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

E Loveman, GK Frampton and AJ Clegg

April 2008
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The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review

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Southampton Health Technology Assessments Centre (SHTAC), Wessex Institute for Health Research and Development (WIHRD), University of Southampton, UK

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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.

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Abstract

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

E Loveman,* GK Frampton and AJ Clegg

Southampton Health Technology Assessments Centre (SHTAC), Wessex Institute for Health Research and Development (WIHRD), University of Southampton, UK

* Corresponding author

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.
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List of abbreviations and acronyms

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<tr>
<td>AADE</td>
<td>American Association of Diabetes Educators</td>
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<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>ADDQoL</td>
<td>Audit of Diabetes-Dependent Quality of Life</td>
</tr>
<tr>
<td>AIC</td>
<td>academic in confidence</td>
</tr>
<tr>
<td>BDA</td>
<td>British Diabetic Association (former name for Diabetes UK)</td>
</tr>
<tr>
<td>BIPOD</td>
<td>Bangladeshi Initiative for Prevention of Diabetes</td>
</tr>
<tr>
<td>BG</td>
<td>blood glucose</td>
</tr>
<tr>
<td>BMI</td>
<td>body mass index</td>
</tr>
<tr>
<td>BP</td>
<td>blood pressure</td>
</tr>
<tr>
<td>CCT</td>
<td>controlled clinical trial</td>
</tr>
<tr>
<td>CI</td>
<td>confidence interval</td>
</tr>
<tr>
<td>CRD</td>
<td>Centre for Reviews and Dissemination</td>
</tr>
<tr>
<td>CVD</td>
<td>cardiovascular disease</td>
</tr>
<tr>
<td>DAFNE</td>
<td>Dose Adjustment For Normal Eating</td>
</tr>
<tr>
<td>DCCT</td>
<td>Diabetes Control and Complications Trial</td>
</tr>
<tr>
<td>DESMOND</td>
<td>Diabetes Education and Self-Management for Ongoing and Newly Diagnosed</td>
</tr>
<tr>
<td>DKNA</td>
<td>Diabetes Knowledge scale – form A</td>
</tr>
<tr>
<td>DQOL</td>
<td>Diabetes Quality of Life measure</td>
</tr>
<tr>
<td>DSN</td>
<td>diabetes specialist nurse</td>
</tr>
<tr>
<td>FBG</td>
<td>fasting blood glucose</td>
</tr>
<tr>
<td>GHb</td>
<td>glycated haemoglobin</td>
</tr>
<tr>
<td>GISED</td>
<td>Group of the Italian Society for Diabetes</td>
</tr>
<tr>
<td>GMS</td>
<td>General Medical Services</td>
</tr>
<tr>
<td>HbA1c</td>
<td>glycated haemoglobin A1c</td>
</tr>
<tr>
<td>HDL</td>
<td>high-density lipoprotein</td>
</tr>
<tr>
<td>IDDM</td>
<td>insulin-dependent diabetes mellitus</td>
</tr>
<tr>
<td>ITT</td>
<td>intention-to-treat</td>
</tr>
<tr>
<td>LDL</td>
<td>low-density lipoprotein</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>NIDDM</td>
<td>non-insulin-dependent diabetes mellitus</td>
</tr>
<tr>
<td>NSF</td>
<td>National Service Framework</td>
</tr>
<tr>
<td>OHA</td>
<td>oral hypoglycaemic agent</td>
</tr>
<tr>
<td>PCT</td>
<td>Primary Care Trust</td>
</tr>
<tr>
<td>PEWG</td>
<td>Patient Education Working Group</td>
</tr>
<tr>
<td>QoL</td>
<td>quality of life</td>
</tr>
<tr>
<td>QBW</td>
<td>quality of well-being scale</td>
</tr>
<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
</tr>
<tr>
<td>SD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>SDIS</td>
<td>Stockholm Diabetes Intervention Study</td>
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*continued*
<table>
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>SE</td>
<td>Standard error</td>
<td>SEM</td>
<td>standard error of the mean</td>
</tr>
<tr>
<td>SF-36</td>
<td>Short-Form with 36 Items</td>
<td>SMBG</td>
<td>self-monitoring of blood glucose</td>
</tr>
<tr>
<td>UKPDS</td>
<td>United Kingdom Prospective Diabetes Study</td>
<td>VAS</td>
<td>visual analogue scale</td>
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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 ≥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 autoimmune process. Patients with Type 1 diabetes are ‘insulin dependent’ and need insulin for survival; it was formerly called insulin-dependent diabetes (IDDM). 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).

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.

**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. 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.

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). Diabetes is the single most common cause of blindness among adults aged 16–64 years. Nephropathy may develop in 20–25% of people with diabetes and may progress to kidney failure. 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. Stroke risk is increased two- to three-fold.

People with diabetes are prone to foot ulceration and gangrene of the lower limb (which can result in amputation). 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. The main cause of death in diabetes is heart disease.

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) and the Diabetes Control and Complications Trial (DCCT). 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. Metformin reduces BG predominantly by improved regulation of hepatic glucose production, which shows little dependence on the residual effectiveness of insulin-secreting cells. Metformin is commonly prescribed as the first-line treatment of choice. 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. More than one-fifth of older white British citizens have either undiagnosed Type 2 diabetes or impaired fasting glucose. 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. 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). Based on these data 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. It has been estimated that the number of people in the UK with diabetes will reach 3 million by 2010. Rising levels of obesity and an ageing population...
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**

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

Source: Office for National Statistics.
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.\(^{26}\) 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.\(^{32-34}\)

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. 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". 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. 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.

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. 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, 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.

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. 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. 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. 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. 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.

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)\(^2\) (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. HbA1c) 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 417 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 and for the two CCTs (Table 3). One of the published RCTs compared education in more than two groups of patients. Another published RCT compared ‘extended’ and ‘compressed’ versions of an intervention. 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. Six of the published trials were carried out in primary care, two in secondary care, one in a university clinic (three publications), one in pharmacies, one across both primary and secondary care (three publications) and one which started in secondary care but continued reinforcement interventions after hospital discharge. One trial did not report the setting for the study.

In two published studies the duration of diabetes was within 1 year of diagnosis [AIC data removed]. The duration of diabetes in the remaining trials ranged from 2.6 years to 9.8 years. 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)]

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>No. of participants</th>
<th>Duration of intervention</th>
<th>Timing of evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>44[AIC data removed]</strong></td>
<td>Ko et al., 2007</td>
<td>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</td>
<td>437</td>
<td>5 days inpatient followed by annual 3-hour outpatient sessions</td>
</tr>
<tr>
<td>RCT</td>
<td>Ko et al., 2007</td>
<td>45</td>
<td>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</td>
<td>437</td>
</tr>
<tr>
<td>Deakin et al., 2003, 2006</td>
<td>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)</td>
<td>314</td>
<td>6 weeks</td>
<td>14 months</td>
</tr>
<tr>
<td>RCT</td>
<td>Deakin et al., 2003, 2006</td>
<td>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)</td>
<td>314</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Brown et al., 2002</td>
<td>Two groups: 1. Self-management education. Team provided group education for 52 contact hours 2. Usual care by physicians and waiting list</td>
<td>256</td>
<td>9 months + 3 months of support group sessions = 1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>RCT</td>
<td>Brown et al., 2002</td>
<td>Two groups: 1. Self-management education. Team provided group education for 52 contact hours 2. Usual care by physicians and waiting list</td>
<td>256</td>
<td>9 months + 3 months of support group sessions = 1 year</td>
</tr>
<tr>
<td>Campbell et al., 1996</td>
<td>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</td>
<td>238</td>
<td>Differed between and within groups. Up to 1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>RCT</td>
<td>Campbell et al., 1996</td>
<td>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</td>
<td>238</td>
<td>Differed between and within groups. Up to 1 year</td>
</tr>
<tr>
<td>Brown et al., 2005</td>
<td>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</td>
<td>216</td>
<td>1 year</td>
<td>3 years (but extractable data not given for &gt;1 year)</td>
</tr>
<tr>
<td>RCT</td>
<td>Brown et al., 2005</td>
<td>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</td>
<td>216</td>
<td>1 year</td>
</tr>
<tr>
<td>Trento et al., 2001, 2002, 2004</td>
<td>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)</td>
<td>112</td>
<td>Varied amongst patients; up to 5 years</td>
<td>5 years</td>
</tr>
<tr>
<td>RCT</td>
<td>Trento et al., 2001, 2002, 2004</td>
<td>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)</td>
<td>112</td>
<td>Varied amongst patients; up to 5 years</td>
</tr>
<tr>
<td>Reference and design</td>
<td>Intervention</td>
<td>No. of participants</td>
<td>Duration of intervention</td>
<td>Timing of evaluation(^a)</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------</td>
<td>---------------------</td>
<td>--------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Cooper et al., 2002(^{,56}) 2003(^{,57,58})</td>
<td>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</td>
<td>89</td>
<td>8 weeks</td>
<td>1 year</td>
</tr>
<tr>
<td>Heller et al., 1988(^{,59})</td>
<td>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</td>
<td>87</td>
<td>6 months</td>
<td>1 year</td>
</tr>
<tr>
<td>Sarkadi and Rosenqvist, 2004(^{,60})</td>
<td>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)</td>
<td>77</td>
<td>1 year</td>
<td>2 years</td>
</tr>
<tr>
<td>Goudswaard et al., 2004(^{,61})</td>
<td>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</td>
<td>58</td>
<td>6 months</td>
<td>18 months</td>
</tr>
<tr>
<td>Raz et al., 1988(^{,62})</td>
<td>Two groups: 1. Self-management group education. Team-delivered. Minimum of 12 contact hours 2. Usual care. Follow-up every 2 months</td>
<td>51</td>
<td>1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>Kronsbein et al., 1988(^{,63})</td>
<td>Two groups: 1. Self-management education. Group education by physician assistants. ~7 contact hours 2. Usual care with GP. No details</td>
<td>127</td>
<td>1 month</td>
<td>1 year</td>
</tr>
<tr>
<td>Domenech et al., 1995(^{,64})</td>
<td>Two groups: 1. Self-management education. Group education by physicians. ~7 hours contact time 2. Usual care. No details</td>
<td>124</td>
<td>1 month</td>
<td>1 year</td>
</tr>
</tbody>
</table>

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.
Assessment of clinical effectiveness

Diabetes duration was similar in the intervention and control groups (difference <0.6 year). In the remaining published trial, 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. 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). The longest periods of follow up were 5 years, 4 years, 18 months, and 14 months.

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, Goudswaard and colleagues, Ko and colleagues, and Cooper and colleagues [AIC data removed]. Concealment of allocation was adequately reported in only four of the published trials, and only three published trials reported whether outcome assessors were blinded to treatment identity [AIC data removed]. 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 [AIC data removed].

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, and only two studies did not include exercise or physical activity. The majority of studies (apart from four) also discussed diabetes complications and/or management of complications. Seven studies described education for foot care specifically, and five included consideration of how to handle sick days. Two studies 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 [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), pharmacists (two studies), and dieticians (five studies). All teams that had dieticians also included nurses. Other members of the education teams were physicians (three studies), community workers (two studies), pharmacists (two studies), and an educationalist and medical students (one study) [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, diabetes nurse, physician, or physician assistant. In the remaining study it is unclear how many people provided the training [AIC data removed].

Only three published studies [AIC data removed] mentioned that they trained educators. In two studies by Brown and colleagues, 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, 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)]

<table>
<thead>
<tr>
<th>Study</th>
<th>Randomisation</th>
<th>Concealment of allocation</th>
<th>Baseline characteristics</th>
<th>Eligibility criteria</th>
<th>Blinding of assessors</th>
<th>Primary outcome results</th>
<th>ITT analysis</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ko et al., 2007&lt;sup&gt;45&lt;/sup&gt;</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Reported</td>
<td>Yes</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Partial</td>
</tr>
<tr>
<td>Deakin et al., 2003, 2006&lt;sup&gt;46–48&lt;/sup&gt;</td>
<td>Partial</td>
<td>Adequate</td>
<td>Reported</td>
<td>No</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Adequate</td>
</tr>
<tr>
<td>Brown et al., 2002&lt;sup&gt;49,50&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Partial</td>
</tr>
<tr>
<td>Campbell, et al., 1996&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Partial</td>
<td>Unknown</td>
<td>Partial</td>
</tr>
<tr>
<td>Brown et al., 2005&lt;sup&gt;52&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Trento et al., 2001–4&lt;sup&gt;53–55&lt;/sup&gt;</td>
<td>Adequate</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Inadequate</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Adequate</td>
</tr>
<tr>
<td>Cooper et al., 2002–3&lt;sup&gt;56–58&lt;/sup&gt;</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Partial</td>
</tr>
<tr>
<td>Heller et al., 1988&lt;sup&gt;59&lt;/sup&gt;</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Reported</td>
<td>Yes</td>
<td>Partial</td>
<td>Adequate</td>
<td>Unknown</td>
<td>Adequate</td>
</tr>
<tr>
<td>Sarkadi and Rosenqvist, 2004&lt;sup&gt;60&lt;/sup&gt;</td>
<td>Partial</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Partial</td>
<td>Inadequate</td>
<td>Partial</td>
</tr>
<tr>
<td>Goudswaard et al., 2004&lt;sup&gt;61&lt;/sup&gt;</td>
<td>Adequate</td>
<td>Adequate</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Adequate</td>
</tr>
<tr>
<td>Raz et al., 1988&lt;sup&gt;62&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Unknown</td>
<td>Adequate</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Baseline characteristics</th>
<th>Eligibility criteria</th>
<th>Blinding of assessors</th>
<th>Primary outcome results</th>
<th>ITT analysis</th>
<th>Missing values</th>
<th>Representativeness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domenech et al., 1995&lt;sup&gt;64&lt;/sup&gt;</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Partial</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Yes</td>
</tr>
<tr>
<td>Kronsbein et al., 1988&lt;sup&gt;63&lt;/sup&gt;</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Unknown</td>
<td>Partial</td>
<td>No</td>
</tr>
</tbody>
</table>
provider(s) for each intervention. This ranged from approximately 2.5 hours (in a 6-month intervention) to 52 hours (in a 1-year intervention). Some interventions began with 2–4 intensive sessions of 90–120 minutes followed up with additional sessions at, for instance, 3 and 6 months. 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. 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, 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. [AIC data removed]. In two studies the total contact time is unclear and in two studies it was not reported.

Interventions were provided to groups of participants in all but two of the studies. Of three interventions compared by Campbell and colleagues 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, two developed a culturally specific intervention aimed at Mexican-Americans based on four meta-analytic reviews of previous diabetes education interventions, two used cognitive-behavioural strategies in a behaviour change intervention, 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. [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. All six of these were RCTs (Table 6). Ko and colleagues 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 HbA1c, 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 HbA1c in both the intervention and control groups over the duration of the RCT. Fourteen months after the intervention in the Deakin and colleagues trial, the change from baseline in HbA1c 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 had HbA1c approximately 0.75% lower than the control group. In this study, the baseline HbA1c of participants in both groups was high. The intervention group in the Trento and colleagues study had HbA1c 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 had HbA1c approximately 1.35% lower than the control group at 12 months. In the Sarkadi and Rosenqvist trial, HbA1c was
TABLE 6 Glycated haemoglobin in studies of self-management education in adults with Type 2 diabetes. Data may represent HbA1 or HbA1c (details in Appendix 5). The studies are ordered by type (RCT, CCT) and size (largest first)

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Time-point</th>
<th>Intervention Mean (SD) (unless stated) HbA1 or HbA1c (%)</th>
<th>Control Mean (SD) (unless stated) HbA1 or HbA1c (%)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>[AIC data removed]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ko et al., 200745</td>
<td>Baseline</td>
<td>9.4 (2.0) (n = 219)</td>
<td>9.2 (1.9) (n = 211)</td>
<td>NS</td>
</tr>
<tr>
<td>RCT</td>
<td>1 year</td>
<td>7.9 (1.7) (n = 174)</td>
<td>8.1 (1.5) (n = 187)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>2 years</td>
<td>7.9 (1.5) (n = 168)</td>
<td>8.2 (1.5) (n = 169)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>3 years</td>
<td>7.8 (1.5) (n = 167)</td>
<td>8.4 (1.6) (n = 148)</td>
<td>p = 0.004</td>
</tr>
<tr>
<td></td>
<td>4 years</td>
<td>7.9 (1.2) (n = 161)</td>
<td>8.7 (1.6) (n = 147)</td>
<td>p = 0.0001</td>
</tr>
<tr>
<td>Deakin et al., 2003;47,48 200646</td>
<td>Baseline</td>
<td>7.7 (1.6) (n = 157)</td>
<td>7.7 (1.6) (n = 157)</td>
<td>NS</td>
</tr>
<tr>
<td>RCT</td>
<td>Change</td>
<td>–0.6</td>
<td>0.1</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brown et al., 200249,50</td>
<td>Baseline</td>
<td>11.81 (3.0) (n = 128)</td>
<td>11.8 (3.02) (n = 128)</td>
<td>–</td>
</tr>
<tr>
<td>RCT</td>
<td>1 year</td>
<td>10.89 (2.56) (n = 112)</td>
<td>11.64 (2.85) (n = 112)</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>Campbell et al., 199651</td>
<td>Mean (SEM)</td>
<td>Individual education group  n = 57 at baseline, n = 25 at end-point</td>
<td>(all pairwise contrasts)</td>
<td></td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td>–3.3 (0.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group education group  n = 66 at baseline, n = 19 at end-point</td>
<td>–3.0 (1.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Behavioural education group  n = 56 at baseline, n = 39 at end-point</td>
<td>–4.8 (0.7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brown et al., 200552</td>
<td>Baseline</td>
<td>11.5 (3.5) (n = 102)</td>
<td>11.8 (3.4) (n = 114)</td>
<td>–</td>
</tr>
<tr>
<td>RCT</td>
<td>1 year</td>
<td>10.5 (3.0) (n = 89)</td>
<td>11.1 (3.2) (n = 96)</td>
<td>–</td>
</tr>
<tr>
<td>Trento et al., 2001;53 2002;54 200455</td>
<td>Baseline</td>
<td>7.4 (1.4) (n = 56)</td>
<td>7.4 (1.4) (n = 56)</td>
<td>–</td>
</tr>
<tr>
<td>RCT</td>
<td>Change</td>
<td>–1.0</td>
<td>0.7</td>
<td>NS</td>
</tr>
<tr>
<td>Cooper et al., 2002;56 2003;57,58</td>
<td>Baseline</td>
<td>7.9 (range 4.5–11) (n = 53)</td>
<td>7.0 (range 4.6–10.6) (n = 36)</td>
<td>–</td>
</tr>
<tr>
<td>RCT</td>
<td>1 year</td>
<td>7.9 (2.1) (n = 48)</td>
<td>7.2 (1.6) (n = 30)</td>
<td>NS</td>
</tr>
<tr>
<td>Heller et al., 198859</td>
<td>Baseline</td>
<td>12.3 (95% CI [11.4 to 13.2]) (n = 40)</td>
<td>12.7 (95% CI 11.9 to 13.5) (n = 47)</td>
<td>–</td>
</tr>
<tr>
<td>RCT</td>
<td>1 year</td>
<td>9.0 (95% CI 8.2 to 9.8)</td>
<td>9.9 (95% CI 8.9 to 10.9) (n = 36)</td>
<td>NS</td>
</tr>
</tbody>
</table>

continued
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,\textsuperscript{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\textsubscript{1c} at 12 months.

