS)
Weight (kg)	75.2 ± 13.0	–2.6 ($p < 0.001$)	76.9 ± 16.1	–0.9 (NS)
Fasting BG (mmol/l)	9.3 ± 2.6	–0.5 (NS)	11.0 ± 4.6	0.8 (NS)
Total cholesterol (mmol/l)	5.77 ± 1.34	–0.07 (NS)	5.59 ± 1.29	0.13 (NS)
HDL cholesterol (mmol/l)	1.42 ± 0.31	0.15 ($p < 0.001$)	1.37 ± 0.28	0.05 (NS)
Triglycerides (mmol/l) (range)	2.11 (0.45 – 10.93)	–0.43 (NS)	1.64 (0.43–3.47)	–0.17 (NS)
Creatinine (μmol/l)	86.63 ± 15.91	–5.31 (NS)	97.24 ± 25.64	6.19 (NS)
Microalbuminuria	6.26	–25.52 (NS)	6.15	1.18 (NS)
Systolic BP (mmHg)	154 ± 21	–5.9 (NS)	149 ± 15	–1.9 (NS)
Diastolic BP (mmHg)	88 ± 7	–7.1 ($p < 0.001$)	86 ± 9	–6.3 ($p < 0.001$)
Urea nitrogen (mmol/l)	13.67 ± 3.82	–0.75 (NS)	15.74 ± 5.78	2.18 ($p < 0.05$)
Hypoglycaemic treatment (diet only/oral agents/oral agents and insulin/insulin alone)	2/38/4/1		2/37/3/3	

continued

	Mean ± SD of outcomes and mean (95% CI) changes from baseline at 5-year follow-up				
	Intervention (n = 42)		Control (n = 42)		Difference in change from baseline between intervention and control
	At 5 years	Change from baseline	At 5 years	Change from baseline	
HbA_{1c} (%)	7.3 ± 1.0	–0.1 (–0.5 to 0.4)	9.0 ± 1.6	1.7 (1.1 to 2.2)	$p < 0.001$
DQOL score	43.7 ± 7.2	–23.7 (–30.0 to –17.3)	89.2 ± 30.1	19.2 (8.4 to 29.9)	$p < 0.001$
GISED (knowledge) score	27.9 ± 5.7	12.4 (9.7 to 15.2)	18 ± 8.5	–3.4 (–1.1 to –5.7)	$p < 0.001$
BMI (kg/m^2)	28.6 ± 4.1	–1.4 (–2.0 to –0.7)	27.6 ± 4.4	–0.10 (–0.7 to 0.5)	$p = 0.067$
Weight (kg)	76.1 ± 12.9	–3.5 (–5.2 to –1.8)	77.3 ± 16.0	–0.24 (–1.9 to 1.5)	$p = 0.015$
Fasting BG (mmol/l)	9.4 ± 2.3	–0.4 (–1.52 to 0.70)	10.2 ± 2.9	0.3 (–0.99 to 1.51)	NS
Total cholesterol (mmol/l)	5.50 ± 1.06	–0.32 (–0.68 to 0.03)	5.27 ± 1.13	–0.43 (–0.54 to 0.10)	NS
HDL cholesterol (mmol/l)	1.39 ± 0.33	0.14 (0.07 to 0.22)	1.42 ± 0.31	0.10 (–0.02 to 0.23)	NS
Triglycerides (mmol/l)	2.17 ± 2.30	–0.48 (–1.15 to 0.20)	1.52 ± 0.75	–0.28 (–0.60 to 0.03)	NS
Creatinine (μmol/l)	75.14 ± 25.63	–16.79 (–25.63 to –10.60)	78.67 ± 47.73	–12.37 (–26.52 to 2.65)	NS

Methodological comments
Allocation to treatment groups: random number tables
Blinding of outcome assessors: not reported
Allocation concealment: not reported
Analysis by ITT: no: narrative indicates ITT, but in reality not analysed that way
Comparability of treatment groups: control participants had higher levels of education and better knowledge of diabetes
Some differences observed in baseline measurements between the three publications may be due to rounding; for others the explanation is unclear
Method of data analysis: means, with SD, range or CIs given with significance ($p < 0.05$ significant). Paired Student's t-test or Wilcoxon rank-sum test. Generalised linear model. ANCOVA was used to test for differences between groups in changes from baseline to 5 years and adjust for baseline differences. Between-group comparisons were not made at 4 years
Sample size/power calculation: not reported
Attrition/drop-outs: reported as above

General comments
Generalisability: unknown [ethnicity not stated; different baseline data reported in each paper (see above)]
Conflict of interests: none evident; Turin University research grant
Other: three related publications

[a] Data not extracted.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Adequate
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Inadequate
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Adequate

Reference and design	Intervention	Participants	Outcome measures
Study: Domenech *et al.*, 1995[64] **Source**: Journal article **Country**: Argentina **Setting**: Community **Language**: English **Trial design**: CCT	Patients had previously received dietary advice from their physicians and/or had been treated with OHAs **Treatment intervention**: Group intervention of up to 8 patients incorporating group discussion and teaching *Provider*: physicians who had previously participated in a 2-day instruction of the teaching programme *Sessions*: 4 teaching units (90–120 minutes each) carried out once per week for 1 month *Topics*: normal physiological range for serum glucose, symptoms of hypoglycaemia, hyperglycaemia, the renal threshold for glucose, self-monitoring of glycosuria, the effect of obesity, planning of an individual meal plan, foot care, physical activity and basic rules to be applied on sick days *Delivery*: group education. Materials: flip charts, teaching files, photographs of different food representing 1000 cal, question cards to verify knowledge, an individual log book, a patient booklet including the main contents, a questionnaire Each patient was encouraged to attend accompanied by spouse After session 1, a very low-calorie diet (600 cal) was recommended for alternative days for 1 week and to stop the intake of OHA, thereby giving an opportunity to test the effect of diet upon glucose levels. Testing for glycosuria was recommended for twice per day 2 h after food **Control intervention**: Usual care **Duration of intervention**: 1 month	**Eligibility/exclusion criteria**: *Exclusion*: excluded if newly diagnosed Type 2 diabetes, aged over 60 years, presence of advanced microangiopathic complications and presence of other severe diseases (e.g. cancer) **How selected**: the first 6–7 patients consulting each physician were selected for inclusion. In the control groups a larger number were included as were expecting a larger drop-out and in order to obtain a better match by age, gender and duration of diabetes **Numbers involved**: total $N = 124$, intervention (int.) 53; control (con.) 71 NB: Baselines based on those completing study **Numbers on insulin**: not reported, assume none. Tablets: int. 29; con. 32. Diet alone: assume int. 11; con. 7 **Type of diabetes?**: Type 2 **Duration of diabetes**: int. 6.9 (±0.7); con. 6.3 (±1.3) years **Baseline measurements of outcome parameter**: HbA_1 int. 9% (± 2.6); con. 9% (± 2.2) **Gender (M/F)**: int.18/22; con. 17/22 **Age ranges**: int. 52.7 (SE 3.1); con. 53.1 (SE 1.1) years **Ethnic groups**: not reported **Losses to follow-up**: int. 13; con. 32 (details given for intervention group only)	**Primary outcomes used**: HbA_1 **Secondary outcomes used**: knowledge weight in kg, daily intake of OHAs **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: HbA_1 <7.5% **How outcomes assessed?**: laboratory, knowledge by self-report **Validated?**: HbA_1 yes, knowledge no **Timing of outcomes same for both groups**: yes **Length of follow-up**: 12 months from inception

continued

Outcome changes (mean difference ± SD)	**Intervention (*n* = 40)**	**Control (*n* = 39)**	**Differences between groups**
HbA_1	–0.2 (0.4)	+0.8 (0.4)	
Weight in (kg)	–2.4 (0.5)	–0.4 (0.5)	$p < 0.01$
Daily intake OHA (no. of tablets)	–1.4 (0.2)	+0.9 (0.2)	$p < 0.01$

Knowledge not reported as not a valid measure
Also reports percentage of patients who showed an improvement of more than 0.5% which was not significant between groups (data in figure only)
Also reports that within groups a significant correlation in those who exhibited a significant decrease in HbA_1 (>0.5%) was associated with significant weight loss and a reduction in OHAs.