It should be noted that although the Campbell and colleagues study\textsuperscript{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.\textsuperscript{46–48}

In the studies demonstrating a statistically significant effect of education on HbA\textsubscript{1c}, the difference between the intervention and control groups was on or around 1\%, which may represent

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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Time-point</th>
<th>Mean (SD) (unless stated) HbA\textsubscript{1} or HbA\textsubscript{1c} (%)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Sarkadi and Rosenvist,</td>
<td>Baseline</td>
<td>~6.5 (n = 39)</td>
<td>~6.5 (n = 38)</td>
</tr>
<tr>
<td>2004\textsuperscript{60}</td>
<td>1 year</td>
<td>6.2 (95% CI 5.7 to 6.7) (n = 33)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>2 years</td>
<td>6.1 (95% CI 5.5 to 6.7) (n = 33)</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td></td>
<td>Baseline</td>
<td>8.2 (1.1) (n = 28)</td>
<td>8.8 (1.5) (n = 30)</td>
</tr>
<tr>
<td>RCT</td>
<td>18 months</td>
<td>7.8 (0.9) (n = 25)</td>
<td>8.2 (1.4) (n = 29)</td>
</tr>
<tr>
<td></td>
<td>Change</td>
<td>~0.4 (adjusted)</td>
<td>~0.6 (adjusted)</td>
</tr>
<tr>
<td>Goudswaard et al., 2004\textsuperscript{61}</td>
<td>Baseline</td>
<td>10.0 (2.7) (n = 25)</td>
<td>9.6 (2.6) (n = 26)</td>
</tr>
<tr>
<td>RCT</td>
<td>1 year</td>
<td>8.25 (n = 23)</td>
<td>9.6 (n = 26)</td>
</tr>
<tr>
<td></td>
<td>Change</td>
<td>~1.75 (estimated from graph)</td>
<td>0 (estimated from graph)</td>
</tr>
<tr>
<td>Raz et al., 1988\textsuperscript{62}</td>
<td>Baseline</td>
<td>7.1(1.6) (n = 65)</td>
<td>6.5 (1.6) (n = 62)</td>
</tr>
<tr>
<td>CCT</td>
<td>1 year</td>
<td>7.1 (1.6) (n = 50)</td>
<td>6.7 (1.5) (n = 49)</td>
</tr>
<tr>
<td>Domenech et al., 1995\textsuperscript{64}</td>
<td>Change from baseline</td>
<td>~0.2% (0.4) (n at baseline 53, n at end-point 40)</td>
<td>0.8% (0.4) (n at baseline 71, n at end-point 39)</td>
</tr>
</tbody>
</table>

NS, not statistically significant; SD, standard deviation; SEM, standard error of the mean.

\textsuperscript{a} Based on 95% confidence interval (CI) (p > 0.05 if CI for a difference includes zero).
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. The results are shown in **Table 7**.

The behavioural intervention in the Campbell and colleagues study 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, 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, 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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Time-point</th>
<th>Mean (SD) BP (mmHg) (unless stated)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[AIC data removed]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deakin et al., 2003&lt;sup&gt;46&lt;/sup&gt;, 2006&lt;sup&gt;48&lt;/sup&gt;</td>
<td>Systolic BP: Baseline</td>
<td>147.5 (19.8) (n = 157)</td>
<td>147.8 (23.7) (n = 157)</td>
</tr>
<tr>
<td>RCT</td>
<td>14 months</td>
<td>141.3 (16.8) (n = 150)</td>
<td>144.4 (23.5) (n = 141)</td>
</tr>
<tr>
<td></td>
<td>Systolic BP: Baseline</td>
<td>82.6 (11.0) (n = 157)</td>
<td>82.2 (12.2) (n = 157)</td>
</tr>
<tr>
<td></td>
<td>14 months</td>
<td>78.4 (9.6) (n = 150)</td>
<td>80.2 (10.9) (n = 141)</td>
</tr>
<tr>
<td>Campbell et al., 1996&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Systolic BP: Mean (SEM) change from baseline</td>
<td>Individual education</td>
<td>(n at baseline 57, n at end-point 16)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td>Group education (n at baseline 66, n at end-point 11)</td>
<td>–12.4 (6.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Behavioural education (n at baseline 56, n at end-point 37)</td>
<td>–16.9 (3.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diastolic BP: Mean (SEM) change from baseline</td>
<td>Individual education</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group education (n at baseline 66, n at end-point 11)</td>
<td>–5.0 (4.0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Behavioural education (n at baseline 56, n at end-point 37)</td>
<td>–7.9 (2.6)</td>
</tr>
<tr>
<td>Trento et al., 2001&lt;sup&gt;53&lt;/sup&gt;</td>
<td>No. hypertensive: Baseline</td>
<td>34 (n = 56)</td>
<td>25 (n = 56)</td>
</tr>
<tr>
<td>RCT</td>
<td>2 years</td>
<td>26 (n = 43)</td>
<td>22 (n = 47)</td>
</tr>
</tbody>
</table>

NS, not statistically significant.

<sup>a</sup>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)]

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study and design</th>
<th>Time-point</th>
<th>Mean (SD) (unless stated)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>BMI (kg/m$^2$) [AIC data removed]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deakin et al., 2003;47,48 200646</td>
<td>Baseline</td>
<td>14 months</td>
<td>30.8 (5.3) ($n = 157$)</td>
<td>30.6 (5.7) ($n = 157$)</td>
</tr>
<tr>
<td>RCT</td>
<td>Change</td>
<td>-0.2</td>
<td>31.0 (4.4) ($n = 141$)</td>
<td>0.4</td>
</tr>
<tr>
<td>Brown et al., 2002;49,50</td>
<td>Baseline</td>
<td>1 year</td>
<td>32.3 (5.97) ($n = 128$)</td>
<td>32.12 (6.35) ($n = 128$)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
<td>32.17 (6.45) ($n = 113$)</td>
<td>32.28 (6.52) ($n = 114$)</td>
</tr>
<tr>
<td>Campbell et al., 199651</td>
<td>Mean (SEM)</td>
<td>change from baseline</td>
<td>Individual education (baseline $n = 57$, end-point $n = 30$)</td>
<td>-2.0 (0.4)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
<td>(all pairwise contrasts)</td>
<td></td>
</tr>
<tr>
<td>Trento et al., 2001;53 2002;54 200455</td>
<td>Baseline</td>
<td>2 years</td>
<td>29.7 (4.5) ($n = 56$)</td>
<td>27.8 (4.1) ($n = 56$)</td>
</tr>
<tr>
<td>RCT</td>
<td>Change</td>
<td>-1.4</td>
<td>27.6 (4.2) ($n = 47$)</td>
<td>-0.1</td>
</tr>
<tr>
<td>Cooper et al., 2002;56 2003;57,58</td>
<td>Baseline</td>
<td>1 year</td>
<td>32.5 (6.7) ($n = 53$)</td>
<td>32.1 (6.1) ($n = 36$)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
<td>31.3 (5.7) ($n = 48$)</td>
<td>30.5 (3.9) ($n = 30$)</td>
</tr>
<tr>
<td>Weight (kg) [AIC data removed]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deakin et al., 2003;47,48 200646</td>
<td>Baseline</td>
<td>14 months</td>
<td>83.2 (14.5) ($n = 157$)</td>
<td>82.8 (17.6) ($n = 157$)</td>
</tr>
<tr>
<td>RCT</td>
<td>Change</td>
<td>-0.3</td>
<td>83.9 (18.8) ($n = 141$)</td>
<td>1.1</td>
</tr>
<tr>
<td>Trento et al., 2001;53 2002;54 200455</td>
<td>Baseline</td>
<td>2 years</td>
<td>77.4 (13.1) ($n = 56$)</td>
<td>78.2 (14.6) ($n = 56$)</td>
</tr>
<tr>
<td>RCT</td>
<td>Change</td>
<td>-3.50</td>
<td>76.0 (13.4) ($n = 43$)</td>
<td>-0.24</td>
</tr>
</tbody>
</table>

continued
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.\[^{46,47}\]

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.\[^{46,47}\]

**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 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 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)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study and design</th>
<th>Time-point</th>
<th>Mean (SD) (unless stated)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(mean (95% CI) change from baseline)</td>
<td>(mean (95% CI))</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(n = 40 at baseline, n = 36 at end-point)</td>
<td>(n = 47 at baseline, n = 39 at end-point)</td>
</tr>
<tr>
<td>Heller et al., 1988(^{59})</td>
<td>RCT</td>
<td>Baseline</td>
<td>75.4 (11.7) (n = 25)</td>
<td>73.4 (11.5) (n = 26)</td>
</tr>
<tr>
<td>Raz et al., 1988(^{62})</td>
<td>Baseline</td>
<td>76.5 (12.6) (n = 65)</td>
<td>73.8 (12.6) (n = 50)</td>
<td>75.1 (12.9) (n = 62)</td>
</tr>
<tr>
<td>Kronsbein et al., 1988(^{63})</td>
<td>Baseline</td>
<td>75.4 (11.7) (n = 25)</td>
<td>73.4 (11.5) (n = 26)</td>
<td>73 (n = 23)</td>
</tr>
<tr>
<td>Domenech et al., 1995(^{64})</td>
<td>Baseline</td>
<td>76.5 (12.6) (n = 65)</td>
<td>73.8 (12.6) (n = 50)</td>
<td>75.1 (12.9) (n = 62)</td>
</tr>
</tbody>
</table>

---

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.
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).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study and design</th>
<th>Time-point</th>
<th>Mean (SD) (unless stated)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l) [AIC data removed]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deakin et al., 200347,48 200649</td>
<td>Baseline</td>
<td>5.1 (1.1) (n = 157)</td>
<td>4.9 (1.0) (n = 157)</td>
<td>NS</td>
</tr>
<tr>
<td>14 months Change</td>
<td>4.8 (1.1) (n = 150)</td>
<td>4.7 (1.0) (n = 141)</td>
<td>NS</td>
<td>p = 0.01</td>
</tr>
<tr>
<td>Brown et al., 200249,50</td>
<td>Baseline</td>
<td>21.7 (2.5) (n = 128)</td>
<td>11.3 (2.7) (n = 128)</td>
<td>–</td>
</tr>
<tr>
<td>1 year</td>
<td>10.5 (2.0) (n = 112)</td>
<td>10.4 (2.4) (n = 113)</td>
<td>NS</td>
<td></td>
</tr>
</tbody>
</table>

RCT

Campbell et al., 199651 Mean (SEM) change from baseline

|         |                 | | Individual education | Group education | Behavioural education |
|---------|-----------------| | (baseline n = 57, end-point n = 23) | (baseline n = 66, end-point n = 19) | (baseline n = 56, end-point n = 34) |
|         |                 | | 0.12 (0.20) | 0.16 (0.16) | –0.33 (0.15) |

Trento et al., 200153, 200254 200455 | Baseline | 5.8 (1.1) (n = 56) | 5.5 (0.9) (n = 56) | – |
| 2 years | 5.7 (1.2) (n = 43) | 5.6 (1.2) (n = 47) | NS |
| 5 years Change | 5.50 (1.06) (n = 42) | 5.27 (1.13) (n = 42) | – |
| 0–5 years | –0.32 | –0.43 | NS |

Raz et al., 198862 | Baseline | 12.5 (2.4) (n = 25) | 12.2 (3.1) (n = 26) | – |
| 1 year | 11.8 (2.1) (n = 23) | 12.5 (3.4) (n = 26) | NS |

HDL cholesterol (mmol/l) [AIC data removed]

|         |                 | | Individual education | Group education | Behavioural education |
|---------|-----------------| | (baseline n = 57, end-point n = 21) | (baseline n = 66, end-point n = 16) | (baseline n = 56, end-point n = 27) |
|         |                 | | 0.02 (0.04) | 0.18 (0.10) | 0.06 (0.08) |

RCT

continued
for the control group. Analysis of the 5-year data in a secondary publication\textsuperscript{55} showed no statistically significant differences between groups on either HDL cholesterol or triglycerides. In the trial by Deakin and colleagues,\textsuperscript{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].

### TABLE 9 Lipid characteristics (cholesterol and triglycerides) 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)

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

NS, not statistically significant.
\textsuperscript{a} Based on 95% CI ($p > 0.05$ if CI for a difference includes zero, or if CI for a ratio includes 1).
\textsuperscript{b} Based on baseline values for those participants followed up to end-point.
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 trials46,47,53 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.

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,64 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,65 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].

Assessment of clinical effectiveness
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.

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 \(\{\text{baseline } 72.8 \text{ (SD } 13.2\}, 12 \text{ months } 75.1 \text{ (SD } 11.0)\}, p < 0.01\].

The test measured the integration of diabetes and

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study and design</th>
<th>Time-point</th>
<th>Intervention</th>
<th>Control</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic retinopathy</td>
<td>Trento et al., 2001;(^53) 2002;(^54) 2004;(^55) RCT</td>
<td>Baseline 2 years</td>
<td>42/8/6 ((n = 56))</td>
<td>38/13/5 ((n = 56))</td>
<td>–</td>
</tr>
<tr>
<td>Foot ulcers</td>
<td>Trento et al., 2001;(^53) 2002;(^54) 2004;(^55) RCT</td>
<td>Baseline 2 years</td>
<td>54/0/2 ((n = 56))</td>
<td>53/2/1 ((n = 56))</td>
<td>–</td>
</tr>
<tr>
<td>Mean (SD) creatinine ((\mu\text{mol/l}))</td>
<td>Trento et al., 2001;(^53) 2002;(^54) 2004;(^55) RCT</td>
<td>Baseline 2 years</td>
<td>91.94 (14.14) ((n = 56))</td>
<td>91.05 (14.14) ((n = 56))</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 years</td>
<td>88.8 (16.5) ((n = 43))</td>
<td>87.5 (17.2) ((n = 47))</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Change 0–5 years</td>
<td>–16.79 (95% CI –26.52 to 2.65)</td>
<td>–12.37 (95% CI –25.63 to –10.60)</td>
</tr>
<tr>
<td>Proportion consulting ophthalmology (%)</td>
<td>Campbell et al., 1996;(^61) RCT</td>
<td>(No baseline data) 1 year</td>
<td>Individual education ({\text{baseline } n = 57, \text{end-point } n = 38})</td>
<td>–</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Group education ({\text{baseline } n = 66, \text{end-point } n = 37})</td>
<td>–</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Behavioural education ({\text{baseline } n = 56, \text{end-point } n = 47})</td>
<td>–</td>
<td>89</td>
</tr>
<tr>
<td>Proportion consulting podiatry (%)</td>
<td>Campbell et al., 1996;(^61) RCT</td>
<td>(No baseline data) 1 year</td>
<td>Individual education ({\text{baseline } n = 57, \text{end-point } n = 31})</td>
<td>–</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Group education ({\text{baseline } n = 66, \text{end-point } n = 30})</td>
<td>–</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Behavioural education ({\text{baseline } n = 56, \text{end-point } n = 42})</td>
<td>–</td>
<td>74</td>
</tr>
</tbody>
</table>

NS, not statistically significant.

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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 HbA1c, 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

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

<table>
<thead>
<tr>
<th>Outcome (scale)</th>
<th>Study and design</th>
<th>Time-point</th>
<th>Mean (SD) (unless stated) of outcome</th>
<th>Differences between groups</th>
</tr>
</thead>
</table>
| QoL (ADDQoL: –9 to +9) | Deakin et al., 2003,47,48, 200646 | Baseline 14 months | Intervention: –2.2 (2.2) (n = 157) | Control: –1.9 (2.2) (n = 157) | NS
| QoL (Modified DQOL: 39 questions: each 1 to 5) | Trento et al., 2001,53, 2002,54 | Baseline 2 years | Intervention: 67.6 (19) (n = 56) | Control: 66.7 (25) (n = 56) | NS
|                 |                   | Baseline 5 years | Intervention: 43.7 (7.2) (n = 42) | Control: 89.2 (30.1) (n = 42) | NS
| Knowledge (0–14) | Deakin et al., 2003,47,48, 200646 | Baseline 14 months | Intervention: 7.5 (3.5) (n = 157) | Control: 7.0 (3.1) (n = 157) | NS
| Knowledge (DKNA) | Campbell et al., 199651 | Mean (SEM) change from baseline | Individual education (baseline n = 57, end-point n = 29) | 4.4 (0.6) | NS (all pairwise contrasts)
| Knowledge (GISED: 0 to 38) | Trento et al., 2001,53, 2002,54 | Baseline 2 years | Intervention: 14.9 (7.9) (n = 56) | Control: 20.2 (7.4) (n = 56) | NS
|                 |                   | Baseline 5 years | Intervention: 27.9 (5.7) (n = 42) | Control: 18.0 (8.5) (n = 42) | NS
| Knowledge (based on NIDDM questionnaire) | Kronsbein et al., 198863 | Baseline 1 year | Intervention: 9 (3) (n = 65) | Control: 9 (3) (n = 62) | NS

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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.