Methodological comments
Allocation to treatment groups: non-randomised trial
Blinding of outcome assessors?: not reported
Allocation concealment?: non-randomised trial
Analysis by ITT?: no
Comparability of treatment groups: reported to be comparable in socio-economic levels and matched for age, gender and duration of diabetes. Also strict criteria were adopted to standardise between the two groups the level of dietary caloric intake and OHA prescription
Method of data analysis: method not reported, assume ± = SD
Sample size/power calculation: no
Attrition/drop-outs: percentages reported

General comments
Generalisability: few baseline data reported
Conflict of interests: course materials were provided by Boehringer Mannheim
Other: unsure of control group intervention; patients in intervention groups all had different tutors

Quality criteria for CCTs (CRD Report 4)

Were the groups similar at baseline in terms of prognostic factors?	Reported
Were the eligibility criteria specified?	Yes
Were outcome assessors blinded to the treatment allocation?	Unknown
Were the point estimates and measure of variability presented for the primary outcome measure?	Partial
Did the analyses include an ITT analysis?	Unknown
Were withdrawals and drop-outs completely described?	Adequate
Were participants likely to be representative of the intended population?	Yes

Reference and design	Intervention	Participants	Outcome measures
Study: Kronsbein, *et al*., 1988[63] **Source**: Journal article **Country**: Germany **Setting**: general practices **Language**: English **Trial design**: CCT, conditions implemented by practice	**Treatment intervention**: *Provider*: specially trained physicians' assistants *Topics*: basic information, metabolic self-monitoring, reasons for raised BG levels, OHAs, diet, foot care, physical activities, sick-day rules, late complications *Sessions*: 90–120 minutes each week for 4 weeks; groups of 4–6 patients; focus on group interaction with each session including experiential, theoretical and practical aspects *Treatment changes*: unknown *Training trainers*: unknown *Theory*: unknown *Mode*: unknown **Control intervention**: Usual care within general practices; all patients before trial had been given unstructured dietary advice by physicians and/or were treated with oral sulfonylureas **Duration of intervention**: 4 weeks	**Eligibility**: WHO criteria for NIDDM *Exclusion*: physical or mental handicaps that prevented them from following the intervention programme **How selected**: 8 GPs attending teaching programme volunteered to introduce programme – 5 practices immediately, 3 after 1 year. Intervention participants: all consecutive patients who participated in first three courses **Numbers involved**: starting total: 127, intervention (int.) 65; control (con.) 62 Total (those completing follow-up) 99, int. 50; con. 49 **Type of diabetes**: Type 2 **Duration of diabetes (year ± SD)**: int. 7 ± 5; con. 7 ± 6 **Baseline measurements of outcome parameter (mean ± SD)**: *HbA_{1c}*: int. 7.1 ± 1.6%; con. 6.5 ± 1.6% *Weight (kg)*: int. 76.5 ± 12.6; con. 75.1 + 12.9 *Knowledge*: int. 9 ± 3; con. 9 ± 3 **No. without glucose-lowering medication:** int. 32%; con. 39% **Gender (M/F)**: int. 42/58%; con. 39/61% **Age ranges (mean ± SD)**: int. 65 ± 9 years; con. 63 ± 8 years **Ethnic groups**: not reported **Losses to follow-up**: int. 15; con. 13	**Primary outcomes used**: HbA_{1c} **Secondary outcomes used**: knowledge score, no. on BG-lowering medications, treatment with insulin, frequency self-monitoring urine, body weight **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: HbA_{1c} up to 5.6% **How outcomes assessed**: HbA_{1c} by laboratory, knowledge by specially designed questionnaire, no. on medication not reported, self-report glycosuria testing **Validated**: knowledge questionnaire assumed validated, reference provided **Timing of outcomes same for both groups?**: unknown **Length of follow-up**: 1 year from inception

continued

Outcome (mean and SD)	Intervention (n = 50)	Control (n = 49)	Difference between groups (95% CI)
HbA_{1c}	7.1 ± 1.6	6.7 ± 1.5	NS
Knowledge	13 ± 4	10 ± 4	3 (16 to 48)[a]
% without BG-lowering medication	62	39	23 (3 to 43)[b]
Treatment with insulin	0	10	10 (2 to 18)[b]
Body weight (kg)	73.8 ± 12.6	74.8 ± 13.2	2.3 (1.0 to 3.6)[a]
Self-monitoring glycosuria (%)	72	2	70 (57 to 83)[a]

Methodological comments
Allocation to treatment groups: group formed by treatment within participating practices or not, all GPs received programme training
Blinding of outcome assessors: not reported
Allocation concealment: not randomised
Analysis by ITT: no
Comparability of treatment groups: reported that baseline characteristics of those completing and not completing follow-up did not differ
Method of data analysis: hypothesis tests with CIs for within-group and between-group differences
Sample size/power calculation: reported power required ~55 patients per group
Attrition/drop-outs: yes

General comments
Generalisability: both patient groups started with relatively low HbA_{1c} and therefore may not be representative
Conflict of interests: none reported
Other: none

[a] Difference between groups $p < 0.0001$.
[b] Difference between groups, $p < 0.05$.

Quality criteria for CCTs (CRD Report 4)

Were the groups similar at baseline in terms of prognostic factors?	Reported
Were the eligibility criteria specified?	Yes
Were outcome assessors blinded to the treatment allocation?	Unknown
Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
Did the analyses include an ITT analysis?	Unknown
Were withdrawals and drop-outs completely described?	Partially
Were participants likely to be representative of the intended population?	No

Interventions of focused self-management education

Reference and design	Intervention	Participants	Outcome measures
Study: Kaplan *et al*., 1987[67] **Source**: Journal article **Country**: USA **Setting**: Unclear **Language**: English **Trial design**: RCT	Four groups: diet education (group 1), exercise education (group 2), diet and exercise education (group 3) and control education (control) All given the exchange diet (1200 cal) recommended by ADA and each received an exercise prescription based on baseline exercise test. A deposit of US$40 was requested with return if attend and meet predetermined goals. Treatment interventions incorporated behavioural modification (stretching and walking and target heart rate) and strategies to increase compliance. The control did not **Sessions**: Groups 2 h once per week for 10 weeks **Treatment intervention**: **Group 1 (diet)**: *Provider*: dietician explained the diet *Topics*: identification of goals, used principles of modern learning theory. Diary monitoring of eating behaviour. Identification of external cues that lead to over/inappropriate eating *Theory*: used positive reinforcement. Also recorded own cognitions (positive and negative self-statements) and discussed in group. Also brief relaxation. Ref. 11 for fuller details *Treatment changes*: *Training trainers*: *Mode*: **Group 2 (exercise)**: *Provider*: *Topics*: goal setting, planning for exercise, self-monitoring introduced, completion of diary, question answering and group exercise sessions. Used positive feedback and gave suggestions for managing problems *Treatment changes*: *Training trainers*: *Theory*: *Mode*: **Group 3 (diet and exercise):** *Provider*: *Topics*: modified dietary intervention for 5 weeks, then focused on	**Eligibility/exclusion criteria**: *Inclusion*: confirmed diagnosis, fasting plasma glucose >3.62 mmol/l **How selected**: radio and newspaper advertisements and physicians **Numbers involved**: total $N = 87$, unsure of group numbers **Numbers on insulin**: 19 *Tablets*: 29 *Diet alone*: 28 **Type of diabetes?**: Type 2 **Duration of diabetes**: not recorded **Baseline measurements of outcome parameter**: *HbA_{1c}*: group 1 8.97% (SD 2.82), group 2 8.16% (SD 3.44), group 3 9.18% (SD 2.46), control 8.21 (SD 1.54) **Gender (M/F)**: 32/44 **Age ranges**: group 1 54.87 (SD 12.32), group 2 53.81 (8.04), group 3 56.96 (SD 8.95), control 54.5 (8.83) years **Ethnic groups**: not reported **Losses to follow-up**: 11 (reasons given) **Compliance**: average attendance >80% for all groups	**Primary outcomes used**: HbA_{1c}, QoL **Secondary outcomes used**: weight in (kg) **Individual preferred learning style addressed?:** **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: see Appendix in text **How outcomes assessed?**: HbA_{1c} laboratory, QoL self-report questionnaire **Validated?**: QoL yes **Timing of outcomes same for all groups**: yes **Length of follow-up**: 18 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
	exercise, self-monitoring, foot care and stretching, then followed exercise and behaviour modification format *Treatment changes*: *Training trainers*: *Theory*: *Mode*: **Control intervention**: *Education*: *Provider*: exposed to healthcare specialists including an endocrinologist, podiatrist, ophthalmologist, psychologist, dietician, official from ADA, representative from company that manufactures home glucose monitoring equipment and physiologist *Session*: each provider presented for 1 session (2 h) in form of lecture providing diabetes care *Treatment changes*: *Training trainers*: *Theory*: *Mode*: **Duration of intervention**: 10 weeks		

Outcomes (18 months)	Group 1 (diet)	Group 2 (exercise)	Group 3 (diet+ exercise)	Group 4 (control – education)
HbA_{1c}[a]	8.51	9.46	7.70[b]	8.57
QoL (change scores)[a]	+0.03[b]	No improvement	+0.06[b]	–0.04
Weight	Data not reported, no changes	Data not reported, no changes	Data not reported, no changes	Data not reported, no changes

Methodological comments
Allocation to treatment groups: states randomly chosen otherwise no details
Blinding of outcome assessors?: not reported
Allocation concealment?: not reported
Analysis by ITT?: not reported
Comparability of treatment groups: no significant differences reported
Method of data analysis: change scores compared with ANOVA, no estimate of variance given
Sample size/power calculation: *post hoc* power analysis
Attrition/drop-outs: percentages given

General comments
Generalisability: minimal eligibility criteria, baseline characteristics suggest generalisable
Conflict of interests: funding support not mentioned
Other: unsure of *N* in each group

[a] Overall marginally significant difference between groups ($p < 0.10$).
[b] Significant from group 4, $p < 0.05$.
There were significant correlations between improvements in QoL and decreases in HbA_{1c} ($r = –0.22$, $p < 0.05$). Some costs–utility analysis reported.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Inadequate
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Reported

Reference and design	Intervention	Participants	Outcome measures
Study: Ridgeway, *et al*., 1999[69] **Source**: Journal article **Country**: USA **Setting**: community – ambulatory clinic **Language**: English **Trial design**: RCT	**Treatment intervention**: *Topics*: dieting and exercise were emphasised as important in the control of diabetes. Diet and exercise prescriptions and goals set individually. Contracts made to emphasise patient participation and personal responsibility *Provider*: registered nurse and a dietician *Sessions*: 1.5 h per month × 6 *Delivery*: group intervention, didactic and interactive *Treatment changes*: both groups seen by physicians in the usual manner *Training of trainers*: certified diabetes educators *Theory*: didactic based on life skills programme **Control intervention**: assume normal care with clinic visits **Duration of intervention**: 6 months *Treatment changes*: OHA medication started or increased intervention (int.) 1; control (con.) 4, stopped or decreased int. 1; con. 0, insulin increased int. 2; con. 2, OHA replaced by insulin, int. 0; con. 3	**Eligibility/exclusion criteria**: *Inclusion*: Type 2 diabetes (defined), at least 20% over ideal weight, able to travel to clinic monthly, judged by physician to be able to comprehend dietary and diabetic teaching, had inadequately controlled diabetes (fasting BG >150 mg/dl and HbA_{1c} above normal range) **How selected**: computerised audit was conducted and yielded 150 patients, of whom 56 met inclusion criteria **Numbers involved**: *N* = 56, int. 28; con. 28. **Numbers on insulin**: int. 3; con. 3, tablets int. 12; con. 13, diet alone: int. 3; con. 4 **Type of diabetes**: Type 2 **Duration of diabetes**: int. 10 years; con. 13 years **Baseline measurements of outcome parameter (mean ± SD)**: *GHb*: int. 12.3 + 2.2%; con. 12.3 ± 3.0% *Knowledge*: int. (*n* = 17) 74.2; con. not reported *QoL*: not reported *Diabetes symptoms*: int. 43.8 ± 14.7; con. 44.5 ± 19 *Fasting BG*: int. 215; con. 210 *Total cholesterol*: int. 259; con. 224 *HDL-cholesterol*: int. 40; con. 40 *Triglyceride*: int. 634; con. 381 *LDL-cholesterol*: int. 133; con. 119 **Gender (M/F)**: int. 6/12; con. 5/15 *Mean age*: int. 62 years; con. 65 years *Ethnic groups*: not reported NB: baseline characteristics based on those completing study *Losses to follow-up*: int. 10; cont. 8 (reasons given) *Compliance*: int. at least 5 classes	**Primary outcomes used:** GHb, QoL (MOS SF-36 and DRP questionnaires), symptoms **Secondary outcomes used**: knowledge (life skills test), fasting BG, total cholesterol, HDL cholesterol, triglyceride, LDL cholesterol **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: **Normal range(s) for outcomes**: GHb 4.8–7.8%. Knowledge scored as percentage of correct answers. No values for QoL **How outcomes assessed?**: GHb by laboratory. Others by questionnaire, presume self-report **Validated**: GHb yes, MOS SF-36 unclear whether validated; unclear whether DRP and life skills tests validated **Timing of outcomes same for both groups**: assume yes **Length of follow-up**: 12 months from inception

continued

Outcome (12 months)	Intervention group (n = 18)	Control group (n = 20)	Differences between groups
GHb (%)	11.52	11.64	NS
QoL	No data presented	No 12-month	
Knowledge	85.7	data presented	
Symptoms	No data presented		
Weight (lb)	186	186	NS
Fasting BG	205	185	NS
Total cholesterol	219	234	$p = 0.09$
HDL cholesterol	36	37	NS
Triglyceride	485	336	NS
LDL cholesterol (in patients with triglyceride <400)	130	125	NS

Methodological comments
Allocation to treatment groups: states randomly assigned in text but no details of method of any randomisation; also states that education was recommended to patients after 'randomisation' which all in education group accepted
Blinding of outcome assessors?: not reported
Allocation concealment?: not reported
Analysis by ITT?: no
Comparability of treatment groups: groups similar on baseline characteristics
Method of data analysis: *t*-Tests. Standard error (difference within groups) given. No other measure of variance reported. No CIs
Sample size/power calculation: not calculated, reported to be likely numbers available in a small general internal medicine group practice
Attrition/drop-outs: yes

General comments
Generalisability: small group, large proportion of drop-outs, GHb poor at outset in both groups, patients judged to be able to comprehend teaching by physicians
Conflict of interests: funding by Department of Medicine
Other: cost estimate for programme is US$95 for educational materials and salaries, excluding laboratory costs