* Based on 95% CI (p > 0.05 if CI for a difference includes zero).
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 studies67–69,74), diet,70 exercise,72 weight versus self-regulation73 or weight versus self-monitoring of blood glucose (SMBG).71 Study sample sizes were generally small, varying from 2073 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.67,75 Duration of diabetes was not widely reported. In the four trials that reported duration it ranged from newly diagnosed68 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 colleagues67 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 four68,69 used individualised dietary programmes. Another67 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 studies67,69 and in one other study68 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 study67 required a monetary deposit that was returned with the meeting of goals and meeting attendance. One used contracts69 and the other68 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)]

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>No. of participants</th>
<th>Duration of intervention</th>
<th>Timing of evaluation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaplan et al., 198767</td>
<td>Four groups</td>
<td>87</td>
<td>10 weeks</td>
<td>18 months</td>
</tr>
<tr>
<td>RCT</td>
<td>1. Group diet education. Dietician delivered. 20 contact hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Group exercise education. Contact hours not given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Group diet and exercise education over 5 weeks, no details contact time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Control education in group with team – each gave a lecture. ~14 contact hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uusitupa et al., 1992–6</td>
<td>Two groups</td>
<td>86</td>
<td>12 months</td>
<td>24 months</td>
</tr>
<tr>
<td>RCT</td>
<td>1. Diet and exercise education. Provided by a team. Contact = 6 clinic visits (duration not given)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Usual care control. Local health centre visits every 2–3 months + outpatient clinics Both groups given basic diabetes education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ridgeway et al., 19996</td>
<td>Two groups:</td>
<td>56</td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>RCT</td>
<td>1. Group diet and exercise education. Nurse and dietician delivered. 9 contact hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Usual care control. No details</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wing et al., 198570</td>
<td>Three groups:</td>
<td>53</td>
<td>16 weeks</td>
<td>16 months</td>
</tr>
<tr>
<td>RCT</td>
<td>1. Diet – behaviour modification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Nutrition education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Usual care (with nutrition education) Group 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</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wing et al., 198671</td>
<td>Two groups:</td>
<td>50</td>
<td>12 months</td>
<td>62 weeks</td>
</tr>
<tr>
<td>RCT</td>
<td>1. Diet – weight control. Contact time not given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Diet – SMBG. Contact time ~ 20 meetings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Samaras et al., 199772</td>
<td>Two groups:</td>
<td>26</td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>RCT</td>
<td>1. Exercise education. Group sessions provided by a team. Contact time ~6 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Usual care. routine clinic visits + 3 assessment visits (no details of duration)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wing et al., 198873</td>
<td>Two groups:</td>
<td>20</td>
<td>10 months</td>
<td>68 weeks</td>
</tr>
<tr>
<td>RCT</td>
<td>1. SMBG with education on meaning of SMBG (‘self-regulation’), 13 sessions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. SMBG (‘self-monitoring’). Contact time not given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gilliland et al., 200274</td>
<td>Three groups:</td>
<td>104</td>
<td>10 months</td>
<td>12 months</td>
</tr>
<tr>
<td>CCT</td>
<td>1. Friends and family. Group culturally appropriate diet and exercise education with support. 5 sessions, one every 6 weeks, for ~2 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. One-on-one. Individual culturally appropriate diet and exercise education. 5 sessions, once every 6 weeks for ~45 minutes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Usual care control (some education but not culturally appropriate and no details given)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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)]

<table>
<thead>
<tr>
<th>Study</th>
<th>Randomisation</th>
<th>Concealment of allocation</th>
<th>Baseline characteristics</th>
<th>Eligibility criteria</th>
<th>Blinding of assessors</th>
<th>Primary outcome results</th>
<th>ITT analysis</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaplan et al., 1987&lt;sup&gt;67&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Inadequate</td>
<td>Unknown</td>
<td>Reported</td>
</tr>
<tr>
<td>Uusitupa et al., 1992–6&lt;sup&gt;68&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Unknown</td>
</tr>
<tr>
<td>Ridgeway et al., 1999&lt;sup&gt;69&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Inadequate</td>
<td>Inadequate</td>
<td>Adequate</td>
</tr>
<tr>
<td>Wing et al., 1985&lt;sup&gt;70&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Partial</td>
<td>Unknown</td>
<td>Partial</td>
</tr>
<tr>
<td>Wing et al., 1986&lt;sup&gt;71&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Adequate</td>
<td>Partial</td>
<td>Unknown</td>
<td>Reported</td>
</tr>
<tr>
<td>Samaras et al., 1997&lt;sup&gt;72&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Partial</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Wing et al., 1988&lt;sup&gt;73&lt;/sup&gt;</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Reported</td>
<td>Yes</td>
<td>Not applicable</td>
<td>Partial</td>
<td>Inadequate</td>
<td>Partial</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Baseline characteristics</th>
<th>Eligibility criteria</th>
<th>Blinding of assessors</th>
<th>Primary outcome results</th>
<th>ITT analysis</th>
<th>Missing values</th>
<th>Representativeness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilliland et al., 2002&lt;sup&gt;74&lt;/sup&gt;</td>
<td>Reported</td>
<td>Yes</td>
<td>Unknown</td>
<td>Adequate</td>
<td>Inadequate</td>
<td>Partial</td>
<td>No</td>
</tr>
</tbody>
</table>
bimonthly. Another67 involved 20 hours of contact in 10 2-hour meetings over 10 weeks. The group intervention in the Gilliland and colleagues study74 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 study72 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 study70 compared a diet intervention with a weight loss-focused intervention. This study only reported within-group differences and is not discussed further.

One study71 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 study73 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 exercise67 produced significantly lower HbA1c than in a control group who received only didactic education. The diet plus exercise intervention produced a sizeable reduction in HbA1c (−1.48%), whereas the drop was small in the diet group (−0.46%) and HbA1c 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 HbA1c did not differ between the intervention and control groups (although there was a marginal difference at 12 months), but the proportion of patients with HbA1c ≤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 HbA1c but the two intervention groups combined showed a significantly smaller rise than the control group.

The Samaras and colleagues exercise study72 reported no overall significant differences in HbA1c between intervention and control patients. However, HbA1c 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’ study69) or between different interventions (Wing and colleagues’ studies70,71,73).

#### Blood pressure

Only two studies68,74 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))

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Outcome</th>
<th>Time-point</th>
<th>(Mean ± SD) (unless stated)</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Diet and exercise interventions</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Kaplan et al., 1987&lt;sup&gt;23&lt;/sup&gt;</td>
<td>HbA₁ (%)</td>
<td>Baseline 18 months</td>
<td>8.97 (2.82) (group n values not reported)</td>
<td>8.51 (group n values not reported)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Baseline 18 months</td>
<td>8.16 (3.44) (group n values not reported)</td>
<td>9.46 (group n values not reported)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diet + exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baseline 18 months</td>
<td>9.18 (2.46) (group n values not reported)</td>
<td>7.70 (group n values not reported)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uusitupa et al., 1992–668</td>
<td>HbA₁c (%)</td>
<td>Baseline 12 months</td>
<td>7.1 (1.8) (n = 40)</td>
<td>7.8 (2.0) (n = 46)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td>24 months</td>
<td>6.6 (1.6) (n not reported)</td>
<td>7.5 (1.7) (n not reported)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baseline 24 months</td>
<td>7.2 (1.9) (n = 38)</td>
<td>8.0 (1.6) (n = 44)</td>
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<tr>
<td></td>
<td></td>
<td>Diet</td>
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<tr>
<td></td>
<td></td>
<td>Baseline 24 months</td>
<td>7.4 (n = 40)</td>
<td>7.8 (n = 46)</td>
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<td></td>
<td></td>
<td>Exercise</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Baseline 24 months</td>
<td>6.7 (n not reported)</td>
<td>7.3 (n not reported)</td>
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<tr>
<td></td>
<td></td>
<td>Diet + exercise</td>
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<tr>
<td></td>
<td></td>
<td>Baseline 24 months</td>
<td>7.4 (n = 38)</td>
<td>7.9 (n = 44)</td>
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<tr>
<td></td>
<td></td>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uusitupa et al., 1992–668</td>
<td>HbA₁c (%)</td>
<td>Baseline 12 months</td>
<td>74.4% (n not reported)</td>
<td>47.8% (n not reported)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td>24 months</td>
<td>55.3% (n = 38)</td>
<td>31.8% (n = 44)</td>
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<tr>
<td></td>
<td></td>
<td>Diet</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Baseline 24 months</td>
<td>Not reported (NR) (n = 40)</td>
<td>NR (n = 46)</td>
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<tr>
<td></td>
<td></td>
<td>Exercise</td>
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<tr>
<td></td>
<td></td>
<td>Baseline 24 months</td>
<td>Not reported (NR) (n = 38)</td>
<td>Not reported (NR) (n = 44)</td>
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<tr>
<td></td>
<td></td>
<td>Diet + exercise</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Baseline 24 months</td>
<td>Not reported (NR) (n = 39)</td>
<td>Not reported (NR) (n = 39)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ridgeway et al., 1999&lt;sup&gt;69&lt;/sup&gt;</td>
<td>GHb</td>
<td>Baseline 12 months</td>
<td>12.3 (2.2) (n = 28)</td>
<td>12.3 (SD 3.0) (n = 28)</td>
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<tr>
<td>RCT</td>
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</tr>
<tr>
<td>Gilliland et al., 2002&lt;sup&gt;74&lt;/sup&gt;</td>
<td>HbA₁c (%)</td>
<td>Reported values are changes from baseline</td>
<td>Friends and family</td>
<td>One-to-one</td>
</tr>
<tr>
<td>CCT</td>
<td></td>
<td></td>
<td>+0.5 (0.3) (baseline n = 32)</td>
<td>+0.2 (0.3) (baseline n = 39)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>+1.2 (0.4) (end-point n = 32)</td>
<td>+1.2 (0.4) (end-point n = 39)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Between 3 groups, p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Between Friends family and One-to-one combined and control, p &lt; 0.05</td>
</tr>
<tr>
<td>Other focused interventions</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Wing et al., 1986&lt;sup&gt;71&lt;/sup&gt;</td>
<td>HbA₁</td>
<td>Baseline 12 months</td>
<td>10.86 (2.0) (n = 25)</td>
<td>10.44 (2.16) (n = 22)</td>
</tr>
<tr>
<td>RCT</td>
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continued
control group [-0.3 (±2.1)] in the Gilliland and colleagues CCT\(^7\).

**BMI or weight**

Five studies reported either BMI or weight\(^6\)\(^8\)\(^9\)\(^7\)\(^2\)-\(^7\)\(^4\) In none of these studies was there a significant difference between the intervention and control groups. In one study\(^7\)\(^4\) 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\(^6\)\(^8\)\(^9\)\(^7\)\(^2\)-\(^7\)\(^4\) 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\(^6\) 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\(^7\)\(^1\) 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\(^6\)\(^7\) 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, as did one focused intervention. 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. 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.

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.
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\cite{76-80} and brief summaries are provided below.

In a review by Norris and colleagues\cite{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\cite{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\cite{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.\cite{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\cite{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 HbA1c (%) (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 HbA1c 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\textsuperscript{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\textsuperscript{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\textsubscript{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\textsuperscript{83} aim to evaluate interventions for individual patient education, whereas Armour and colleagues\textsuperscript{84} intend to evaluate interventions for maintaining physical activity in diabetic patients, which could include educational strategies.
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 HbA1c, BMI or cholesterol, were variable. Whereas some studies showed a statistically significant effect of education on HbA1c, others did not. In the case of reduction in HbA1c, 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 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 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. 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 HbA1c at earlier analyses (<12 months) than the end-point analysis. Only three of these also demonstrated significant effects of the intervention on HbA1c at end-point analysis (≥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.
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 (HbA1c, weight, BMI, cholesterol and lipids, complications, QoL and diabetes knowledge) the proportion of studies that demonstrated significant effects of education was similar.
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.
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.
References


References


44. [AIC data removed]


85. Medical Research Council. A framework for development and evaluation of RCTs for complex...
References


Appendix I

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).

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.

Report methods

- The review will be undertaken as systematically as time allows following the general principles outlined in NHS CRD Report 4.
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 (HbA1c), 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 through 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$)).ti,ab. (4092)
10 5 or 6 or 7 or 8 or 9 (6577)
11 10 and 4 (108)
12 limit 29 to English language (83)
13 randomized controlled trial.pt. (286)
14 controlled clinical trial.pt. (20)
15 clinical trial.pt. (312)
16 (clini$ 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 double$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw. (1665)
19 placebo$tw. (2287)
20 random$tw. (16773)
21 or/13-20 (20459)
22 21 and 12 (26)
23 (review or review-tutorial or review-academic).pt. (499)
24 meta-analysis.pt. (2)
25 (meta-analy$ or meta analy$ 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)
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)

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

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

Included studies from the 2002 diabetes education review which were of type 2 diabetes: 16

* AIC data obtained from contacting experts
## Appendix 3

### Inclusion criteria worksheet

<table>
<thead>
<tr>
<th>Trial name or number:</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients with Type 2 diabetes?</strong>&lt;br&gt;NB exclude gestational diabetes</td>
<td>Yes</td>
</tr>
<tr>
<td>Patients described as ‘adults’ or &lt;20% under 18 years old?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>RCT or CCT or Sys review/MA</strong>&lt;br&gt;NB CCT must have concurrent control</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Education programme?</strong>&lt;br&gt;NB exclude purely psychological/counselling interventions</td>
<td>Yes</td>
</tr>
<tr>
<td>Education for self-management of diabetes?&lt;br&gt;NB exclude education for prevention/treatment of specific complications (e.g. foot ulcer)</td>
<td>Yes</td>
</tr>
<tr>
<td>Comparators: Educational programme vs usual care OR another ed. programme? OR Group programme vs individual programme?&lt;br&gt;Is description of intervention sufficient to reproduce?&lt;br&gt;NB must include topics (or content obtainable). Other characteristics: provider, length &amp; no. of sessions, target audience, mode of delivery (in person or distance), group or individual, didactic/interactive, changes in treatment</td>
<td>Yes</td>
</tr>
<tr>
<td>Follow-up from inception ≥1 year?</td>
<td>Yes</td>
</tr>
<tr>
<td>Report one or more of primary outcomes: HbA1c OR severe hypos OR diabetic complications OR QoL?&lt;br&gt;NB other outcomes will also be included if primary outcomes reported.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Final Decision</strong></td>
<td>INCLUDE</td>
</tr>
</tbody>
</table>

---

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?
7. Was the patient blinded?
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?

Quality criteria for assessment of experimental studies

<table>
<thead>
<tr>
<th>Quality item</th>
<th>Coding</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the assignment to the treatment groups really random?</td>
<td>Adequate</td>
<td>Adequate: random numbers table or computer and central office or coded packages</td>
</tr>
<tr>
<td>Random sequence generation</td>
<td>Partial</td>
<td>Partial: (sealed) envelopes without further description or serially numbered opaque, sealed envelopes</td>
</tr>
<tr>
<td></td>
<td>Inadequate</td>
<td>Inadequate: alternation, case record number, birth date or similar procedures</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>Unknown: just the term ‘randomised’ or ‘randomly allocated’, etc.</td>
</tr>
<tr>
<td>2. Was the treatment allocation concealed?</td>
<td>Adequate</td>
<td>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</td>
</tr>
<tr>
<td>Concealment of randomisation</td>
<td>Inadequate</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>Unknown: no details in text. Disagreements or lack of clarity should be discussed in the review team</td>
</tr>
</tbody>
</table>

Some instructions for using a checklist for RCTs

continued
### Quality item

<table>
<thead>
<tr>
<th>3. Were the groups similar at baseline regarding the prognostic factors?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline characteristics</strong></td>
</tr>
<tr>
<td>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)</td>
</tr>
<tr>
<td><strong>Coding</strong></td>
</tr>
<tr>
<td>Reported: Consult the list of prognostic factors or baseline characteristics (not included in this appendix)</td>
</tr>
<tr>
<td>Unknown: Reviewer decides</td>
</tr>
</tbody>
</table>

### 4. Were the eligibility criteria specified?

<table>
<thead>
<tr>
<th>Prestratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult the list of prognostic factors or baseline characteristics (not included in this Appendix)</td>
</tr>
</tbody>
</table>

**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

**Coding**
- 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

**Coding**
- 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 co-interventions (not included in this Appendix)

**Coding**
- 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*
<table>
<thead>
<tr>
<th>Quality item</th>
<th>Coding</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7. Was the patient blinded?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of patients</td>
<td>Adequate</td>
<td>Adequate: placebo described as ‘indistinguishable’ and procedures watertight</td>
</tr>
<tr>
<td>This item is hard to define. Just the statement ‘double blind’ in the paper</td>
<td>Partial</td>
<td>Partial: just ‘double blind’ in text and no further description of procedures or nature of the placebo</td>
</tr>
<tr>
<td>is really insufficient if the procedure to accomplish this is not described</td>
<td>Inadequate</td>
<td>Inadequate: wrong placebo</td>
</tr>
<tr>
<td>or reasonably deducible by the reviewer. Good placebos (see, hear, taste,</td>
<td>Unknown</td>
<td>Unknown: no details in text</td>
</tr>
<tr>
<td>feel, smell), tricky unmasking side-effects accounting for the subjectivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of the outcome measurements and the accessibility of co-interventions by</td>
<td></td>
<td></td>
</tr>
<tr>
<td>the patient are required.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dosing errors and timing errors</td>
<td>Adequate</td>
<td>Adequate: Medication Event Monitoring System (MEMS or eDEM)</td>
</tr>
<tr>
<td></td>
<td>Partial</td>
<td>Partial: blood samples, urine samples (use of indicator substances)</td>
</tr>
<tr>
<td></td>
<td>Inadequate</td>
<td>Inadequate: pill count or self-report</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>Unknown: not mentioned</td>
</tr>
<tr>
<td>Check on blinding</td>
<td>Reported</td>
<td>Reviewer decides</td>
</tr>
<tr>
<td>Questionnaire for patients, care givers, assessors and analysis of the</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>results; the (early) timing is critical because the treatment effect may</td>
<td></td>
<td></td>
</tr>
<tr>
<td>be the cause of unblinding, in which case it may be used as an outcome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>measure.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>**8. Were the point estimates and measure of variability presented for the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>primary outcome measure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results for the primary outcome measure</td>
<td>Adequate</td>
<td>Adequate: mean outcome in each group together with mean difference and its</td>
</tr>
<tr>
<td></td>
<td>Partial</td>
<td>standard error (SE) or standard deviation (SD) or any CI around it or the</td>
</tr>
<tr>
<td></td>
<td>Inadequate</td>
<td>possibility to calculate those from the paper. Survival curve with log-rank</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>test and patient numbers at later time-points</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Partial: partially reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inadequate: no SE or SD or SD without N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(SE = SD/N)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unknown: very unlikely</td>
</tr>
<tr>
<td><strong>9. Did the analysis include an ITT analysis?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ITT analysis</td>
<td>Adequate</td>
<td>Reviewers should not just look for the term ITT but assure themselves that</td>
</tr>
<tr>
<td>Early drop-out can make this very difficult. Strictest requirement is</td>
<td>Inadequate</td>
<td>the calculations were according to the ITT principle</td>
</tr>
<tr>
<td>sensitivity analysis including early drop-outs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dealing with missing values</td>
<td>Adequate</td>
<td>Adequate: percentage of missing values and distribution over the groups and</td>
</tr>
<tr>
<td>The percentage missing values on potential confounders and outcome</td>
<td>Partial</td>
<td>procedure of handling this stated</td>
</tr>
<tr>
<td>measurements (seldom given) is a rough estimate of a trial’s quality. One</td>
<td>Inadequate</td>
<td>Partial: some statement on numbers or percentages</td>
</tr>
<tr>
<td>can carry them forward, perform sensitivity analysis assuming the worst and</td>
<td>Unknown</td>
<td>Inadequate: wrong procedure (a matter of great debate)</td>
</tr>
<tr>
<td>best case scenarios, use statistical imputation techniques, etc. Note that</td>
<td></td>
<td>Unknown: no mention at all of missing and not deducible from tables</td>
</tr>
<tr>
<td>the default option (deletion) assumes that the value is randomly missing,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>which seems seldom justified</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Quality criteria for assessment of CCTs – CRD Report 4