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Inadequate
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Adequate

Reference and design	Intervention	Participants	Outcome measures
Study: Samaras *et al.*, 1997[72] **Source**: published **Country**: Australia **Setting**: Community – hospital outpatient clinic **Language**: English **Trial design**: RCT	**Treatment intervention**: *Topics*: initially a needs assessment undertaken using focus groups of outpatients where contributing factors for exercise non-compliance were identified and classified. Strategies to overcome barriers, build self-esteem and motivation and provide professional and peer support. Safe exercise, exercise-specific education to improve confidence, coping with diabetes and exercise, self-esteem issues, decision-making, goal setting and achieving mastery and enjoyment in exercise *Provider*: designed and undertaken by nurse educator, also involved exercise physiologist, dietician, group facilitator and physician *Sessions*: monthly sessions for 1 h followed by a moderately paced aerobic exercise session *Delivery*: group intervention, in person *Treatment changes*: unclear *Training of trainers*: *Theory*: health promotion model 'proceed–precede' (reference given) **Control intervention**: usual treatment with assessment visits at baseline, 6 and 12 months and routine clinic visits **Duration of intervention**: 6 months (after programme exercise sessions still available to int. group)	**Eligibility/exclusion criteria**: *Inclusion*: Type 2 diabetes, aged 40–70 years, performing less than 1 h of exercise per week *Exclusion*: if history or signs of ischaemic heart disease, current smoker, poor comprehension of English **How selected**: endocrinologists completed questionnaires on all their patients 40–70 years old at routine clinic for 2 months **Numbers involved**: *N* = 26 [(intervention (int.) 13; control (con.) 13)] **Numbers on insulin**: int. 3; con. 4; Sulfonylurea: int. 5; con. 5; metformin or diet alone: int. 5; con. 4 **Type of diabetes**: Type 2 **Duration diabetes**: not reported **Baseline measurements of outcome parameter (mean ± SE)**: *HbA_{1c}*: int: 5.6% ± 0.3; con. 6.8% ± 0.6 (not significant) *BMI*: int. 32.3 ± 1.1; con. 35.7 ± 1.6 *Weight*: int. 83 ± 3.6; con. 98.2 ± 3.4 *Skinfolds*: int. 99.4 ± 6.0; con. 119.4 ± 9.4 *% body fat*: int. 40.3 ± 1.7; con. 40.3 ± 2.4 *Waist:hip*: int. 0.94 ± 0.1; con. 0.94 ± 0.08 *Activity score*: int. 164 ± 28; con. 168 ± 16 *Total cholesterol*: int. 5.6 ± 0.3; con. 5.6 ± 0.2 *HDL cholesterol*: int. 1.1 ± 0.1; con. 1.1 ± 0.1 *Triglycerides*: int. 3.1 ± 1.1; con. 2.3 ± 0.3 *Fasting glucose*: int. 9.3 ± 1.0; con. 7.9 ± 0.7 *Fasting insulin*: int. 22.4 ± 4.1; con. 21.4 ± 2.2 **Gender (M/F)**: int. 4/9; con. 6/7 **Age ranges**: int. 60.5 years (SE 7.8); con. 60.5 years (SE 2.1) **Ethnic groups**: not reported, varied cultural backgrounds **Losses to follow-up**: assume none **Compliance**: full	**Primary outcomes used**: HbA_{1c}, QoL (SF-36) **Secondary outcomes used**: BMI **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: those managed with metformin or diet alone and those taking sulfonylurea or insulin therapy **Normal range(s) for outcomes**: not reported **How outcomes assessed**: physiological measures laboratory, QoL self-report, activity = meter **Validated?**: HbA_{1c} yes, QoL by SF-36 – validated. **Timing of outcomes same for both groups**: yes **Length of follow-up**: 12 months from baseline

continued

Outcome (values are changes from baseline, mean ± SE)	Intervention group	Control group	Differences between groups
HbA_{1c} %	+0.86 (0.29)	+0.86 (0.27)	NS
QoL	No data presented		
BMI	–0.1 (0.5)	+0.29 (0.45)	NS
Weight (kg)	+0.14 (1.09)	+0.79 (1.09)	NS
Skinfolds	+6.18 (2.2)	–3.7 (4.8)	NS
% body fat	+1.2 (0.5)	+1.1 (0.9)	NS
Waist:hip	–0.02 (0.02)	+0.01 (0.001)	NS
Activity score (metabolic equivalents or task)	+1 (12)	–23 (11)	NS
Total cholesterol (mmol/l)	–0.22 (0.27)	–0.33 (0.18)	NS
HDL cholesterol (mmol/l)	–0.01 (0.04)	–0.07 (0.04)	NS
Triglycerides (mmol/l)	–0.46 (1.02)	–0.23 (0.23)	NS
Fasting glucose (mmol/l)	+0.97 (0.64)	+1.5 (0.98)	NS
Fasting insulin	–3.3 (3.5)	+1.5 (2.2)	NS
Subgroup: metformin or diet-alone HbA_{1c} (changes from baseline)	+0.4 ± 0.3	+1.5 ± 0.14	$p = 0.02$
Subgroup: metformin or diet-alone FBG (changes from baseline)	+1.1 ± 0.3	+3.1 ± 0.4	$p = 0.003$

Methodological comments
Allocation to treatment groups: no details of method of randomisation
Blinding of outcome assessors?: not reported
Allocation concealment?: not reported
Analysis by ITT?: no drop-outs reported
Comparability of treatment groups: weight significantly higher, BMI and skinfolds marginally significantly higher in control group at baseline
Method of data analysis: ANOVA and Mann–Whitney statistics employed. SD given in some cases. No CIs given
Sample size/power calculation: not reported
Attrition/drop-outs: not reported

General comments
Generalisability: small sample size, smokers excluded
Conflict of interests: funding support not mentioned

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Partial
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Unknown