<table>
<thead>
<tr>
<th>Quality item</th>
<th>Coding</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss to follow-up</td>
<td>Adequate</td>
<td>Adequate: number randomised must be stated.</td>
</tr>
<tr>
<td>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.</td>
<td>Partial</td>
<td>Number(s) lost to follow-up (dropped out) stated or deducible (from tables) for each group and reasons summarised for each group</td>
</tr>
<tr>
<td></td>
<td>Inadequate</td>
<td>Partial: numbers, but not the reasons (or vice versa)</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>Inadequate: numbers randomised not stated or not specified for each group</td>
</tr>
<tr>
<td></td>
<td>Adequate</td>
<td>Unknown: no details in text</td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Brown et al., 2002&lt;sup&gt;49,50&lt;/sup&gt;</td>
<td>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</td>
<td>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): HbA1c: 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.</td>
<td>Primary outcomes used: HbA1c. 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.</td>
</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Country:</strong> USA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Setting:</strong> Community</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Continued...*
<table>
<thead>
<tr>
<th>Outcome (mean ± SD)</th>
<th>Intervention</th>
<th>Control</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (n = 112)</td>
<td>10.89% (2.56), adjusted 10.87%*</td>
<td>11.64% (2.85), adjusted 11.66%</td>
<td>*p &lt; 0.05</td>
</tr>
<tr>
<td>FBG (n = int. 114; con. 113)</td>
<td>194.95 (63.27)*</td>
<td>210.51 (66.55)</td>
<td>*p &lt; 0.05</td>
</tr>
<tr>
<td>Cholesterol (n = int. 112; con. 113)</td>
<td>189.88 (36.35)</td>
<td>187.64 (42.66)</td>
<td></td>
</tr>
<tr>
<td>Triglycerides (n = 113)</td>
<td>214.43 (194.93)</td>
<td>198.65 (148.38)</td>
<td></td>
</tr>
<tr>
<td>BMI (n = int. 113; con. 114)</td>
<td>32.17 (6.45)</td>
<td>32.28 (6.52)</td>
<td></td>
</tr>
</tbody>
</table>

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 HbA1c 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
<table>
<thead>
<tr>
<th><strong>Reference and design</strong></th>
<th><strong>Intervention</strong></th>
<th><strong>Participants</strong></th>
<th><strong>Outcome measures</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Brown et al., 2005</td>
<td><strong>Treatment intervention:</strong> Some data <em>(italics)</em> here taken from previous publication. Topics: nutrition, home glucose monitoring, physical activity, other self-management topics <em>(Hygiene, illness days, foot care, complications (short and long term)). Promotion of behaviour changes through problem solving and goal setting.</em></td>
<td><strong>Eligibility/exclusion criteria:</strong> Inclusion: age 35–70 years, diagnosed with Type 2 diabetes (two verifiable FBG results &gt; 140 mg/dl or taking or having taken insulin or hypoglycaemic agents for ≥ 1 year). Exclusion: pregnant or had medical conditions for which changes in diet and walking were contraindicated <em>(e.g. renal failure or previous amputation)</em></td>
<td><strong>Primary outcomes used:</strong> HbA1c; FBG</td>
</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td><strong>Control intervention:</strong></td>
<td><strong>Secondary outcomes used:</strong> diabetes knowledge *(data not extracted as the outcome was not validated). Also BP, BMI, cholesterol, triglycerides <em>(data not presented in publication).</em></td>
<td></td>
</tr>
<tr>
<td><strong>Country:</strong> USA</td>
<td><em>Culturally referenced compressed (shorter) educational intervention which was informed by focus groups from a previous publication. NB: some data <em>(italics)</em> here taken from previous publication</em></td>
<td><strong>How selected:</strong> 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 <em>(and support people)</em> constituted each cohort, two groups were randomly assigned to each intervention. The same process occurred every 3 months until 23 groups were enrolled</td>
<td><strong>Individual preferred learning style addressed?</strong>: no</td>
</tr>
<tr>
<td><strong>Setting:</strong> Community <em>(schools, churches, day care centres, health clinics)</em></td>
<td><strong>Sessions:</strong> 52 contact hours over 12 months: 12 weekly 2-h sessions, followed by 14 2-h support group sessions</td>
<td><strong>Numbers involved:</strong> 216 participants selected. 114 to ‘compressed’ groups and 102 to ‘extended’ groups</td>
<td><strong>Subgroups:</strong> high and low attendance, gender <em>(not data extracted)</em></td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td><strong>Audience:</strong> group based with family member support</td>
<td><strong>Losses to follow-up:</strong> 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</td>
<td><strong>Normal range(s) for outcomes:</strong> not reported</td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td><strong>Delivery:</strong> didactic and interactive approach</td>
<td><strong>Numbers on insulin:</strong> 6.3% extended, 5.3% compressed Tablets: 81.1% extended, 78.0% compressed No medication <em>(diet alone)</em>: 10.5% extended, 10.6% compressed</td>
<td><strong>How outcomes were assessed:</strong> HbA1c by Glyc-Affin GHb</td>
</tr>
<tr>
<td></td>
<td><strong>T</strong>reatment changes: Not reported</td>
<td><strong>Duration of diabetes:</strong> not reported</td>
<td><strong>Validation of outcomes:</strong> not reported; knowledge instrument was from an unpublished thesis – not validated</td>
</tr>
</tbody>
</table>
| | **Training trainers:** 4 nurses and 4 dietitians 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 | **Gender *(F/M)*:** extended 61/41, compressed 69/45 | **Timing of outcomes the same for both groups?**: intervention groups began immediately after baseline data collection and data were collected as

**continued**
## Results

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Extended group, ( n = 114 )</th>
<th>Compressed group, ( n = 102 )</th>
<th>Comparisons between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean HbA1c change from baseline at 12 months</td>
<td>( n = 89 ), -1.0%</td>
<td>( n = 96 ), -0.7%</td>
<td>Not significant (p-values of differences between groups not given).</td>
</tr>
<tr>
<td>HbA1c end-point value (12 months), mean ± SD</td>
<td>( n = 89 ), 10.5 ± 3.0</td>
<td>( n = 96 ), 11.1 ± 3.2</td>
<td>Not reported</td>
</tr>
<tr>
<td>FBG change from baseline at 12 months</td>
<td>( n = 89 ), -16.7</td>
<td>( n = 97 ), -12.4</td>
<td>Not reported</td>
</tr>
<tr>
<td>FBG end-point value (12 months), mean ± SD</td>
<td>( n = 89 ), 173.8 ± 63.6</td>
<td>( n = 97 ), 179.7 ± 61.6</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

## 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 HbA1c (reference given). They oversampled by 30% to help account for attrition.

**Attrition/drop-out:** numbers reported but no reasons given.

**General comments**

**Generalisability:** high HbA1c 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

### Study: Campbell et al., 1996

**Source:** Journal article

**Country:** Australia

**Setting:** Unclear

**Language:** English

**Trial design:** RCT

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Campbell et al., 1996</td>
<td><strong>Treatment intervention:</strong> 4 programmes: minimal instruction (1), individual education (2), group education (3), behavioural programme (4). All encouraged to bring a support person.</td>
<td><strong>Eligibility/exclusion criteria:</strong> Inclusion: &lt;80 years, Type 2 for &lt;5 years, speak and write English, had received no previous formal instruction, not taking &gt;75% of the maximum dose OHAs, had no terminal illness.</td>
<td><strong>Primary outcomes used:</strong> HbA1c</td>
</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td></td>
<td><strong>How selected:</strong> patients referred by GP</td>
<td><strong>Secondary outcomes used:</strong> BP, knowledge, satisfaction, uptake podiatry, ophthalmology, hospitalisations, BMI</td>
</tr>
<tr>
<td><strong>Country:</strong> Australia</td>
<td><strong>Numbers involved:</strong> total N = 238; group (1) 59, (2) 57, (3) 66, (4) 56</td>
<td></td>
<td><strong>Individual preferred learning style addressed?:</strong> no</td>
</tr>
<tr>
<td><strong>Setting:</strong> Unclear</td>
<td><strong>Numbers on insulin:</strong> none</td>
<td></td>
<td><strong>Any subgroups:</strong> no</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td><strong>Diet alone:</strong> group (1) 40, (2) 35, (3) 42, (4) 33</td>
<td></td>
<td><strong>Normal range(s) for outcomes:</strong> HbA1c &lt;8.5%, knowledge</td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td><strong>Type of diabetes:</strong> Type 2</td>
<td><strong>How outcomes assessed?:</strong> HbA1c, laboratory, knowledge, satisfaction, hospitalisations self-report, BP unclear</td>
<td><strong>Validated?:</strong> HbA1c, knowledge (DKNA) yes, satisfaction reported to have shown good internal consistency and reliability</td>
</tr>
<tr>
<td></td>
<td><strong>Duration of diabetes (mean years + SE):</strong> group (1) 0.5 (0.1), (2) 0.5 (0.2), (3) 0.4 (0.1), (4) 0.36 (0.1)</td>
<td><strong>Timing of outcomes:</strong> same for both groups</td>
<td><strong>Timing of outcomes:</strong> same for both groups</td>
</tr>
<tr>
<td></td>
<td><strong>Baseline measurements of outcome parameter:</strong> HbA1c; group (1) 11.9% (SE 0.6), (2) 12.2% (0.5), (3) 12.1% (0.6), (4) 13.3% (0.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference and design</td>
<td>Intervention</td>
<td>Participants</td>
<td>Outcome measures</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------</td>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>Topics</strong>: same topics as the other programme. 2-h follow-ups were scheduled at 3 and 9 months</td>
<td><strong>Treatment intervention 4 = behavioural</strong>: 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</td>
<td><strong>Knowledge</strong>: No follow-up</td>
<td>Length of follow-up: 12 months (minimal instruction only 6 months) from inception</td>
</tr>
<tr>
<td><strong>All groups</strong>:</td>
<td><strong>Treatment changes: no details</strong></td>
<td><strong>Systolic BP (mgHg)</strong>: No follow-up</td>
<td></td>
</tr>
<tr>
<td><strong>Training trainers: no details</strong></td>
<td><strong>Theory: no details except for group 4: based on cognitive–behavioural strategies</strong></td>
<td><strong>Diastolic BP (mgHg)</strong>: No follow-up</td>
<td></td>
</tr>
<tr>
<td><strong>Participants in groups 2 and 3 also had opportunity to attend a 2-h lecture on diet (group)</strong></td>
<td><strong>BMI</strong>: No follow-up</td>
<td><strong>Cholesterol (mmol/l)</strong>: No follow-up</td>
<td></td>
</tr>
<tr>
<td><strong>Duration of intervention</strong>: Up to 12 months</td>
<td><strong>HDL cholesterol (mmol/l)</strong>: No follow-up</td>
<td><strong>Cholesterol risk ratio</strong>: No follow-up</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes (mean change ± SE unless otherwise noted)</th>
<th>Group 1 (minimal education)</th>
<th>Group 2 (individual education)</th>
<th>Group 3 (group education)</th>
<th>Group 4 (behavioural)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1 (%)</td>
<td>No follow-up</td>
<td>−3.3 (0.9)</td>
<td>−3.0 (1.1)</td>
<td>−4.8 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td>No follow-up</td>
<td>4.4 (0.6)</td>
<td>4.2 (0.5)</td>
<td>5.6 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Systolic BP (mgHg)</td>
<td>No follow-up</td>
<td>−6.8 (5.8)</td>
<td>−12.4 (6.8)</td>
<td>−16.9 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Diastolic BP (mgHg)</td>
<td>No follow-up</td>
<td>−5.3 (3.0)*</td>
<td>−5.0 (4.0)*</td>
<td>−7.9 (2.6)</td>
<td>*Significant from group 4, p &lt; 0.05</td>
</tr>
<tr>
<td>BMI</td>
<td>No follow-up</td>
<td>−2.0 (0.4)</td>
<td>−1.4 (0.5)</td>
<td>−2.6 (0.5)</td>
<td></td>
</tr>
<tr>
<td>Cholesterol (mmol/l)</td>
<td>No follow-up</td>
<td>0.12 (0.20)</td>
<td>0.16 (0.16)</td>
<td>−0.33 (0.15)</td>
<td></td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>No follow-up</td>
<td>0.02 (0.04)</td>
<td>0.18 (0.10)</td>
<td>0.06 (0.08)</td>
<td></td>
</tr>
<tr>
<td>Cholesterol risk ratio (total/HDL)</td>
<td>No follow-up</td>
<td>−0.25 (0.03)</td>
<td>−0.35 (0.46)</td>
<td>−0.59 (0.20)</td>
<td></td>
</tr>
<tr>
<td>Treatment intensity</td>
<td>No follow-up</td>
<td>% unchanged: 75</td>
<td>% unchanged: 70</td>
<td>% unchanged: 74</td>
<td></td>
</tr>
<tr>
<td>Satisfaction (actual score + SE)</td>
<td>No follow-up</td>
<td>74.8 (2.2)</td>
<td>77.9 (2.0)</td>
<td>77.0 (2.3)</td>
<td></td>
</tr>
</tbody>
</table>

continued
### Outcomes (mean change ± SE unless otherwise noted)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Group 1 (minimal education)</th>
<th>Group 2 (individual education)</th>
<th>Group 3 (group education)</th>
<th>Group 4 (behavioural)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion consulting ophthalmology (%)</td>
<td>No follow-up</td>
<td>97</td>
<td>95</td>
<td>89</td>
<td></td>
</tr>
<tr>
<td>Proportion consulting podiatry (%)</td>
<td>No follow-up</td>
<td>55</td>
<td>73</td>
<td>74</td>
<td></td>
</tr>
</tbody>
</table>

(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 – $\chi^2$ 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 HbA1c 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?  
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. Were the point estimates and measure of variability presented for the primary outcome measure?  
7. Did the analyses include an ITT analysis?  
8. Were withdrawals and drop-outs completely described?

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<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Cooper et al., 2002, 2003</td>
<td><strong>Treatment intervention:</strong> Diabetes Look After Yourself (DLAY) course (for further details of constituent patient groups, see the next column)</td>
<td><strong>Eligibility/exclusion criteria:</strong> Inclusion: Type 2 diabetes diagnosed for at least 1 year, able to give written consent, undergoing regular diabetes screening. Exclusion: if &lt;21 or &gt;75 years old, persistent defaults, with alcohol problem, language problem or a physical handicap which precluded participation in the activity/exercise programme (more details provided).</td>
<td><strong>Primary outcomes used:</strong> HbA1c. <strong>Secondary outcomes used:</strong> summary of Diabetes Self-Care Activities Questionnaire. Diabetes Integration Questionnaire (attitudes to diabetes and its treatment). Population Models of Diabetes Questionnaire (treatment effectiveness). (qualitative outcomes on patient’s perspectives based on focus group interviews not reported here).</td>
</tr>
<tr>
<td><strong>Source:</strong> Published and unpublished</td>
<td><strong>Topics:</strong> 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)</td>
<td><strong>How selected:</strong> not reported.</td>
<td><strong>Individual preferred learning style addressed:</strong> no. <strong>Subgroups:</strong> none reported. <strong>Normal range(s)</strong> for outcomes: HbA1c: 4–6%. <strong>How outcomes were assessed:</strong> HbA1c, by lab, others by self-report. <strong>Validation of outcomes:</strong> yes. Quantitative measures were validated. <strong>Timing of outcomes same for both groups:</strong> yes (if allowing for staggered design).</td>
</tr>
<tr>
<td><strong>Country:</strong> UK</td>
<td><strong>Provider:</strong> specialist diabetes nurses (supported by dieticians – personal communication by author)</td>
<td><strong>Allocation to treatments:</strong> staggered over a 14-month period with five trial courses running over 1 year.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
<tr>
<td><strong>Setting:</strong> Multi-centre: 2 hospitals and 1 health centre</td>
<td><strong>Sessions:</strong> 8 weekly sessions of approximately 2 h each. Delivered at staggered intervals over 14 months. <strong>Delivery:</strong> largely interactive, small and plenary group discussions, problem-based learning, goal setting, exercise, relaxation and practice of skills in 3 centres (see first column)</td>
<td><strong>Numbers involved:</strong> 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).</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td><strong>Treatment changes:</strong> 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 ($\chi^2, p = 0.16$). Four people (2 in each group) were changed to insulin therapy during the course of the trial. <strong>Training of trainers:</strong> nurse trainers trained together and were provided with a teaching manual. <strong>Theory:</strong> 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. <strong>Control group:</strong> randomised but on a waiting list for 12 months. <strong>Duration of intervention:</strong> 8 weeks.</td>
<td><strong>Numbers on diabetes treatment:</strong> insulin: none. <strong>Diet:</strong> intervention 75%; control 66% (insulin: intervention 32.5 ± 6.7 kg/m2; control 32.1 ± 6.1 kg/m2; self-monitoring: intervention 67%; control 47%). <strong>Mean (range) duration of diabetes since diagnosis:</strong> intervention 6 (1–28) years; control 6 (1–30) years.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 1**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender (M/F):</strong> intervention 57/43%; control 58/42%</td>
<td><strong>Primary outcomes used:</strong> HbA1c. <strong>Secondary outcomes used:</strong> summary of Diabetes Self-Care Activities Questionnaire. Diabetes Integration Questionnaire (treatment effectiveness). (qualitative outcomes on patient’s perspectives based on focus group interviews not reported here). <strong>Individual preferred learning style addressed:</strong> no. <strong>Subgroups:</strong> none reported. <strong>Normal range(s)</strong> for outcomes: HbA1c: 4–6%. <strong>How outcomes were assessed:</strong> HbA1c, by lab, others by self-report. <strong>Validation of outcomes:</strong> yes. Quantitative measures were validated. <strong>Timing of outcomes same for both groups:</strong> yes (if allowing for staggered design).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numbers involved:</strong> 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).</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numbers on diabetes treatment:</strong> insulin: none.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 3**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (range) duration of diabetes since diagnosis:</strong> intervention 6 (1–28) years; control 6 (1–30) years.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 4**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean ± SD baseline measurements of relevant parameters:</strong> HbA1c: intervention 7.9 ± 1.7% (range 4.5–11.0); control 7.0 ± 1.6% (range 4.6–10.6).</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 5**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI:</strong> intervention 32.5 ± 6.7 kg/m²; control 32.1 ± 6.1 kg/m²; self-monitoring: intervention 67%; control 47%.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 6**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Attitudes (scale 0–100%):</strong> intervention 73.1 ± 11.9; control 74.6 ± 11.0.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 7**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exercise (scale 0–100%):</strong> intervention 50.8 ± 25.5; control 48.8 ± 31.6.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 8**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diet (scale 0–100%):</strong> intervention 71.6 ± 18.2; control 69.6 (15.5).</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 9**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment effectiveness (Likert scale 0–5):</strong> intervention 4.4; control 4.0.</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>