Reference and design	Intervention	Participants	Outcome measures
Study: Uusitupa, *et al.*, 1992–96[68,86–90] **Source**: Journal article **Country**: Finland **Setting**: Hospital outpatient **Language**: English **Trial design**: RCT	**Basic education to both groups**: prior to randomisation for 3 months, both groups received basic education (basic knowledge of NIDDM, dietary advice to lose weight, reduce intake of saturated fat and cholesterol and increase the use of unsaturated fat and unrefined carbohydrates) **Both groups, after the 1-year intervention period**: were advised to visit local health centres at 3-month intervals and the research centre at 21 and 27 months **Treatment intervention**: *Topics*: 1. *Individualised intensified dietary education*: principles of the diabetic diet, fat, carbohydrate, fibre, sweeteners, special diabetic products, behaviour modification, review of important things in diet, food preparation: recommended an individually tailored diet, compliance measured by food records and fatty acids of serum lipids 2. *Exercise training*: oral and written instructions – proposed walking, jogging, cycling, swimming, cross-country skiing. Recommended heart rate during sessions 110–140 beats per minute. Recommended 3–4 times per week for 30–60 minutes *Provider*: physician, DSN(s), clinical nutritionist *Length and number of sessions*: six visits to the clinic (at 2-month intervals). Recommended frequency of exercise training 3–4 sessions per week of 30–60 minutes each *Mode*: given in person at the local health centre *Treatment changes*: no *Training of trainers*: *Theory*: **Control intervention**: usual education given at the local health centres that originally referred them. They visited at 2–3-month intervals, plus twice visited the outpatient clinics **Duration of intervention**: 12 months	**Eligibility criteria**: *Inclusion*: obese, newly diagnosed Type 2 patients aged 40–64 years, FBG levels of $\geqslant$6.7 mmol/l **How selected**: physicians working in five rural and one urban health centre in Kuopio, referred all newly diagnosed patients from 1987 to 1989 **Numbers involved**: total $n = 86$, intervention (int.) 40; control (con.) 46 **Numbers on insulin**: none. Tablets: 7 (int. = 2; con. = 5) (1 in trial 2283); diet alone: assume 79 (85 in trial 2283) **Type of diabetes**: Type 2 **Duration of diabetes**: all newly diagnosed **Baseline measurements of outcome parameters – mean (SD)**: *Weight (kg)*: int. 88.3 (14.1); con. 88.8 (14) *BMI*: int: 32.0 (5.2); con. 31.6 (4.8) *FBG (mmol/l)*: int. 6.6 (1.9); con. 7.5 (2.9) *FBG adjusted (mmol/l)*: int. 7.0; con. 7.2 *% patients with FBG $\leqslant$6.7 mmol/l*: int. 37.5; con. 26.1 *HbA_{1c} (%)*: int. 7.1 (1.8); con. 7.8 (2.0) *HbA_{1c} adjusted (%)*: int. 7.4; con. 7.8 *% patients with HbA_{1c} $\leqslant$7.0%*: no data reported *Total cholesterol (mmol/l)*: int. 6.1 (1.2); con. 6.3 (1.0) *HDL cholesterol (mmol/l)*: int. 1.07 (0.25); con. 1.17 (0.29) *Non-HDL cholesterol (mmol/l)*: int. 5.1 (1.3); con. 5.1 (1.0) *Triglycerides (mmol/l)*: int. 2.50 (1.44); con. 2.26 (1.33) *Systolic BP (mmHg)*: int. 140 (16); con. 137 (16) *Diastolic (mmHg)*: int. 87 (11); cont. 83 (9) **Gender (M/F)**: int. 21/19; con. 28/18 **Age ranges**: 40–64 years. Mean (SD) ages at diagnosis: int: 52.2 (6.5); con. 54.2 (6.5). **Ethnic groups**: not reported **Losses to follow-up**: at 2-year follow-up 2 lost in each group. Reasons not given	**Primary outcomes used**: HbA_{1c} **Secondary outcomes used**: BP, FBG, weight, BMI, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, food intake, apolipoproteins A_1 and B, HDL cholesterol/ cholesterol, drug treatment, aerobic capacity **Individual preferred learning style addressed**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: not reported **How outcomes assessed**: body weight measured with electric scale; physiological measures by laboratory, BP nurse measured (mean of 3 measurements), food intake self-report **Validated**: yes, except self-report measures **Timing of outcomes same for both groups**: yes **Length of follow-up**: after the 1-year intervention period, patients followed up for a further 12 months

continued

Outcome (24 months: int. *N* = 38, con. *N* = 44), mean ± SD	Intervention	Control	Differences between groups
HbA_{1c} (%)			
12 months	6.6 (1.6)	7.5 (1.7)	
24 months	7.2 (1.9)	8.0 (1.6)	
HbA_{1c} (%) adjusted			
12 months	6.7	7.3	
24 months	7.4	7.9	
% patients with HbA_{1c} ≤7.0%			
12 months	74.4[a]	47.8	[a] $p = 0.005$
24 months	55.3[b]	31.8	[b] $p = 0.016$
BMI			
12 months	31.4 (5.0)	31.9 (4.6)	
24 months	31.9 (5.0)	32.2 (4.5)	
Systolic BP (mmHg)			
12 months	137 (16)	144 (18)	
24 months	146 (19)	150 (22)	
Diastolic BP (mmHg)			
12 months	83 (9)	85 (9)	
24 months	88 (10)	87 (9)	
Total cholesterol (mmol/l)			
12 months	6.0 (1.0)	6.4 (1.0)	
24 months	6.4 (1.3)	6.5 (1.1)	
HDL cholesterol (mmol/l)			
12 months	1.20 (0.29)	1.21 (0.28)	
24 months	1.17 (0.24)	1.19 (0.29)	
Non-HDL cholesterol (mmol/l)			
12 months	4.8 (1.0)		
24 months	5.2 (1.0)		
Triglycerides (mmol/l)			
12 months	1.96 (0.89)	2.33 (1.19)	
24 months	2.34 (1.19)	2.25 (1.25)	
Weight (kg)			
12 months	86.5 (13.7)	90.2 (14.3)	
24 months	Men (*n* = 20) 91.8 (10.7); women (*n* = 18) 83.1 (14.2)	Men (*n* = 26) 95.1 (10.3); women (*n* = 18) 84.8 (18.1)	
FBG (mmol/l)			
12 months	6.2 (1.8)	7.5 (2.2)	
24 months	7.1 (2.4)	8.2 (2.3)	
FBG (mmol/l) adjusted			
12 months	6.4[a]	7.3	[a] $p < 0.02$
24 months	7.4	8.0	
% patients with FBG ≤6.7 mmol/l			
12 months	75[a]	52.2	[a] $p = 0.005$
24 months	55.3[b]	31.8	[b] $p = 0.016$
Apolipoprotein A_1			
12 months	1.38 (0.19)	1.41 (0.18)	
Apolipoprotein B			
12 months	1.13 (0.24)[a]	1.26 (0.27)	[a] $p < 0.02$
HDL cholesterol/total cholesterol			
12 months	0.20 (0.05)	0.19 (0.05)	
Drug treatment (% taking)			
24 months	12.5[a]	34.8	[a] Significant from control, $p = 0.005$

Most of the comparisons reported were within groups. Only comparisons between groups are reported below. Self-report outcomes not reported here.

continued

Methodological comments
Allocation to treatment groups: unclear, only reports 'randomised'
Blinding of outcome assessors: not relevant
Allocation concealment: not reported
Analysis by ITT: not reported
Comparability of treatment groups: intervention group lower for FBG and HbA_{1c} – difference not tested statistically. Values were adjusted as covariates into MANOVA procedures and into the two-way ANCOVA
Method of data analysis: MANOVA, ANCOVA, *t*-tests. ANOVA used to test differences between groups. *p*-Values reported. Variables expressed as mean (SD)
Sample size/power calculation: no
Attrition/drop-outs: numbers reported, but no reasons given.

General comments
Generalisability: 108 patients were recruited and 86 randomised – 11 did not fulfil selection criteria and 11 refused
Conflict of interests: funding from Finnish Medical Council, Academy of Finland, Finnish Ministry of Education, Finnish Foundation for Diabetes Research
Other: Significant decrease for both groups for body weight, FBG and HbA_{1c} during 3 months of basic education before randomisation

ANCOVA, analysis of covariance; ANOVA, analysis of variance; MANOVA, multivariate analysis of variance.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Unknown