**Table 10**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender (M/F):</strong> intervention 57/43%; control 58/42%</td>
<td><strong>How outcomes were assessed:</strong> yes.</td>
</tr>
</tbody>
</table>
## Reference and design

<table>
<thead>
<tr>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD (unless stated) of outcome at 12 months</td>
<td></td>
</tr>
<tr>
<td><strong>HbA1c (%)</strong></td>
<td>Intervention (n = 48)</td>
</tr>
<tr>
<td></td>
<td>7.9 ± 2.1</td>
</tr>
<tr>
<td><strong>Attitudes (scale 0–100%, ↑ = better)</strong></td>
<td>75.1 ± 11.0</td>
</tr>
<tr>
<td><strong>Treatment effectiveness (median on Likert scale 0–5, ↑ = better)</strong></td>
<td>4.5</td>
</tr>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td>31.3 ± 5.7</td>
</tr>
<tr>
<td><strong>Diet (scale: 0–100%, ↑ = better)</strong></td>
<td>76.5 ± 12.2</td>
</tr>
<tr>
<td><strong>Exercise (scale: 0–100%, ↑ = better)</strong></td>
<td>62.5 ± 25.3</td>
</tr>
<tr>
<td><strong>Self-monitoring (% blood testing)</strong></td>
<td>92</td>
</tr>
</tbody>
</table>

## 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 HbA1c 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 HbA1c 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 HbA1c. 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. HbA1c 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.

---

*Cooper et al., 2002* 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? Partial

Reference and design

Study: Deakin et al., 2006,46 also 200347,48
Source: Journal article
Country: UK
Setting: Community
Language: English
Trial design: RCT

Intervention

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

Participants

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

Outcome measures

Primary outcome used: HbA1c
Secondary outcomes used: BP (systolic and diastolic)
Lipids (total cholesterol, HDL, LDL, Triglycerides
Body weight
BMI
Body fat, waist size
Lifestyle outcomes: perceived frequency of hyper/hypoglycaemia, diabetes knowledge, self-care activity (exercise, foot care, blood testing), diet, nutritional intake, treatment satisfaction, diabetes empowerment, 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**  
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

---

**Outcome measures**  
were obtained from recent guidance reports (data not provided)

**How outcomes were assessed:**  
HbA1c: 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: assessing using validated scale (ADDQoL: audit of Diabetes Dependent Quality of Life; reference cited)

---

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theory:</strong> empowerment and discovery learning (reference cited)</td>
<td><strong>Control intervention:</strong> Routine care plus diabetes education and individual review with a dietician (30 minutes), practice nurse (15 minutes) and GP (10 minutes)</td>
<td><strong>Duration of intervention:</strong> 6 weeks</td>
<td><strong>Were the care programmes identical?</strong> Not reported</td>
</tr>
<tr>
<td><strong>Mean ± SD baseline measurements of relevant parameters in the intervention (int.) and control (con.) and the difference in means (diff., 95% CI in parentheses):</strong></td>
<td><strong>Mean ± SD baseline measurements of relevant parameters in the intervention (int.) and control (con.) and the difference in means (diff., 95% CI in parentheses):</strong></td>
<td><strong>Mean ± SD baseline measurements of relevant parameters in the intervention (int.) and control (con.) and the difference in means (diff., 95% CI in parentheses):</strong></td>
<td><strong>Mean ± SD baseline measurements of relevant parameters in the intervention (int.) and control (con.) and the difference in means (diff., 95% CI in parentheses):</strong></td>
</tr>
<tr>
<td>HbA1c: int. 7.7 ± 1.6%; con. 7.7 ± 1.6%; diff. 0.0 (–0.3 to 0.4 %)</td>
<td>Systolic BP: int. 147.5 ± 19.8 mmHg; con. 147.8 ± 23.7 mmHg; diff. 0.3 (–4.6 to 5.1 mmHg)</td>
<td>Diastolic BP: int. 82.6 ± 11.0 mmHg; con. 82.2 ± 12.2 mmHg; diff. –0.4 (–3.0 to 2.2 mmHg)</td>
<td>Total cholesterol: int. 5.1 ± 1.1 mmol/l; con. 4.9 ± 1.0 mmol/l; diff. –0.2 (–0.4 to 0.1 mmol/l)</td>
</tr>
<tr>
<td>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)</td>
<td>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)</td>
<td>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)</td>
<td>Body weight: int. 83.2 ± 14.5; con. 82.8 ± 17.6 kg; diff. –0.4 (–4.0 to 3.2) kg</td>
</tr>
<tr>
<td>BMI: int. 30.8 ± 5.3 kg/m2; con. 30.6 ± 5.7 kg/m2; diff. –0.3 (–1.5 to 1.0) kg/m2</td>
<td>Diabetes knowledge score (0–14): int. 7.5 ± 3.5; con. 7.0 ± 3.1; diff. –0.5 (–1.3 to 0.3)</td>
<td>Overall ADDQoL score: int. –2.2 ± 2.2; con. –1.9 ± 2.2; diff. 0.3 (–0.3 to 0.8)</td>
<td>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)</td>
</tr>
<tr>
<td>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)</td>
<td></td>
<td></td>
<td>Validation of outcomes: yes: used validated lifestyle, psychosocial and QoL questionnaires; clinical outcomes used standard methods (above)</td>
</tr>
</tbody>
</table>

---

**Timing of outcomes the same for both groups?:** yes

**Length of follow-up:** 14 months

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## Results

<table>
<thead>
<tr>
<th>Outcome (14 months)</th>
<th>Intervention group</th>
<th>Control group</th>
<th>Comparisons between groups: mean difference (95% CI) and significance of overall change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HbA1c (%)</strong></td>
<td>7.1 ± 1.1 (150)</td>
<td>7.8 ± 1.6 (141)</td>
<td>0.7 (0.3 to 1.0) (p &lt; 0.001)</td>
</tr>
<tr>
<td>Change from baseline in HbA1c (%)</td>
<td>–0.6</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>141.3 ± 16.8 (150)</td>
<td>144.4 ± 23.5 (141)</td>
<td>3.1 (–1.6 to 7.9) (p = 0.1)</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>78.4 ± 9.6 (150)</td>
<td>80.2 ± 10.9 (141)</td>
<td>1.7 (–0.6 to 4.1) (p = 0.1)</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>4.8 ± 1.1 (150)</td>
<td>4.7 ± 1.6 (141)</td>
<td>–0.1 (–0.3 to 0.1) (p = 0.01)</td>
</tr>
<tr>
<td>Change from baseline in total cholesterol (mmol/l)</td>
<td>–0.3</td>
<td>–0.2</td>
<td></td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>1.1 ± 0.4 (150)</td>
<td>1.1 ± 0.4 (141)</td>
<td>0.0 (–0.1 to 0.1) (p = 0.3)</td>
</tr>
<tr>
<td>LDL cholesterol (mmol/l)</td>
<td>2.7 ± 0.9 (150)</td>
<td>2.7 ± 0.8 (141)</td>
<td>0.0 (–0.3 to 0.1) (p = 0.1)</td>
</tr>
<tr>
<td>Triglycerides (geometric mean, 95% CI) (mmol/l)</td>
<td>1.8 (1.6 to 2.0)² (150)</td>
<td>1.8 (1.6 to 1.9)² (141)</td>
<td>Ratio of means: 1.0 (0.9 to 1.1) (p = 0.3)</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>82.7 ± 14.8 (150)</td>
<td>83.9 ± 18.8 (141)</td>
<td>1.2 (–2.7 to 5.2) (p &lt; 0.001)</td>
</tr>
<tr>
<td>Change from baseline in body weight (kg)</td>
<td>–0.5</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.6 ± 5.5 (150)</td>
<td>31.0 ± 6.4 (141)</td>
<td>0.4 (–1.0 to 1.7) (p &lt; 0.001)</td>
</tr>
<tr>
<td>Change from baseline in BMI (kg/m²)</td>
<td>–0.2</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Diabetes knowledge score</td>
<td>9.3 ± 3.1 (100)</td>
<td>7.8 ± 2.7 (91)</td>
<td>–1.5 (–2.3 to –0.7) (p &lt; 0.001)</td>
</tr>
<tr>
<td>(0–14 scale; multiple-choice question)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall ADDQoL score</td>
<td>–1.4 ± 1.7 (100)</td>
<td>–1.7 ± 2.1 (91)</td>
<td>–0.3 (–0.8 to 0.3) (p = 0.2)</td>
</tr>
</tbody>
</table>

### 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 HbA1c 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 HbA1c with α = 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) only presents results for <1 year

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¹ Data not extracted for these.

² 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

<table>
<thead>
<tr>
<th>Study: Goudswaard et al., 2004</th>
<th>Intervention: 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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country: The Netherlands</td>
<td>Eligibility/exclusion criteria: Inclusion: patients receiving primary care only, age &lt;76 years and with HbA1c ≥ 7.0% were eligible if, after optimisation of oral medication, their HbA1c remained ≥7.0% while taking the maximum feasible doses of two different OAs (mostly sulfonylurea and metformin) Exclusion: severe co-morbidity, inability to follow instructions spoken in Dutch or short-term insulin requirement for severe hyperglycaemic symptoms</td>
</tr>
<tr>
<td>Setting: Community</td>
<td>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</td>
</tr>
<tr>
<td>Language: English</td>
<td>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</td>
</tr>
<tr>
<td>Trial design: RCT</td>
<td>Losses to follow-up: intervention n = 4 (14.3%); control n = 4 (13.3%)</td>
</tr>
</tbody>
</table>

Participants

<table>
<thead>
<tr>
<th>Study: Goudswaard et al., 2004</th>
<th>Diabetes treatment (in the full population; n = 1810): insulin 12%; tablets 66%; diet alone 22%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country: The Netherlands</td>
<td>Mean ± SD duration of diabetes: intervention 7.3 ± 5.0 years; control: 7.6 ± 3.8 years</td>
</tr>
<tr>
<td>Setting: Community</td>
<td>Gender: intervention 52% male; control: 44% male</td>
</tr>
<tr>
<td>Language: English</td>
<td>Mean ± SD age: intervention 62.6 ± 9.0 years; control 58.7 ± 11.4 years</td>
</tr>
<tr>
<td>Trial design: RCT</td>
<td>Ethnic groups: not reported</td>
</tr>
</tbody>
</table>

Outcome measures

<table>
<thead>
<tr>
<th>Study: Goudswaard et al., 2004</th>
<th>Primary outcomes used: HbA1c at end-point; HbA1c change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country: The Netherlands</td>
<td>Secondary outcomes used: body weight (measured only at 6 months after inception; not reported here)</td>
</tr>
<tr>
<td>Setting: Community</td>
<td>Individual preferred learning style addressed?: not reported.</td>
</tr>
<tr>
<td>Language: English</td>
<td>Subgroups: none reported</td>
</tr>
<tr>
<td>Trial design: RCT</td>
<td>Normal range(s) for outcomes: HbA1c 4–6%</td>
</tr>
</tbody>
</table>

How outcomes were assessed: HbA1c 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 HbA1c 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
Appendix 5

Reference and Intervention Participants Outcome design measures

Results

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention group</th>
<th>Control group</th>
<th>Comparisons between groups: (control – intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD HbA1c at end-point (18 months) (%)</td>
<td>7.8 ± 0.9</td>
<td>8.2 ± 1.4</td>
<td>No statistics were reported for this comparison at end-point</td>
</tr>
<tr>
<td>HbA1c change from baseline to end-point (18 months) (%)</td>
<td>–0.4</td>
<td>–0.6%</td>
<td>Mean difference (95% CI): 0.2% (–0.7 to 0.4%) (p not significant)</td>
</tr>
<tr>
<td>Patients with HbA1c &lt; 7.0% at end-point (18 months) (%)</td>
<td>17</td>
<td>15</td>
<td>Reported as not statistically significant (no p-value given)</td>
</tr>
<tr>
<td>Patients on insulin therapy at end-point (18 months) (%)</td>
<td>6 (25%)</td>
<td>10 (38%)</td>
<td>Reported as not statistically significant (no p-value given)</td>
</tr>
</tbody>
</table>

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 HbA1c for the two groups at baseline are given above)

Method of data analysis: comparison of HbA1c 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 HbA1c < 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, α = 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 generalisability 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 HbA1c 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

Study: Heller et al., 1988
Source: Journal article
Country: UK
Setting: Hospital
Language: English
Trial design: RCT

Intervention

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

Treatement changes:

Training of trainers:

Theory: 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/m²), 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: HbA₁ (mean + 95% CI): int. 12.3% (11.4 to 13.2); cont. 12.7% (11.9 to 13.5)

Gender (M/F): int. 20/16; cont. 16/23

Age ranges (mean + 95% CI):

int. 56.6 (55 to 58) years;

cont. 56.4 (53 to 59.9) years

Ethnic groups: not reported

Losses to follow-up: int. 4; cont. 8 (reasons given)

Compliance: 1 int. con. + 2 int. did not attend 3-month follow-up,

1 int. did not attend at 6 months

Outcome measures

Primary outcomes used:

HbA₁

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:

HbA₁ 5.0–7.5%; knowledge (max. score 36)

How outcomes assessed?: knowledge self-report, laboratory for HbA₁

Validated?: HbA₁ yes; knowledge no details of validation

Timing of outcomes same for both groups: yes

Length of follow-up:

12 months from inception

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## Outcome (mean ± 95% CI)

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 36)</th>
<th>Control (n = 39)</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1</td>
<td>9.0% (8.2 to 9.8)</td>
<td>9.9% (8.9 to 10.9)</td>
<td></td>
</tr>
<tr>
<td>Proportion of patients HbA1 &lt; 7.5% (%)</td>
<td>36</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>FBG (mmol/l)</td>
<td>9.1 (7.9 to 10.3)</td>
<td>10.3 (8.8 to 11.8)</td>
<td></td>
</tr>
<tr>
<td>Weight loss (kg)</td>
<td>-5.5 (4 to 6.5)</td>
<td>-3 (2 to 4)</td>
<td>p &lt; 0.05</td>
</tr>
</tbody>
</table>

### 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: HbA1c 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 χ² 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
<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Ko et al., 2007&lt;sup&gt;65&lt;/sup&gt;</td>
<td>Treatment intervention: Structured Intensive Diabetes Education Programme (SIDEP) based on Bucharest–Dusseldorf study and Diabetes Prevention Programme (DPP) (references available)</td>
<td>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</td>
<td>Primary outcome used: mean value of HbA&lt;sub&gt;1c&lt;/sub&gt; and changes in HbA&lt;sub&gt;1c&lt;/sub&gt; during follow-up</td>
</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td>Topics: diabetes knowledge, diabetes self-management skills, self-monitoring, injection techniques, sick-day care, diet and nutrition, physical activity, foot inspection, hypoglycaemia management</td>
<td>Exclusion: patients who were aged &gt;70 years, mentally ill, unable to undertake recommended physical activity or had any severe illness (e.g. sepsis, severe infection, hypoglycaemia or shock).</td>
<td>Secondary outcomes used: Diet&lt;sup&gt;a&lt;/sup&gt; SMBG&lt;sup&gt;b&lt;/sup&gt; Physical activity&lt;sup&gt;c&lt;/sup&gt; Frequency of admissions related to diabetic complications (BMI, FBG and BP were also monitored but no data provided for follow-up)</td>
</tr>
<tr>
<td><strong>Country:</strong> Korea</td>
<td>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</td>
<td>How selected: consecutive recruitment of inpatients in a hospital-based university-affiliated diabetes centre</td>
<td>Individual preferred learning style addressed?: no (group interventions)</td>
</tr>
<tr>
<td><strong>Setting:</strong> Secondary care (inpatient clinic with patients hospitalised by diabetes-related illnesses)</td>
<td>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</td>
<td>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)</td>
<td>Subgroups: two subgroups were analysed retrospectively, according to the mean of all HbA&lt;sub&gt;1c&lt;/sub&gt; values over the 4-year follow-up period: group 1, HbA&lt;sub&gt;1c&lt;/sub&gt; &lt; 7.0 (well-controlled); group 2, HbA&lt;sub&gt;1c&lt;/sub&gt; &gt; 7.9% (not well controlled) (data not extracted)</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td>Audience: group education with 5–10 patients per group</td>
<td>Losses to follow-up: intervention/control: in total: n = 59 (27%)/n = 70 (32%)</td>
<td>Normal range(s) for outcomes: not stated, but reference range for HbA&lt;sub&gt;1c&lt;/sub&gt; given (see below)</td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td>Delivery: didactic and interactive inpatient sessions to which patients’ family members were also invited (curriculum timetable reported)</td>
<td>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%)</td>
<td>How outcomes were assessed: HbA&lt;sub&gt;1c&lt;/sub&gt; measured using HPLC (laboratory name reported) with reference range 4.6–6.4%. Diet, exercise and workload and disease complications were monitored (data not extracted)</td>
</tr>
</tbody>
</table>