Reference and design	Intervention	Participants	Outcome measures
Study: Wing *et al*., 1985[70] **Source**: Journal article **Country**: USA **Setting**: Community **Language**: English **Trial design**: RCT 3 groups	**Treatment intervention**: **Behaviour modification**: *Provider*: behavioural psychologist and nutritionist *Topics*: information on nutrition, exercise, diabetes, behavioural strategies. Self-monitor diet. Caloric goal for exercise and group exercise. Contingency contract refunded US$3 per lb of weight loss. Changing eating environment. Changing cognitions *Sessions*: weekly for 16 weeks in groups *Treatment changes*: *Training trainers*: *Theory*: *Mode*: lecture + discussion on topic related to diet and exercise **Nutrition education** *Provider*: as above *Topics*: diet – follow exchange list eating plan closest to caloric goal. Nutrition topics. Importance of exercise. No requirement to self-monitor either diet or exercise. No contingency contract for weight loss *Sessions*: weekly for 16 weeks in groups *Treatment changes*: *Training trainers*: *Theory*: *Mode*: as above **Control intervention**: Treatment programme identical in content with nutrition education except only 4 monthly meetings **Duration of intervention**: Intervention for 16 weeks and follow-up for 1 year after intervention	**Eligibility criteria**: *Inclusion*: 30–70 years of age, 20% or more above ideal weight for height, diabetes being treated by diet only or by OHA medication, Type 2 diabetes by criteria specified by National Diabetes Data Group **How selected**: recruited via newspaper advertisements and articles and letters to physicians **Numbers involved**: Total: 53. No. in each group not reported **Numbers on insulin**: 0. Tablets 75%; diet alone 25% **Type of diabetes**: Type 2 **Duration of diabetes**: 5.9 years **Baseline measurements of outcome parameter**: *HbA_1*: 9.3 ± 0.3 (mean ± SEM) *BMI*: 34.8 ± 7 *BDI*: 11.2 **Gender (M/F)**: 20/33 **Age (mean ± SEM)**: 55.1 ± 1 **Ethnic groups**: not reported **Losses to follow-up**: 3	**Primary outcomes used**: HbA_1 **Secondary outcomes used**: BP, Beck Depression Inventory (BDI), BMI, insulin, total cholesterol, total triglycerides, HDL cholesterol, FBG, activity, food frequency, eating behaviour inventory **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: not reported **How outcomes assessed**: laboratory nurse measure and self-report **Validated**: yes, except activity, food frequency, eating behaviour inventory **Timing of outcomes same for both groups**: yes **Length of follow-up**: 12 months post-intervention (16 months from inception)

Results
No physiological measures differed between groups, therefore results were reported for all 3 groups combined

Outcome	Behaviour group	Nutrition group	Standard care	Differences between groups
Weight (kg)	–1.78	–3.03	–3.43	NS

Methodological comments
Allocation to treatment groups: method of randomisation not reported
Blinding of outcome assessors: BP assessment blinded, others not reported
Allocation concealment: not reported
Analysis by ITT: no
Comparability of treatment groups: reported that there were no differences in groups in pretreatment physiological measures
Method of data analysis: hypothesis tests (ANOVA), no CIs
Sample size/power calculation: not reported
Attrition/drop-outs: 3/53, not reported from within groups

General comments
Generalisability: participants self-selected to participate on basis of advertisements or suggestion from physician, therefore may be more motivated than average patient; however, this would be true across conditions
Conflict of interests: no mention
Other: none

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Unknown
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Partially
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Partial

Reference and design	Intervention	Participants	Outcome measures
Study: Wing *et al.*, 1986[71] **Source**: Journal article **Country**: USA **Setting**: Community and home **Language**: English **Trial design**: RCT	**Common treatment components**: All sessions: individual weigh-in, BG measurement, discussion of behaviour modification for weight control. Given a standard behavioural weight control programme. A daily calorie goal set. Calorie books and self-monitoring diaries were distributed. Patients asked to self-monitor their food intake and to walk to exercise. Behaviour modification techniques were presented. All patients deposited US$85, which could be earned back for meeting treatment contingencies **Treatment intervention = glucose monitoring group** *Providers*: *Topics*: Focused on the relationship between weight loss and BG control. Taught to monitor BG and values recorded on a self-monitoring form; both the form and used strips were returned to the office at each meeting. Patients encouraged to keep BG levels normal by adjusting caloric intake and expenditure *Sessions*: weekly meeting for 12 weeks, monthly meetings for the next 6 months and follow-up sessions at 9 and 12 months *Treatment changes*: *Training trainers*: *Theory*: *Mode*: **Control intervention = weight control group**: Focused on weight reduction. BG levels checked at each meeting so adjustments could be made to	**Eligibility**: *Inclusion*: Type II diabetes, aged 35–65 years; 20% over more above ideal weight for height; use of OHA or insulin for control of BG; diagnosis ⩾30 years *Exclusion*: patients having prior experience with home monitoring of BG **How selected**: About two-thirds were self-referred, one-third referred by their physicians **Numbers involved**: *N* = 50 (25 weight control group, 25 glucose monitoring group) **Numbers on insulin**: weight control group 48%, glucose monitoring group 52% **Type of diabetes**: all Type 2 **Duration of diabetes**: not given **Baseline measurements of outcome parameter**: *FBG*: weight control group (*N* = 22) 207 ± 70.5, glucose monitoring group (*N* = 22) 209.2 ± 69.7 *HbA_1 (%)*: weight control group (*N* = 21) 10.86 ± 2.00, glucose monitoring (*N* = 22) 10.19 ± 2.51 **Weight (kg), mean ± SD**: weight control group (*N* = 22) 96.35 ± 23.57 **Gender (% male)**: weight control group 20%, glucose monitoring group 24%, overall 39 women/11 men **Age (years)**: overall average 54 years, weight control group 54.0, glucose monitoring group 53.5 **Ethnic groups**: not given **Losses to follow-up**: 5 (10%) –3 from weight control group and 3 from glucose monitoring group	**Primary outcomes used**: HbA_1 **Secondary outcomes used**: self-reported depression, weight in kg, FBG, BP, triglyceride levels, total cholesterol levels, HDL cholesterol, decreases in medication (others reported only for 12 weeks) **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: **Normal range(s) for outcomes**: FBG levels 60–120 mg/dl HbA_1 6.5 ± 0.5% **How outcomes assessed**: Beck Depression Inventory Scale for depression (self-report), BP nurse, laboratory physiological measures, self-report compliance **Validated**: yes **Timing of outcomes same for both groups**: yes **Length of follow-up**: 12 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
	medication, but no praise or reinforcement was given for BG control. Sessions as intervention group. **Duration of intervention**: 12 weeks	**Compliance**: Assessed by self-report records and by a 'marked item' technique. Patients used 89.1% of the assigned strips during treatment and 70.2% during the follow-up period. They detected 86.7% of the marked items during treatment and 62.8% during follow-up	

Outcomes	Weight control group (n = 22)	Glucose monitoring group (n = 23)	Differences between groups
HbA_1 (%)	10.44 ± 2.16	10.19 ± 2.29	
Beck Depression Inventory	No data provided		
FBG (n = 22)	210 ± 73.1	216.2 ± 58.7	
Decreases in medication (%)	Oral agents: 64 Insulin: 64	Oral agents: 73 Insulin: 83	NS

Serum lipids did not differ between groups. Analysis for BP, triglyceride levels, total cholesterol levels and HDL cholesterol only tested before and after

Methodological comments
Allocation to treatment groups: randomisation blocked according to sex and % overweight, no other details
Blinding of outcome assessors: nurse unaware BP, HbA_1 not applicable, others unclear
Allocation concealment: not stated
Analysis by ITT: no
Comparability of treatment groups: no significant differences between groups reported
Method of data analysis: Repeated-measures ANOVA used to compare physiological changes in patients in two groups. *p*-Values given
Sample size/power calculation: no
Attrition/drop-outs: reports 10%; however, numbers for outcomes also reduced but no details

General comments:
Generalisability: approximately two-thirds of patients were self-referred (and perhaps more motivated), so may not be generalisable to all patients
Other:

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Adequate
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Partially
7. Did the analyses include an ITT analysis?	Unknown
8. Were withdrawals and drop-outs completely described?	Reported