<sup>a</sup>BG monitoring and drug adjustment education reinforcement (focus on physical activity under supervision during hospitalisation (total 30 h), with free physical activity under supervision, plus one 3-h reinforcement outpatient session per year |

<sup>b</sup>Training of trainers: stated only that trainers were professional health providers in the field of diabetes Theory: cognitive-behavioural therapy (references cited) |

<sup>c</sup>Treatment changes: at annual reinforcement sessions physician assessed and adjusted glucose-lowering agents |

<sup>d</sup>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)
Appendix 5

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of intervention:</td>
<td></td>
<td>Mean ± SD baseline measurements of relevant parameters (95% CI in parentheses):</td>
<td>SMBG were monitored by annual questionnaires and scored on a 5-point scale</td>
</tr>
<tr>
<td>30 h over 5 days followed by annual 3-h reinforcement sessions</td>
<td></td>
<td>HbA1c: 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)</td>
<td>Validation of outcomes: unclear if the questionnaires for diet, exercise and SMBG (data not extracted) were validated, but references cited</td>
</tr>
<tr>
<td>Were the care programmes identical?:</td>
<td></td>
<td>BMI: intervention 25.5 ± 3.5 kg/m²; control 25.3 ± 3.2 kg/m² difference p = 0.650</td>
<td>Timing of outcomes the same for both groups?: yes</td>
</tr>
<tr>
<td>Not reported</td>
<td></td>
<td>Fasting plasma glucose: intervention 9.8 ± 3.8 mmol/l; control 9.9 ± 3.6 mmol/l; difference p = 0.712</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total cholesterol: intervention 4.9 ± 1.1 mmol/l; control 4.9 ± 1.0 mmol/l; difference p = 0.752</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Triglycerides: intervention 1.96 ± 1.4 mmol/l; control 1.91 ± 1.5 mmol/l; difference p = 0.726</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>HDL cholesterol: intervention 1.16 ± 0.3 mmol/l; control 1.18 ± 0.4 mmol/l; difference p = 0.558</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Smoking: intervention n = 50 (22.9%); control n = 57 (26.0%); difference p = 0.452</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alcohol: intervention n = 62 (28.3%); control n = 53 (24.3%); difference p = 0.343</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Numbers hypertensive (≥140 mmHg systolic, ≥90 mmHg diastolic, or on treatment): intervention n = 81 (37%); control n = 94 (43.1%); difference p = 0.191</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diabetes family history: intervention n = 64 (29.2%); control n = 58 (26.6%); difference p = 0.542</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMBG were monitored by annual questionnaires and scored on a 5-point scale</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Validation of outcomes: unclear if the questionnaires for diet, exercise and SMBG (data not extracted) were validated, but references cited</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Timing of outcomes the same for both groups?: yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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)</td>
<td></td>
</tr>
</tbody>
</table>

Results

| | SIDEPE group | Control group | Comparison between groups |
| | Mean ± SD (n = 219) | Mean ± SD (n = 218) | |
| Mean (± SD) HbA1c (%) | n = 174 | n = 187 | Mean difference (95% CI) |
| at 12 months | 7.9 ± 1.7 | 8.1 ± 1.5 | 0.14 (–0.20 to 0.47), p = 0.420 |
| Mean (± SD) HbA1c (%) | n = 168 | n = 169 | Mean difference (95% CI) |
| at 24 months | 7.9 ± 1.5 | 8.2 ± 1.5 | 0.28 (–0.04 to 0.61), p = 0.089 |
| Mean (± SD) HbA1c (%) | n = 167 | n = 148 | Mean difference (95% CI) |
| at 36 months | 7.8 ± 1.5 | 8.4 ± 1.6 | 0.51 (0.17 to 0.85), p = 0.004 |
| Mean (± SD) HbA1c (%) | n = 161 | n = 147 | Mean difference (95% CI) |
| at 48 months | 7.9 ± 1.2 | 8.7 ± 1.6 | 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 | n = 148 | p = 0.005 |

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 HbA1c 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 HbA1c in the region of 9%
Conflict of interests: none declared or evident
Other:

- Data not extracted for this review.
- The mean HbA1c 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), $p < 0.0001$].
- 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)

<table>
<thead>
<tr>
<th>Question</th>
<th>Adequate</th>
<th>Inadequate</th>
<th>Reported</th>
<th>Yes</th>
<th>Adequate</th>
<th>Unknown</th>
<th>Partial</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the assignment to the treatment groups really random?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>2. Was the treatment allocation concealed?</td>
<td></td>
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<tr>
<td>3. Were the groups similar at baseline in terms of prognostic factors?</td>
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<tr>
<td>4. Were the eligibility criteria specified?</td>
<td></td>
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<tr>
<td>5. Were outcome assessors blinded to the treatment allocation?</td>
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<tr>
<td>6. Were the point estimates and measure of variability presented for the primary outcome measure?</td>
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<tr>
<td>7. Did the analyses include an ITT analysis?</td>
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<tr>
<td>8. Were withdrawals and drop-outs completely described?</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Reference and design</td>
<td>Intervention</td>
<td>Participants</td>
<td>Outcome measures</td>
<td></td>
<td></td>
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<td></td>
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<tr>
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</tr>
<tr>
<td><strong>Study:</strong> Raz et al., 1988</td>
<td><strong>Treatment intervention:</strong> 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</td>
<td><strong>Eligibility/exclusion criteria:</strong> 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</td>
<td><strong>Primary outcomes used:</strong> HbA1c</td>
<td></td>
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</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td><strong>Study design:</strong> RCT after stratification by pre- and post-prandial glucose and HbA1c</td>
<td><strong>How selected:</strong> states patients were selected from the clinic, no details.</td>
<td><strong>Secondary outcomes used:</strong> knowledge (not reported here), BP, weight (kg – not reported here), pre- and postprandial blood glucose (not reported here), blood cholesterol, HDL cholesterol, blood triglyceride</td>
<td></td>
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</tr>
<tr>
<td><strong>Country:</strong> Israel</td>
<td><strong>Treatment intervention:</strong> 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</td>
<td><strong>Numbers involved:</strong> total N = 51, int 25; cont. 26</td>
<td><strong>Individual preferred learning style addressed?: no</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>Setting:</strong> Hospital</td>
<td><strong>Session:</strong> 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</td>
<td><strong>Type of diabetes:</strong> Type 2</td>
<td><strong>Any subgroups (e.g. ethnic groups): no</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td><strong>Delivery:</strong> assume didactic, group education</td>
<td><strong>Baseline characteristics based on those completing study</strong></td>
<td><strong>Normal range(s) for outcomes:</strong> not reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT after stratification by pre- and postprandial glucose and HbA1c</td>
<td><strong>Treatment changes:</strong> diet and exercise could be manipulated, but drug therapy unchanged</td>
<td><strong>Duration of diabetes:</strong> (intervention) (int.) 9.0 years (SD 4.5); (control) (con.) 9.2 years (SD 5.3)</td>
<td><strong>How outcomes assessed?: HbA1c laboratory, knowledge by self-report</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Training of trainers:</strong> Theory:</td>
<td><strong>Baseline measurements of outcome parameter (mean ± SD):</strong></td>
<td><strong>Validated?: knowledge not validated (prepared for this study)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Control intervention:</strong> Control group were followed up every 2 months</td>
<td>HbA1c: int. 10.0% ± 2.7; con. 9.6% ± 2.6</td>
<td><strong>Timing of outcomes same for both groups:</strong> yes</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Duration of intervention:</strong> 12 months</td>
<td>Fasting glucose: int. 200.1 ± 55.1; con. 200.8 ± 59.9</td>
<td><strong>Length of follow-up:</strong> 12 months from inception</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Postprandial glucose: int. 234.3 ± 68.6; con. 238.5 ± 69.9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Outcomes (many approximations from figure)

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 23)</th>
<th>Control (n = 26)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%) (from Figure 3)</td>
<td>8.25</td>
<td>9.6</td>
<td>Interaction between intervention and time, $p &lt; 0.05^a$</td>
</tr>
<tr>
<td>Preprandial BG (mg/dl) (from Figure 1)</td>
<td>162</td>
<td>210</td>
<td>Interaction between intervention and time, $p &lt; 0.01^a$</td>
</tr>
<tr>
<td>Postprandial BG (mg/dl) (from Figure 2)</td>
<td>190</td>
<td>225</td>
<td>Interaction between intervention and time, $p &lt; 0.05^a$</td>
</tr>
<tr>
<td>BP</td>
<td>Not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean blood cholesterol (mg/dl)</td>
<td>213.8 ± 37.7</td>
<td>226.1 ± 60.8</td>
<td>NS</td>
</tr>
<tr>
<td>Blood triglycerides (mg/dl)</td>
<td>214 ± 24</td>
<td>204 ± 31</td>
<td>NS</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dl)</td>
<td>49.6 ± 4.3</td>
<td>45.2 ± 4.4</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (kg) (from Figure 4)</td>
<td>73</td>
<td>73</td>
<td>Interaction between intervention and time, $p &lt; 0.05^a$</td>
</tr>
</tbody>
</table>

### Methodological comments

**Allocation to treatment groups:** patients stratified according to mean values of pre- and postprandial glucose and HbA1c 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 $\chi^2$ 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.

This interaction represents the difference between groups in the change from baseline to end-point.

### Quality criteria for RCTs (CRD Report 4)

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

Reference and design

**Study:** Sarkadi and Rosenqvist, 2004

**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)

**Auditience:** groups (size, composition and allocation among groups and pharmacies 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 ≤2 years

**Exclusion:** insulin use >2 years, or did not provide an initial HbA1c 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

**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:**

HbA1c 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/m²)

---

**Results**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Intervention (n = 39)</th>
<th>Control (n = 38)</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (95% CI) HbA1c (%) at 1 year (intervention end)</td>
<td>6.2 (5.7 to 6.7)</td>
<td>6.4 (5.8 to 7.0)</td>
<td>Not significant (no p-value provided)</td>
</tr>
<tr>
<td>Mean (95% CI) HbA1c (%) at 2 years (follow-up end)</td>
<td>6.1 (5.5 to 6.7)</td>
<td>6.6 (6.0 to 7.2)</td>
<td>p &lt; 0.01</td>
</tr>
</tbody>
</table>

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 HbA1c. 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 HbA1c 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

*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)

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the assignment to the treatment groups really random?</td>
<td>Partial</td>
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<tr>
<td>2. Was the treatment allocation concealed?</td>
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</tr>
<tr>
<td>3. Were the groups similar at baseline in terms of prognostic factors?</td>
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</tr>
<tr>
<td>4. Were the eligibility criteria specified?</td>
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</tr>
<tr>
<td>5. Were outcome assessors blinded to the treatment allocation?</td>
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<tr>
<td>6. Were the point estimates and measure of variability presented for the primary outcome measure?</td>
<td>Partial</td>
</tr>
<tr>
<td>7. Did the analyses include an ITT analysis?</td>
<td>Inadequate</td>
</tr>
<tr>
<td>8. Were withdrawals and drop-outs completely described?</td>
<td>Partial</td>
</tr>
</tbody>
</table>
### Reference and design

**Study:** Trento et al., 2001, 2002, 2004

**Source:** Journal articles

**Country:** Italy

**Setting:** University clinic

**Language:** English

**Trial design:** RCT

### Intervention

**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

### Participants

**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:**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Int. mean ± SD</th>
<th>Con. mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>7.4% ± 1.4</td>
<td>6.7% ± 1.2</td>
</tr>
<tr>
<td>QoL (DQOL)</td>
<td>int. 67.6 ± 19</td>
<td>con. 66.7 ± 25</td>
</tr>
<tr>
<td>Retinopathy (none/mild/more severe):</td>
<td>int. 42/8/6</td>
<td>con. 38/13/5</td>
</tr>
<tr>
<td>Knowledge</td>
<td>int. 14.9 ± 7.9</td>
<td>con. 20.2 ± 7.4</td>
</tr>
<tr>
<td>BMI</td>
<td>int. 29.7 ± 4.5</td>
<td>con. 27.8 ± 4.1</td>
</tr>
<tr>
<td>No. hypertensive</td>
<td>int. 34</td>
<td>con. 25</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>int. 77.4 ± 13.1</td>
<td>con. 78.2 ± 14.6</td>
</tr>
<tr>
<td>Fasting BG (mmol/l)</td>
<td>int. 9.8 ± 2.6</td>
<td>con. 10.0 ± 3.1</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>int. 5.8 ± 1.1</td>
<td>con. 5.5 ± 0.9</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>int. 1.2 ± 0.3</td>
<td>con. 1.3 ± 0.3</td>
</tr>
<tr>
<td>Triglyceride (mmol/l)</td>
<td>int. 2.6 (0.7–11.5)</td>
<td>con. 1.7 (0.5–5.2)</td>
</tr>
<tr>
<td>Creatinine (umol/l)</td>
<td>int. 91.6 ± 14.2</td>
<td>con. 90.0 ± 14.0</td>
</tr>
<tr>
<td>Albuminuria (none/micro or macro):</td>
<td>int. 32/24</td>
<td>con. 37/19</td>
</tr>
<tr>
<td>Foot ulcers (never/past/active):</td>
<td>int. 54/0/2</td>
<td>con. 53/2/1</td>
</tr>
<tr>
<td>Hypoglycaemic treatment (int./cont.):</td>
<td>diet only 6/10, sulfonylureas 27/21, metformin 5/6, sulfonylureas + metformin 18/19, insulin 0/0</td>
<td></td>
</tr>
</tbody>
</table>

### Outcome measures

**Primary outcomes used:**
- body weight, fasting BG
- HbA1c, diabetic retinopathy, blood lipids, knowledge of diabetes, health behaviour (Contact and Disorder Rating), QoL (DQOL)

**Secondary outcomes used:**
- hypoglycaemic medication, microalbuminuria, systolic and diastolic BP

**Individual preferred learning style addressed:** not reported

**Normal range(s) for outcomes:**
- not reported

**How outcomes were assessed:**
- not reported

**Validation of outcomes:**
- HbA1c 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**
<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>reference to eating habits, home monitoring of glucose and prevention of complications</td>
<td><strong>2. Reported by Trento et al.</strong>\textsuperscript{54} in their comparison with 4-year follow-up:</td>
<td></td>
<td>Timing of outcomes the same for both groups: yes</td>
</tr>
<tr>
<td><strong>Duration of intervention:</strong> Varied among patients; up to 5 years</td>
<td><em>HbA$_1c$</em>: int. 7.4% ± 1.4; con. 7.4% ± 1.4</td>
<td></td>
<td>Length of follow-up: 5 years from inception, with reporting at 2, 4 and 5 years</td>
</tr>
<tr>
<td></td>
<td><em>QoL (DQOL)</em>: int. 67.6 ± 19; con. 70.5 ± 21.7</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><em>Retinopathy</em> (none/mild/more severe): int. 33/12/0; con. 28/14/0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Knowledge</em>: int. 14.9 ± 7.9; con. 20.4 ± 7.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>BMI</em>: int. 29.8 ± 4.5; con. 27.9 ± 4.5</td>
<td></td>
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<tr>
<td></td>
<td><em>Weight</em> (kg): int. 77.8 ± 13.6; con. 77.8 ± 15.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Fasting BG</em> (mmol/l): int. 9.8 ± 2.6; con. 10.2 ± 3.2</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><em>Total cholesterol</em> (mmol/l): int. 5.84 ± 1.11; con. 5.46 ± 0.93</td>
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<tr>
<td></td>
<td><em>HDL cholesterol</em> (mmol/l): int. 1.27 ± 0.31; con. 1.32 ± 0.31</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Triglyceride</em> (mmol/l): int. 2.54 (0.66–11.49); con. 1.81 (0.51–5.22)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><em>Creatinine</em> (µmol/l): int. 91.94 ± 14.14; con. 91.05 ± 14.14</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><em>Microalbuminuria</em>: int. 31.79; con. 4.96</td>
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<tr>
<td></td>
<td><em>Hypoglycaemic treatment</em> (int./con.): diet only: 6/10; OHAs: 0/46</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><em>Systolic BP</em> (mmHg): int. 160 ± 26; con. 151 ± 19</td>
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<tr>
<td></td>
<td><em>Diastolic BP</em> (mmHg): int. 95 ± 11; con. 92 ± 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>3. Reported by Trento et al.</strong>\textsuperscript{55} in their comparison with 5-year follow-up:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>HbA$_1c$</em>: int. 7.4% ± 1.4; con. 7.4% ± 1.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>QoL (DQOL)</em>: int. 67.4 ± 19; con. 70.0 ± 21.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Knowledge</em>: int. 15.5 ± 7.9; con. 21.4 ± 7.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>BMI</em>: int. 30.0 ± 4.7; con. 27.7 ± 4.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Weight</em> (kg): int. 79.6 ± 13.7; con. 77.5 ± 16.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Fasting BG</em> (mmol/l): int. 9.8 ± 2.6; con. 9.9 ± 3.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Total cholesterol</em> (mmol/l): int. 5.84 ± 1.11; con. 5.46 ± 0.93</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>HDL cholesterol</em> (mmol/l): int. 1.27 ± 0.31; con. 1.32 ± 0.31</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Triglyceride</em> (mmol/l): int. 2.54 (0.66–11.49); con. 1.81 (0.51–5.22)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Creatinine</em> (µmol/l): int. 91.94 ± 14.14; con. 91.05 ± 14.14</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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)
### Mean ± SD of outcomes at 2-year follow-up

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention (n = 43)</th>
<th>Control (n = 47)</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>7.5% ± 1.4</td>
<td>8.3% ± 1.8</td>
<td>p &lt; 0.002</td>
</tr>
<tr>
<td>DQOL score</td>
<td>55.6 ± 15.9</td>
<td>80.8 ± 31.5</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Diabetic retinopathy (none/mild/more severe)</td>
<td>35/5/3</td>
<td>33/7/7</td>
<td>NS</td>
</tr>
<tr>
<td>GISED (knowledge) score</td>
<td>24 ± 6.6</td>
<td>17.4 ± 8.6</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.0 ± 4.4</td>
<td>27.6 ± 4.2</td>
<td>p = 0.06</td>
</tr>
<tr>
<td>Number hypertensive</td>
<td>26</td>
<td>22</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>76.0 ± 13.4</td>
<td>77.1 ± 14.7</td>
<td>NS</td>
</tr>
<tr>
<td>Fasting BG (mmol/l)</td>
<td>9.9 ± 2.6</td>
<td>9.2 ± 2.9</td>
<td>NS</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>5.7 ± 1.2</td>
<td>5.6 ± 1.2</td>
<td>NS</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>1.4 ± 0.4</td>
<td>1.3 ± 0.3</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>Triglycerides (mmol/l) (range)</td>
<td>2.1 (0.7–6.9)</td>
<td>1.7 (0.6–3.9)</td>
<td>p = 0.53</td>
</tr>
<tr>
<td>Creatinine (μmol/l)</td>
<td>88.8 ± 16.5</td>
<td>87.8 ± 17.2</td>
<td>NS</td>
</tr>
<tr>
<td>Albuminuria (none/micro or macro)</td>
<td>20/21</td>
<td>19/22</td>
<td>NS</td>
</tr>
<tr>
<td>Number with foot ulcers (never/past/active)</td>
<td>42/1/0</td>
<td>45/1/1</td>
<td>NS</td>
</tr>
<tr>
<td>SMBG</td>
<td>10</td>
<td>14</td>
<td>NS</td>
</tr>
</tbody>
</table>

### Hypoglycaemic treatment:
- Diet only: 2/38/4/1
- 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

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention (n = 45)</th>
<th>Change from baseline</th>
<th>Control (n = 45)</th>
<th>Change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>7.0 ± 1.1</td>
<td>−0.3 (NS)</td>
<td>8.6 ± 2.1</td>
<td>1.3 (p &lt; 0.001)</td>
</tr>
<tr>
<td>DQOL score</td>
<td>44.0 ± 7.5</td>
<td>−23.6 (p &lt; 0.001)</td>
<td>89.8 ± 28.1</td>
<td>19.2 (p &lt; 0.001)</td>
</tr>
<tr>
<td>Diabetic retinopathy (none/mild/more severe)</td>
<td>35/10/0</td>
<td>19/20/3</td>
<td>27.1 ± 6.6</td>
<td>12.2 (p &lt; 0.001)</td>
</tr>
<tr>
<td>GISED (knowledge) score</td>
<td>27.1 ± 6.6</td>
<td>12.2 (p &lt; 0.001)</td>
<td>17.2 ± 8.7</td>
<td>−3.2 (p &lt; 0.05)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.7 ± 4.0</td>
<td>−1.0 (p &lt; 0.001)</td>
<td>27.6 ± 4.7</td>
<td>−0.3 (NS)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>75.2 ± 13.0</td>
<td>−2.6 (p &lt; 0.001)</td>
<td>76.9 ± 16.1</td>
<td>−0.9 (NS)</td>
</tr>
<tr>
<td>Fasting BG (mmol/l)</td>
<td>9.3 ± 2.6</td>
<td>−0.7 (NS)</td>
<td>11.0 ± 4.6</td>
<td>0.8 (NS)</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>5.77 ± 1.34</td>
<td>−0.07 (NS)</td>
<td>5.59 ± 1.29</td>
<td>0.13 (NS)</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>1.42 ± 0.31</td>
<td>0.15 (p &lt; 0.001)</td>
<td>1.37 ± 0.28</td>
<td>0.05 (NS)</td>
</tr>
<tr>
<td>Triglycerides (mmol/l) (range)</td>
<td>2.11 (0.45 – 10.93)</td>
<td>−0.43 (NS)</td>
<td>1.64 (0.43–3.47)</td>
<td>−0.17 (NS)</td>
</tr>
<tr>
<td>Creatinine (μmol/l)</td>
<td>86.63 ± 15.9</td>
<td>−5.31 (NS)</td>
<td>97.24 ± 25.64</td>
<td>6.19 (NS)</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>6.26</td>
<td>−25.52 (NS)</td>
<td>6.15</td>
<td>1.18 (NS)</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>154 ± 21</td>
<td>−5.9 (NS)</td>
<td>149 ± 15</td>
<td>−1.9 (NS)</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>88 ± 7</td>
<td>−7.1 (p &lt; 0.001)</td>
<td>86 ± 9</td>
<td>−6.3 (p &lt; 0.001)</td>
</tr>
<tr>
<td>Urea nitrogen (mmol/l)</td>
<td>13.67 ± 3.82</td>
<td>−0.75 (NS)</td>
<td>15.74 ± 5.78</td>
<td>2.18 (p &lt; 0.05)</td>
</tr>
<tr>
<td>Hypoglycaemic treatment (diet only/oral agents/oral agents and insulin/insulin alone)</td>
<td>2/38/4/1</td>
<td>2/37/3/3</td>
<td>continued</td>
<td></td>
</tr>
</tbody>
</table>
### Mean ± SD of outcomes and mean (95% CI) changes from baseline at 5-year follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 42)</th>
<th>Control (n = 42)</th>
<th>Difference in change from baseline and control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At 5 years</td>
<td>Change from baseline</td>
<td>At 5 years</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7.3 ± 1.0</td>
<td>−0.1 (−0.5 to 0.4)</td>
<td>9.0 ± 1.6</td>
</tr>
<tr>
<td>DQOL score</td>
<td>43.7 ± 7.2</td>
<td>−23.7 (−30.0 to −17.3)</td>
<td>89.2 ± 30.1</td>
</tr>
<tr>
<td>GISED (knowledge) score</td>
<td>27.9 ± 5.7</td>
<td>12.4 (9.7 to 15.2)</td>
<td>18 ± 8.5</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.6 ± 4.1</td>
<td>−1.4 (−2.0 to −0.7)</td>
<td>27.6 ± 4.4</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>76.1 ± 12.9</td>
<td>−3.5 (−5.2 to −1.8)</td>
<td>77.3 ± 16.0</td>
</tr>
<tr>
<td>Fasting BG (mmol/l)</td>
<td>9.4 ± 2.3</td>
<td>−0.4 (−1.52 to 0.70)</td>
<td>10.2 ± 2.9</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>5.50 ± 1.06</td>
<td>−0.32 (−0.68 to 0.03)</td>
<td>5.27 ± 1.13</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>1.39 ± 0.33</td>
<td>0.14 (0.07 to 0.22)</td>
<td>1.42 ± 0.31</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)</td>
<td>2.17 ± 2.30</td>
<td>−0.48 (−1.15 to 0.20)</td>
<td>1.52 ± 0.75</td>
</tr>
<tr>
<td>Creatinine (µmol/l)</td>
<td>75.14 ± 25.63</td>
<td>−16.79 (−25.63 to −10.60)</td>
<td>78.67 ± 47.73</td>
</tr>
</tbody>
</table>

### 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

* 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
Appendix 5

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
</table>
| Study: Domenech et al., 1995 64 | Patients had previously received dietary advice from their physicians and/or had been treated with OHAs | 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 | Primary outcomes used: HbA1 |
| Source: Journal article | 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 | 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: HbA1 <7.5%  
How outcomes assessed?: laboratory, knowledge by self-report  
Validated?: HbA1 yes, knowledge no  
Timing of outcomes same for both groups: yes  
Length of follow-up: 12 months from inception | |
| Country: Argentina | | | |
| Setting: Community | Control intervention:  
Usual care | | |
| Language: English | Duration of intervention:  
1 month | | |
<p>| Trial design: CCT | | | |</p>
<table>
<thead>
<tr>
<th>Outcome changes</th>
<th>Intervention (n = 40)</th>
<th>Control (n = 39)</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1</td>
<td>-0.2 (0.4)</td>
<td>+0.8 (0.4)</td>
<td></td>
</tr>
<tr>
<td>Weight in (kg)</td>
<td>-2.4 (0.5)</td>
<td>-0.4 (0.5)</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Daily intake OHA (no. of tablets)</td>
<td>-1.4 (0.2)</td>
<td>+0.9 (0.2)</td>
<td>p &lt; 0.01</td>
</tr>
</tbody>
</table>

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 HbA1 (>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)

<table>
<thead>
<tr>
<th>Question</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were the groups similar at baseline in terms of prognostic factors?</td>
<td>Reported</td>
</tr>
<tr>
<td>Were the eligibility criteria specified?</td>
<td>Yes</td>
</tr>
<tr>
<td>Were outcome assessors blinded to the treatment allocation?</td>
<td>Unknown</td>
</tr>
<tr>
<td>Were the point estimates and measure of variability presented for the primary outcome measure?</td>
<td>Partial</td>
</tr>
<tr>
<td>Did the analyses include an ITT analysis?</td>
<td>Unknown</td>
</tr>
<tr>
<td>Were withdrawals and drop-outs completely described?</td>
<td>Adequate</td>
</tr>
<tr>
<td>Were participants likely to be representative of the intended population?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Reference and design

**Study:** Kronsbein, et al., 1988

**Source:** Journal article

**Country:** Germany

**Setting:** General practices

**Language:** English

**Trial design:** CCT, conditions implemented by practice

### Intervention

**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

**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

### Participants

**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):**
- HbA1c: 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

### Outcome measures

**Primary outcomes used:** HbA1c

**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:**
- HbA1c, up to 5.6%

**How outcomes assessed:**
- HbA1c 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)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention (n = 50)</th>
<th>Control (n = 49)</th>
<th>Difference between groups (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>7.1 ± 1.6</td>
<td>6.7 ± 1.5</td>
<td>NS</td>
</tr>
<tr>
<td>Knowledge</td>
<td>13 ± 4</td>
<td>10 ± 4</td>
<td>3 (16 to 48)&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>% without BG-lowering medication</td>
<td>62</td>
<td>39</td>
<td>23 (3 to 43)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Treatment with insulin</td>
<td>0</td>
<td>10</td>
<td>10 (2 to 18)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>73.8 ± 12.6</td>
<td>74.8 ± 13.2</td>
<td>2.3 (1.0 to 3.6)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Self-monitoring glycosuria (%)</td>
<td>72</td>
<td>2</td>
<td>70 (57 to 83)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

### 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 HbA1c and therefore may not be representative

**Conflict of interests:** none reported

**Other:** none

<sup>a</sup> Difference between groups p < 0.0001.

<sup>b</sup> Difference between groups, p < 0.05.

### Quality criteria for CCTs (CRD Report 4)

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

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## Interventions of focused self-management education

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Kaplan et al., 1987&lt;sup&gt;67&lt;/sup&gt;</td>
<td>Four groups: diet education (group 1), exercise education (group 2), diet and exercise education (group 3) and control education (control)</td>
<td>Eligibility/exclusion criteria: Inclusion: confirmed diagnosis, fasting plasma glucose &gt;3.62 mmol/l</td>
<td>Primary outcomes used: HbA&lt;sub&gt;1c&lt;/sub&gt;, QoL</td>
</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td>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</td>
<td>How selected: radio and newspaper advertisements and physicians</td>
<td>Secondary outcomes used: weight in (kg)</td>
</tr>
<tr>
<td><strong>Country:</strong> USA</td>
<td></td>
<td>Numbers involved: total N = 87, unsure of group numbers</td>
<td>Individual preferred learning style addressed?: no</td>
</tr>
<tr>
<td><strong>Setting:</strong> Unclear</td>
<td></td>
<td>Numbers on insulin: 19</td>
<td>Normal range(s) for outcomes: see Appendix in text</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td></td>
<td>Tablets: 29</td>
<td>Validated?: QoL yes</td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td></td>
<td>Diet alone: 28</td>
<td>Timing of outcomes same for all groups: yes</td>
</tr>
<tr>
<td>Sessions:</td>
<td></td>
<td>Type of diabetes?: Type 2</td>
<td>Length of follow-up: 18 months from inception</td>
</tr>
<tr>
<td>Groups 2 h once per week for 10 weeks</td>
<td></td>
<td>Duration of diabetes: not recorded</td>
<td>continued</td>
</tr>
<tr>
<td><strong>Treatment intervention:</strong></td>
<td></td>
<td>Baseline measurements of outcome parameter: HbA&lt;sub&gt;1c&lt;/sub&gt;: 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 1.34)</td>
<td>Details not provided: see Appendix in text</td>
</tr>
<tr>
<td><strong>Group 1 (diet):</strong></td>
<td></td>
<td>Gender (M/F): 32/44</td>
<td>How outcomes assessed?: HbA&lt;sub&gt;1c&lt;/sub&gt; laboratory, QoL self-report questionnaire</td>
</tr>
<tr>
<td>Provider: dietician explained the diet</td>
<td>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</td>
<td>Ethnic groups: not reported</td>
<td>Validated?: No</td>
</tr>
<tr>
<td>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</td>
<td>Ethnic groups: not reported</td>
<td>Losses to follow-up: 11 (reasons given)</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>Compliance: average attendance &gt;80% for all groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment changes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training trainers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Group 2 (exercise):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theory:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mode:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment changes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training trainers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Group 3 (diet and exercise):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topics: modified dietary intervention for 5 weeks, then focused on</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference and design</td>
<td>Intervention</td>
<td>Participants</td>
<td>Outcome measures</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------</td>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td></td>
<td>exercise, self-monitoring, foot care and stretching, then followed exercise and behaviour modification format</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment changes:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Training trainers:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Theory:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mode:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Outcomes (18 months)</th>
<th>Group 1 (diet)</th>
<th>Group 2 (exercise)</th>
<th>Group 3 (diet + exercise)</th>
<th>Group 4 (control – education)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c$^a$</td>
<td>8.51</td>
<td>9.46</td>
<td>7.70$^b$</td>
<td>8.57</td>
</tr>
<tr>
<td>QoL (change scores)$^a$</td>
<td>+0.03$^b$</td>
<td>No improvement</td>
<td>+0.06$^b$</td>
<td>–0.04</td>
</tr>
<tr>
<td>Weight</td>
<td>Data not reported, no changes</td>
<td>Data not reported, no changes</td>
<td>Data not reported, no changes</td>
<td>Data not reported, no changes</td>
</tr>
</tbody>
</table>

**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 HbA1c ($r = –0.22, p < 0.05$). 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Source</th>
<th>Country</th>
<th>Setting</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ridgeway, et al., 1999</td>
<td>Journal article</td>
<td>USA</td>
<td>community – ambulatory clinic</td>
<td>English</td>
</tr>
</tbody>
</table>

**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 HbA1c 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; con. 8 (reasons given)

**Compliance**: int. at least 5 classes

**Primary outcomes used**: GHb, QoL

- **(MOS SF-36 and DRP questionnaires)**:

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

**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
<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Samaras et al., 1997&lt;sup&gt;72&lt;/sup&gt;</td>
<td><strong>Treatment intervention:</strong> 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</td>
<td><strong>Eligibility/exclusion criteria:</strong> 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.</td>
<td><strong>Primary outcomes used:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;, QoL (SF-36)</td>
</tr>
<tr>
<td><strong>Source:</strong> published</td>
<td><strong>How selected:</strong> endocrinologists completed questionnaires on all their patients 40–70 years old at routine clinic for 2 months</td>
<td></td>
<td><strong>Secondary outcomes used:</strong> BMI</td>
</tr>
<tr>
<td><strong>Country:</strong> Australia</td>
<td><strong>Numbers involved:</strong> N = 26 [(intervention (int.) 13; control (con.) 13)]</td>
<td></td>
<td><strong>Individual preferred learning style addressed?:</strong> no</td>
</tr>
<tr>
<td><strong>Setting:</strong> Community – hospital outpatient clinic</td>
<td><strong>Numbers on insulin:</strong> int. 3; con. 4; Sulfonylurea: int. 5; con. 5; metformin or diet alone: int. 5; con. 4</td>
<td></td>
<td><strong>Any subgroups (e.g. ethnic groups):</strong> those managed with metformin or diet alone and those taking sulfonylurea or insulin therapy</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td><strong>Type of diabetes:</strong> Type 2</td>
<td></td>
<td><strong>Normal range(s) for outcomes:</strong> not reported</td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td><strong>Duration diabetes:</strong> not reported</td>
<td></td>
<td><strong>How outcomes assessed:</strong> physiological measures laboratory, QoL self-report, activity = meter</td>
</tr>
<tr>
<td></td>
<td><strong>Baseline measurements of outcome parameter (mean ± SE):</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;: 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</td>
<td></td>
<td><strong>Validated?:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt; yes, QoL by SF-36 – validated.</td>
</tr>
<tr>
<td></td>
<td><strong>Gender (M/F):</strong> int. 4/9; con. 6/7</td>
<td></td>
<td><strong>Timing of outcomes same for both groups:</strong> yes</td>
</tr>
<tr>
<td></td>
<td><strong>Age ranges:</strong> int. 60.5 years (SE 7.8); con. 60.5 years (SE 2.1)</td>
<td></td>
<td><strong>Length of follow-up:</strong> 12 months from baseline</td>
</tr>
<tr>
<td></td>
<td><strong>Ethnic groups:</strong> not reported, varied cultural backgrounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Losses to follow-up:</strong> assume none</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Compliance:</strong> full</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Outcome (values are changes from baseline, mean ± SE)