Reference and design	Intervention	Participants	Outcome measures
Study: Wing *et al*., 1988[73] **Source**: Journal article **Country**: USA **Setting**: Unclear **Language**: English **Trial design**: RCT	**Common procedure to both groups**: Weight control programme. Participated in a lecture-discussion on behavioural weight control, given individualised calorie goals and recorded all intake. Taught about caloric values of food groups and trained in portion size estimation. Exercise (walking) was stressed, and given gradually increasing exercise goals. Other lessons focused on behavioural strategies for controlling cues for eating, dealing with social situations involving food, changing cognitions about food, motivation and self-reinforcement and problem solving. Deposited money at start and refunded for every pound of weight lost and for attending Both groups given free glucometers and asked to monitor BG 12 times/week. Trained in its use **Intervention 1: self-regulation education**: *Topics*: extensive training in how to use SMBG information; this information was given gradually over the course of the programme. Meetings 1–5 given homework tasks to demonstrate the effect of diet and exercise on BG control, and given examples; these were then discussed at later group meetings. Meetings 6–9 given goals for BG which were 'good' and 'fair'. Monitored how many within each range. Then taught to use the readings to self-regulate their behaviours using reinforcement. Meetings 10–13 refunded deposit money for behaviour changes and other criteria used in previous phases. Not asked to adjust treatments in response to SMBG. *Provider*: *Sessions*: 13 sessions *Delivery*: in person *Treatment changes*: treatment changes in both groups monitored by physician and followed standard algorithm *Training of trainers*: *Theory*: **Intervention 2: self-monitoring education** No additional training in using SMBG information (as int. 1 had) **Duration of both interventions**: 13 meetings over 16 weeks (held weekly for 10 weeks and every 2 weeks for the following 6 weeks). Follow-up meetings held every 2 weeks for the next 3 months and at monthly intervals for the following 3 months. 10 months total **Were care programmes identical**: unclear	**Eligibility criteria**: *Inclusion*: >20% overweight, 30–65 years old, met NDDG (1979) criteria for Type 2 diabetes **How selected**: newspaper advertisements used to recruit **Numbers involved**: total $N = 20$, int. 1 = 10, int. 2 = 10 **Numbers on insulin**: 0. Tablets 16; diet alone 4 **Type of diabetes**: Type 2 **Duration of diabetes**: not reported **Baseline measurements of outcome parameter (mean ± SE)**: *HbA_1*: int. 1 10.57% ± 0.44, int. 2 10.54% ± 0.55 *BMI*: 35.4 ± 1.05 **Gender (M/F)**: 7/13 **Age ranges**: average 53.3 years (range 38–60) **Ethnic groups**: not reported **Losses to follow-up**: 3 in total, 1 in int. 1, 2 in int. 2 (1 death, 2 refusal) **Compliance**: all attended all 16 weeks	**Primary outcomes used**: HbA_1 **Secondary outcomes used**: BMI **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: HbA_1 6.1 ± 0.5% **How outcomes assessed?**: laboratory **Validated?**: yes **Timing of outcomes same for both groups**: yes **Length of follow-up**: week 68 from inception

continued

Outcome (mean ± SE)	Intervention 1 (*n* = 9)	Intervention 2 (*n* = 8)	Differences between groups
HbA_1 (%)	10.8 ± 0.8	9.71 ± 0.78	Time × condition interaction, NS (based analysis on baseline of those attending for follow-up)
Weight (BMI not reported at follow-up) (kg)	86.6 ± 5.6	94.8 ± 5. 9	Time × condition interaction, NS (based analysis on baseline of those attending for follow-up)

Methodological comments
Allocation to treatment groups: not described
Blinding of outcome assessors?: not described – not relevant for HbA_1
Allocation concealment?: not described
Analysis by ITT?: no
Comparability of treatment groups: no report of any differences in baseline, many characteristics reported per total *N* only
Method of data analysis: ANOVA for repeated measures of the two treatment groups pretreatment and 1 year. Standard error of mean reported
Sample size/power calculation: not reported
Attrition/drop-outs: percentages reported

General comments
Generalisability: self-selected sample
Conflict of interests: biodynamics supplied glucometers and strips for SMBG
Other:

NDDG, National Diabetes Data Group.

Quality criteria for RCTs (CRD Report 4)

1. Was the assignment to the treatment groups really random?	Unknown
2. Was the treatment allocation concealed?	Unknown
3. Were the groups similar at baseline in terms of prognostic factors?	Reported
4. Were the eligibility criteria specified?	Yes
5. Were outcome assessors blinded to the treatment allocation?	Not applicable
6. Were the point estimates and measure of variability presented for the primary outcome measure?	Partial
7. Did the analyses include an ITT analysis?	Inadequate
8. Were withdrawals and drop-outs completely described?	Partial

Reference and design	Intervention	Participants	Outcome measures
Study: Gilliland *et al*., 2002[74] **Source**: Journal article **Country**: USA **Setting**: Community **Language**: English **Trial design**: CCT (3 groups)	**Intervention 1: family and friends (FF):** *Topics*: culturally appropriate diabetes education materials, skill building, social support. Three core areas: exercise, diet and support. Sessions named: get more exercise; eat less fat; eat less sugar; together we can (how to get/receive support); staying on the path (maintenance of lifestyle changes) Intervention used Native American values, Native American foods, information on diet and exercise and videos featuring Native Americans. Consistent with Native American learning, stories and prayers were used. There were written materials, in addition to food and physical activity demonstrations. Activities to encourage discussion and sharing of stories about living with diabetes. Group physical activities and shared healthy meal *Provider*: mentor led *Sessions*: 5 sessions, approximately 6 weeks apart for approximately 2 h *Delivery*: in person in groups with FF *Treatment changes*: *Training of trainers*: bilingual community mentors trained on each session *Theory*: social learning theory **Intervention 2: one-on-one (OO)** Same written materials as given to FF but in individual sessions for ~45 minutes **Control: usual care (UC)** Usual schedule of clinic visits and activities. All participants received comprehensive diabetes care including professional and patient education. This group did not receive culturally specific intervention materials **Duration of both interventions:** Sessions conducted during 10-month period **Were care programmes identical**: yes	**Eligibility criteria**: *Inclusion*: all Native American women and men in local diabetes registries ⩾18 years old, mentally and physically able and resided in one of 8 communities **How selected**: placed into groups by community of residence **Numbers involved**: 104 evaluable patients provided both baseline and follow-up data (see below); 32 in FF, 39 in OO, 33 in usual care. **Numbers on insulin**: total = 19: 2 FF, 10 OO, 7 UC. Tablets: total = 63: 25 FF, 23 OO, 15 UC. Diet alone: total = 22: 5 FF, 6 OO, 11 UC **Type of diabetes**: Type 2 **Duration of diabetes (mean ± SD)**: FF 8.1 (5.3), OO 8.3 (6.4), UC 10.0 (6.6) **Baseline measurements of outcome parameter (mean ± SD)**: *HbA_1*: FF 8.3 (1.9), OO 9.2 (2.3), UC 7.9 (2.0) *BMI*: FF 31.0 (5.6), OO 31.2 (6.8), UC 32.0 (6.1) *Weight (lb)*: FF 174.6 (35.4), OO 172.2 (37.2), UC 168.9 (33.8) *Diastolic BP (mmHg)*: FF 80 (9), OO 81 (12), UC 78 (10) *Cholesterol (mg/dl)*: FF 199 (51), OO 218 (50), UC 193 (43) *Triglycerides (mg/dl)*: FF 224(147), OO 290 (214), UC 214 (154) **Gender (M/F)**: FF 9/23, OO 10/29, UC 3/30 **Age (mean ± SD) (years)**: FF 60.2 (12.1), OO 59.9 (13.4), UC 60.2 (11.8) **Ethnic groups**: all participants Native American **Losses to follow-up**: 206 volunteered to participate, 47 withdrew before receiving intervention, 42 dropped out during intervention, 13 did not have information on covariates, 104 were evaluable **Compliance**: all evaluable patients received full intervention	**Primary outcomes used**: HbA_{1c}, weight **Secondary outcomes used**: diastolic BP, cholesterol, triglycerides **Individual preferred learning style addressed?**: no **Any subgroups (e.g. ethnic groups)**: no **Normal range(s) for outcomes**: HbA_1 not reported **How outcomes assessed**: laboratory **Validated**: yes **Timing of outcomes same for both groups**: yes **Length of follow-up**: ~1 year from inception

continued

Outcome groups	FF intervention	OO intervention	Control – usual care (mean ± SD)	Differences between (across 3 arms)
HbA_1 adjusted mean change	+0.5 (0.3)	+0.2 (0.3)	+1.2 (0.4)	$p < 0.05$ Combined interventions vs control, $p < 0.05$
Weight (lb)	–2.0 (1.5)	–1.8 (1.5)	+1.7 (1.8)	NS Combined interventions vs control, $p = 0.05$
Diastolic BP (mmHg)	–6.5 (2.0)	–0.4 (1.7)	–0.3 (2.1)	$p < 0.05$ Combined interventions vs control, NS
Cholesterol (mg/dl)	–22 (11)	–20 (11)	–10 (16)	NS Combined vs control, NS
Triglycerides (mg/dl)	–178 (78)	–48 (48)	–69 (63)	NS Combined vs control, NS

Methodological comments
Allocation to treatment groups: by community
Blinding of outcome assessors: not reported, not of concern for laboratory measures
Allocation concealment: not applicable
Analysis by ITT?: no
Comparability of treatment groups: at baseline groups differed in HbA_{1c}, in number of patients receiving oral agents, in hypertension. These differences were incorporated into statistical analyses
Method of data analysis: ANOVA for continuous variables, χ^2 or Fisher's exact tests for discrete variables. Analysis of covariance for intervention differences in HbA_{1c} and weight. Covariates were sex, age, duration of diabetes, medication use, two preintervention determinations of annual change in HbA_{1c} and factors significantly different at baseline
Sample size/power calculation: none reported. Study size likely underpowered to detect differences in two interventions
Attrition/drop-outs: More women than men and more obese than non-obese participants were evaluable. Participants in usual care were more likely to drop-out

General comments
Generalisability: Compared with the overall population of diabetic patients in the included communities, the patients who were evaluable seem generally representative. However, the evaluable patients were more likely to be women and older. Relatively high drop-out rate is a concern for generalisability
Conflict of interests: none reported
Other:

Quality criteria for CCTs (CRD Report 4)

Were the groups similar at baseline in terms of prognostic factors?	Reported
Were the eligibility criteria specified?	Yes
Were outcome assessors blinded to the treatment allocation?	Unknown
Were the point estimates and measure of variability presented for the primary outcome measure?	Adequate
Did the analyses include an ITT analysis?	Inadequate
Were withdrawals and drop-outs completely described?	Partially
Were participants likely to be representative of the intended population?	No

Appendix 6

Excluded studies

This is a supplement to the list of excluded studies by Loveman and colleagues.[37]

Trials excluded owing to study design (i.e. not RCT or CCT, or inappropriate comparator)

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Trials excluded owing to outcomes (i.e. no reports of diabetic control, QoL or end-points)

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Appendix 7

Psychological instruments used in included trials

Psychometric instruments

A few studies used measures that were constructed for the purposes of the study about which no validation information was provided. Unfortunately, the studies' failure to use validated instruments or to validate their own instrument means that these results cannot be clearly interpreted. The use of unvalidated psychometric instruments represents a lost opportunity to collect valuable information.

Quality of life (QoL)

[AIC data removed]
The ADDQoL (Audit of Diabetes-Dependent Quality of Life) questionnaire was used by Deakin and colleagues.[46] This is a 13-item questionnaire in which questions have the format "if I did not have diabetes, my [employment/social life/etc.] would be [a great deal better – a great deal worse]". Each QoL item is scored by the respondent on a seven-point scale (–3 to +3) and the respondent then indicates which items are very important (score 3), important (2), quite important (1) or not important (0). To obtain the final ADDQoL score, the item scores and importance scores are multiplied for each of the applicable items and the results averaged. ADDQoL has been reported to have relatively high internal consistency (Cronbach's $\alpha = 0.85$) and an independent review found good evidence for reliability and internal and external construct validity. ADDQoL has not been tested specifically on elderly or minority patient groups.

A modified version of the Diabetes Quality of Life (DQoL) measure was used by Trento and colleagues.[53–55] The DQOL measure was originally designed for use in the DCCT (Diabetes Control and Complications Trial). The original intent was to evaluate the burden of an intensive diabetes treatment regimen. However, it was also designed for broader application in diabetes as the scale items cover a range of issues relevant to diabetes and its treatment. The instrument addresses satisfaction with treatment, impact of treatment, worry about the future effects of diabetes and worry about social/vocational issues in addition to an overall well-being scale. The items are answered on a five-point scale. Test–retest reliability ranges from 0.78 to 0.92. The test has also been shown to have good internal consistency in patients with either Type 1 or Type 2 diabetes.

QoL was tested by Kaplan and colleagues[67] using a previously validated scale used in chronic obstructive pulmonary disease. The index conceptualises health as two components: current state of health and prognosis. The measure has three scales: mobility, physical activity and social activity. Patients are also classified as having any of 36 symptoms or problems that might inhibit function. Levels of well-being are the social preferences that society associated with observable levels of functioning.

Knowledge

Deakin and colleagues[46] used a validated diabetes knowledge questionnaire with 14 multiple-choice questions and nine further optional questions for patients using insulin. The questionnaire had been previously validated on two separate populations, one of which received diabetes care in their community from a variety of providers and plans whilst the other received diabetes care from a local health department. The questionnaire was considered reliable (Cronbach's $\alpha > 0.70$) and valid for a variety of settings and patient populations (although it could not clearly discriminate between Type 1 and Type 2 diabetic patients).

Brown and colleagues[52] used a diabetes knowledge instrument developed specifically for the population as part of a graduate nursing thesis project but did not report any other details.

The Diabetes Knowledge scale – form A (DKNA)[91] is a 15-item scale with Cronbach's $\alpha > 0.82$. The scale was used by Campbell and colleagues.[51] The multiple-choice questions include questions on the normal range for BG, the causes of hypoglycaemia, insulin requirements during illness and the status of rice as a carbohydrate food. Additional items test basic survival information and other valid content.

Knowledge of diabetes was tested by Trento and colleagues[53–55] using the GISED. This

questionnaire was developed by the Education Study Group of the Italian Society for Diabetes. The 38-item questionnaire was slightly modified to clarify the meaning of some terms. The internal consistency was found to be acceptable and internal validity was checked by cluster analysis.

Kronsbein and colleagues[63] used a knowledge questionnaire that was designed for the trial (DTTP–NIDDM). The questionnaire consisted of 21 multiple-choice items. Additional information was not evaluated as it was in a German publication.

Other validated instruments used

Additional instruments were used in various studies. These instruments are not described here, because the studies in which they were used did not report the results of these measures at a 12-month or later evaluation.

The SF-36 was used to measure QoL in the trial by Samaras and colleagues.[72] An apparent variation of this scale was also used by Ridgeway and colleagues.[69]

The Beck Depression Inventory was used by Wing and colleagues.[70,71] Although this is a valid psychometric instrument, the use of the instrument has been questioned in patients who are not depressed.

Ridgeway and colleagues[69] used the Life Skills cognitive knowledge of diabetes test provided by the Diabetes Education Society and approved by the American Diabetes Association.

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ISSN 1366-5278