<table>
<thead>
<tr>
<th>Outcome (metabolic equivalents or task)</th>
<th>Intervention group</th>
<th>Control group</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBa1c %</td>
<td>+0.86 (0.29)</td>
<td>+0.86 (0.27)</td>
<td>NS</td>
</tr>
<tr>
<td>QoL</td>
<td>No data presented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>−0.1 (0.5)</td>
<td>+0.29 (0.45)</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>+0.14 (1.09)</td>
<td>+0.79 (1.09)</td>
<td>NS</td>
</tr>
<tr>
<td>Skinfolds</td>
<td>+6.18 (2.2)</td>
<td>−3.7 (4.8)</td>
<td>NS</td>
</tr>
<tr>
<td>% body fat</td>
<td>+1.2 (0.5)</td>
<td>+1.1 (0.9)</td>
<td>NS</td>
</tr>
<tr>
<td>Waist:hip</td>
<td>−0.02 (0.02)</td>
<td>+0.01 (0.001)</td>
<td>NS</td>
</tr>
<tr>
<td>Activity score</td>
<td>+1 (12)</td>
<td>−23 (11)</td>
<td>NS</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>−0.22 (0.27)</td>
<td>−0.33 (0.18)</td>
<td>NS</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/l)</td>
<td>−0.01 (0.04)</td>
<td>−0.07 (0.04)</td>
<td>NS</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)</td>
<td>−0.46 (1.02)</td>
<td>−0.23 (0.23)</td>
<td>NS</td>
</tr>
<tr>
<td>Fasting glucose (mmol/l)</td>
<td>+0.97 (0.64)</td>
<td>+1.5 (0.98)</td>
<td>NS</td>
</tr>
<tr>
<td>Fasting insulin</td>
<td>−3.3 (3.5)</td>
<td>+1.5 (2.2)</td>
<td>NS</td>
</tr>
<tr>
<td>Subgroup: metformin or diet-alone HBa1c (changes from baseline)</td>
<td>+0.4 ± 0.3</td>
<td>+1.5 ± 0.14</td>
<td>( p = 0.02 )</td>
</tr>
<tr>
<td>Subgroup: metformin or diet-alone FBG (changes from baseline)</td>
<td>+1.1 ± 0.3</td>
<td>+3.1 ± 0.4</td>
<td>( p = 0.003 )</td>
</tr>
</tbody>
</table>

### 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
**Appendix 5**

<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Uusitupa, et al., 1992–96</td>
<td>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)</td>
<td>Eligibility criteria: Inclusion: obese, newly diagnosed Type 2 patients aged 40–64 years, FBG levels of ≥6.7 mmol/l</td>
<td>Primary outcomes used: HbA1c</td>
</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td>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</td>
<td>How selected: physicians working in five rural and one urban health centre in Kuopio, referred all newly diagnosed patients from 1987 to 1989</td>
<td>Secondary outcomes used: BP, FBG, weight, BMI, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, food intake, apolipoproteins A1 and B, HDL cholesterol/cholesterol, drug treatment, aerobic capacity</td>
</tr>
<tr>
<td><strong>Country:</strong> Finland</td>
<td></td>
<td>Numbers involved: total n = 86, intervention (int.) 40; control (con.) 46</td>
<td>Individual preferred learning style addressed: no</td>
</tr>
<tr>
<td><strong>Setting:</strong> Hospital outpatient</td>
<td></td>
<td>Numbers on insulin: none. Tablets: 7 (int. = 2; con. = 5) (1 in trial 2268); diet alone: assume 79 (85 in trial 2268)</td>
<td>Any subgroups (e.g. ethnic groups): no</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td></td>
<td>Type of diabetes: Type 2</td>
<td>Normal range(s) for outcomes: not reported</td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td></td>
<td>Duration of diabetes: all newly diagnosed</td>
<td>How outcomes assessed: body weight measured with electric scale; physiological measures by laboratory, BP nurse measured (mean of 3 measurements), food intake self-report</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baseline measurements of outcome parameters – mean (SD): Weight (kg): int. 88.3 (14.1); con. 88.8 (14)</td>
<td>Validated: yes, except self-report measures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BMI: int. 32.0 (5.2); con. 31.6 (4.8)</td>
<td>Timing of outcomes same for both groups: yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FBG (mmol/l): int. 6.6 (1.9); con. 7.5 (2.9)</td>
<td>Length of follow-up: after the 1-year intervention period, patients followed up for a further 12 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FBG adjusted (mmol/l): int. 7.0; con. 7.2</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>% patients with FBG ≤6.7 mmol/l: int. 37.5; con. 26.1</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>HbA1c (%): int. 7.1 (1.8); con. 7.8 (2.0)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>HbA1c adjusted (%): int. 7.4; con. 7.8</td>
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<tr>
<td></td>
<td></td>
<td>% patients with HbA1c ≥7.0%: no data reported</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total cholesterol (mmol/l): int. 6.1 (1.2); con. 6.3 (1.0)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>HDL cholesterol (mmol/l): int. 1.07 (0.25); con. 1.17 (0.29)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Non-HDL cholesterol (mmol/l): int. 5.1 (1.3); con. 5.1 (1.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Triglycerides (mmol/l): int. 2.50 (1.44); con. 2.26 (1.33)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Systolic BP (mmHg): int. 140 (16); con. 137 (16)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Diastolic (mmHg): int. 87 (11); con. 83 (9)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Gender (M/F): int. 21/19; con. 28/18</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Age ranges: 40–64 years. Mean (SD) ages at diagnosis: int. 52.2 (6.5); con. 54.2 (6.5)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Ethnic groups: not reported</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Losses to follow-up: at 2-year follow-up 2 lost in each group. Reasons not given</td>
<td></td>
</tr>
</tbody>
</table>
### Outcome (24 months: int. N = 38, con. N = 44), mean ± SD

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention</th>
<th>Control</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HbA1c (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>6.6 (1.6)</td>
<td>7.5 (1.7)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>7.2 (1.9)</td>
<td>8.0 (1.6)</td>
<td></td>
</tr>
<tr>
<td><strong>HbA1c (%) adjusted</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>6.7</td>
<td>7.3</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>7.4</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td>% patients with HbA1c ≤7.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>74.4&lt;sup&gt;a&lt;/sup&gt;</td>
<td>47.8</td>
<td>&lt;sup&gt;a&lt;/sup&gt; p = 0.005</td>
</tr>
<tr>
<td>24 months</td>
<td>55.3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>31.8</td>
<td>&lt;sup&gt;b&lt;/sup&gt; p = 0.016</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>12 months</td>
<td>31.4 (5.0)</td>
<td>31.9 (4.6)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>31.9 (5.0)</td>
<td>32.2 (4.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Systolic BP (mmHg)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>12 months</td>
<td>137 (16)</td>
<td>144 (18)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>146 (19)</td>
<td>150 (22)</td>
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</tr>
<tr>
<td><strong>Diastolic BP (mmHg)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>83 (9)</td>
<td>85 (9)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>88 (10)</td>
<td>87 (9)</td>
<td></td>
</tr>
<tr>
<td><strong>Total cholesterol (mmol/l)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>6.0 (1.0)</td>
<td>6.4 (1.0)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>6.4 (1.3)</td>
<td>6.5 (1.1)</td>
<td></td>
</tr>
<tr>
<td><strong>HDL cholesterol (mmol/l)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>1.20 (0.29)</td>
<td>1.21 (0.28)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>1.17 (0.24)</td>
<td>1.19 (0.29)</td>
<td></td>
</tr>
<tr>
<td><strong>Non-HDL cholesterol (mmol/l)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>4.8 (1.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>5.2 (1.0)</td>
<td></td>
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</tr>
<tr>
<td><strong>Triglycerides (mmol/l)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>1.96 (0.89)</td>
<td>2.33 (1.19)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>2.34 (1.19)</td>
<td>2.25 (1.25)</td>
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</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>86.5 (13.7)</td>
<td>90.2 (14.3)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>Men (n = 20) 91.8 (10.7); women (n = 18) 83.1 (14.2)</td>
<td>Men (n = 26) 95.1 (10.3); women (n = 18) 84.8 (18.1)</td>
<td></td>
</tr>
<tr>
<td><strong>FBG (mmol/l)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>6.2 (1.8)</td>
<td>7.5 (2.2)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>7.1 (2.4)</td>
<td>8.2 (2.3)</td>
<td></td>
</tr>
<tr>
<td><strong>FBG (mmol/l) adjusted</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>6.4&lt;sup&gt;a&lt;/sup&gt;</td>
<td>7.3</td>
<td>&lt;sup&gt;a&lt;/sup&gt; p &lt; 0.02</td>
</tr>
<tr>
<td>24 months</td>
<td>7.4</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>% patients with FBG ≤6.7 mmol/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>75&lt;sup&gt;a&lt;/sup&gt;</td>
<td>52.2</td>
<td>&lt;sup&gt;a&lt;/sup&gt; p = 0.005</td>
</tr>
<tr>
<td>24 months</td>
<td>55.3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>31.8</td>
<td>&lt;sup&gt;b&lt;/sup&gt; p = 0.016</td>
</tr>
<tr>
<td><strong>Apolipoprotein A1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>1.38 (0.19)</td>
<td>1.41 (0.18)</td>
<td></td>
</tr>
<tr>
<td><strong>Apolipoprotein B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>1.13 (0.24)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.26 (0.27)</td>
<td>&lt;sup&gt;a&lt;/sup&gt; p &lt; 0.02</td>
</tr>
<tr>
<td><strong>HDL cholesterol/total cholesterol</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>0.20 (0.05)</td>
<td>0.19 (0.05)</td>
<td></td>
</tr>
<tr>
<td><strong>Drug treatment (% taking)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>12.5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>34.8</td>
<td>&lt;sup&gt;a&lt;/sup&gt; Significant from control, p = 0.005</td>
</tr>
</tbody>
</table>

Most of the comparisons reported were within groups. Only comparisons between groups are reported below. Self-report outcomes not reported here.
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 HbA1c – 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 HbA1c 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
### Study: Wing et al., 1985

**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, behavioral strategies.  

*Sessions:* weekly for 16 weeks in groups

*Training trainers:*  
*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

*Training trainers:*  
*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

---

### Table: Outcome Measures

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Behaviour group</th>
<th>Nutrition group</th>
<th>Standard care</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>−1.78</td>
<td>−3.03</td>
<td>−3.43</td>
<td>NS</td>
</tr>
</tbody>
</table>

### Results

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

---

### 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
Appendix 5

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

| Study:        | Wing et al., 1986 |
| 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
HbA1 (%) weight control group (N = 21) 10.86 ± 2.00, glucose monitoring group (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%) from weight control group and 3 from glucose monitoring group

Primary outcomes used: HbA1
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 HbA1, 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

medication, but no praise or reinforcement was given for BG control. Sessions as intervention group.

**Duration of intervention:** 12 weeks

### Intervention

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

### Participants

**Weight control group** (*n* = 22)

- HbA1 (%): 10.44 ± 2.16
- FBG (*n* = 22): 210 ± 73.1
- Decreases in medication (%)
  - Oral agents: 64
  - Insulin: 64

**Glucose monitoring group** (*n* = 23)

- HbA1 (%): 10.19 ± 2.29
- FBG (*n* = 22): 216.2 ± 58.7
- Decreases in medication (%)
  - Oral agents: 73
  - Insulin: 83

### Outcome measures

Differences between groups

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Weight control group (<em>n</em> = 22)</th>
<th>Glucose monitoring group (<em>n</em> = 23)</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1 (%)</td>
<td>10.44 ± 2.16</td>
<td>10.19 ± 2.29</td>
<td></td>
</tr>
<tr>
<td>Beck Depression Inventory</td>
<td>No data provided</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBG (<em>n</em> = 22)</td>
<td>210 ± 73.1</td>
<td>216.2 ± 58.7</td>
<td>NS</td>
</tr>
<tr>
<td>Decreases in medication (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral agents: 64</td>
<td>Oral agents: 73</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Insulin: 64</td>
<td>Insulin: 83</td>
<td></td>
</tr>
</tbody>
</table>

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, HbA1 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:** no

**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:** medication, but no praise or reinforcement was given for BG control. Sessions as intervention group.

**Duration of intervention:** 12 weeks

### 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
<table>
<thead>
<tr>
<th>Reference and design</th>
<th>Intervention</th>
<th>Participants</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study:</strong> Wing et al., 1988</td>
<td><strong>Common procedure to both groups:</strong> 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</td>
<td><strong>Eligibility criteria:</strong> <strong>Inclusion:</strong> &gt;20% overweight, 30–65 years old, met NDDG (1979) criteria for Type 2 diabetes</td>
<td><strong>Primary outcomes used:</strong> HbA1c</td>
</tr>
<tr>
<td><strong>Source:</strong> Journal article</td>
<td><strong>Intervention 1: self-regulation education</strong></td>
<td><strong>Numbers involved:</strong> total $N = 20$, int. 1 = 10, int. 2 = 10</td>
<td><strong>Secondary outcomes used:</strong> BMI</td>
</tr>
<tr>
<td><strong>Country:</strong> USA</td>
<td><strong>Topics:</strong> 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. <strong>Provider:</strong> <strong>Sessions:</strong> 13 sessions <strong>Delivery:</strong> in person <strong>Treatment changes:</strong> treatment changes in both groups monitored by physician and followed standard algorithm <strong>Training of trainers:</strong> <strong>Theory:</strong></td>
<td><strong>Numbers on insulin:</strong> 0. Tablets 16; diet alone 4</td>
<td><strong>Individual preferred learning style addressed:</strong> no</td>
</tr>
<tr>
<td><strong>Setting:</strong> Unclear</td>
<td><strong>Intervention 2: self-monitoring education</strong></td>
<td><strong>Type of diabetes:</strong> Type 2</td>
<td><strong>Any subgroups (e.g. ethnic groups):</strong> no</td>
</tr>
<tr>
<td><strong>Language:</strong> English</td>
<td><strong>Duration of diabetes:</strong> not reported</td>
<td><strong>Duration of diabetes:</strong> 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</td>
<td><strong>Normal range(s) for outcomes:</strong> HbA1c 6.1 ± 0.5%</td>
</tr>
<tr>
<td><strong>Trial design:</strong> RCT</td>
<td><strong>Baseline measurements of outcome parameter (mean ± SE):</strong> HbA1c; int. 1 10.57% ± 0.44, int. 2 10.54% ± 0.55 BMI: 35.4 ± 1.05</td>
<td><strong>How outcomes assessed:</strong> laboratory</td>
<td><strong>How outcomes assessed:</strong> yes</td>
</tr>
<tr>
<td></td>
<td><strong>Gender (M/F):</strong> 7/13</td>
<td><strong>Validated:</strong> yes</td>
<td><strong>Timing of outcomes same for both groups:</strong> yes</td>
</tr>
<tr>
<td></td>
<td><strong>Age ranges:</strong> average 53.3 years (range 38–60)</td>
<td><strong>Length of follow-up:</strong> week 68 from inception</td>
<td><strong>Length of follow-up:</strong> week 68 from inception</td>
</tr>
<tr>
<td></td>
<td><strong>Ethnic groups:</strong> not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Losses to follow-up:</strong> 3 in total, 1 in int. 1, 2 in int. 2 (1 death, 2 refusal)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Compliance:</strong> all attended all 16 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
### Outcome (mean ± SE)

<table>
<thead>
<tr>
<th></th>
<th>Intervention 1 (n = 9)</th>
<th>Intervention 2 (n = 8)</th>
<th>Differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1 (%)</td>
<td>10.8 ± 0.8</td>
<td>9.71 ± 0.78</td>
<td>Time × condition interaction, NS (based analysis on baseline of those attending for follow-up)</td>
</tr>
<tr>
<td>Weight (BMI not reported at follow-up) (kg)</td>
<td>86.6 ± 5.6</td>
<td>94.8 ± 5.9</td>
<td>Time × condition interaction, NS (based analysis on baseline of those attending for follow-up)</td>
</tr>
</tbody>
</table>

### Methodological comments

- **Allocation to treatment groups**: not described
- **Blinding of outcome assessors?**: not described – not relevant for HbA1
- **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

**Study:** Gilliland et al., 2002

**Source:** Journal article

**Country:** USA

**Setting:** Community

**Language:** English

**Trial design:** CCT (3 groups)

### Intervention

**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.**
- **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

### 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):**
- **HbA1c:** 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

### Outcome measures

**Primary outcomes used:** HbA1c, 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:** HbA1c not reported

**How outcomes assessed:** laboratory

**Validated:** yes

**Timing of outcomes same for both groups:** yes

**Length of follow-up:** ~1 year from inception

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Continued
<table>
<thead>
<tr>
<th>Outcome groups</th>
<th>FF intervention</th>
<th>OO intervention</th>
<th>Control – usual care (mean ± SD)</th>
<th>Differences between (across 3 arms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1, adjusted mean change</td>
<td>+0.5 (0.3)</td>
<td>+0.2 (0.3)</td>
<td>+1.2 (0.4)</td>
<td>p &lt; 0.05 Combined interventions vs control, p &lt; 0.05</td>
</tr>
<tr>
<td>Weight (lb)</td>
<td>−2.0 (1.5)</td>
<td>−1.8 (1.5)</td>
<td>+1.7 (1.8)</td>
<td>NS Combined interventions vs control, p = 0.05</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>−6.5 (2.0)</td>
<td>−0.4 (1.7)</td>
<td>−0.3 (2.1)</td>
<td>p &lt; 0.05 Combined interventions vs control, NS</td>
</tr>
<tr>
<td>Cholesterol (mg/dl)</td>
<td>−22 (11)</td>
<td>−20 (11)</td>
<td>−10 (16)</td>
<td>NS Combined vs control, NS</td>
</tr>
<tr>
<td>Triglycerides (mg/dl)</td>
<td>−178 (78)</td>
<td>−48 (48)</td>
<td>−69 (63)</td>
<td>NS Combined vs control, NS</td>
</tr>
</tbody>
</table>

**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 HbA1c, in number of patients receiving oral agents, in hypertension. These differences were incorporated into statistical analyses
**Method of data analysis**: ANOVA for continuous variables, χ² or Fisher’s exact tests for discrete variables. Analysis of covariance for intervention differences in HbA1c and weight. Covariates were sex, age, duration of diabetes, medication use, two preintervention determinations of annual change in HbA1c, 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**: Were the groups similar at baseline in terms of prognostic factors? Reported

**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)


Trials excluded owing to inappropriate patient populations (i.e. not adults with Type 2 diabetes)


Trials excluded owing to the nature of the educational intervention (i.e. not an educational programme, insufficient details provided or not reproducible)


Trials excluded owing to the length of follow-up


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

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)

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 α = 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 colleagues67 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 colleagues46 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 α > 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 colleagues52 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 α > 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 colleagues53–55 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 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. An apparent variation of this scale was also used by Ridgeway and colleagues.

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

Ridgeway and colleagues used the Life Skills cognitive knowledge of diabetes test provided by the Diabetes Education Society and approved by the American Diabetes Association.
Health Technology Assessment reports published to date

Volume 1, 1997

No. 1
Home parenteral nutrition: a systematic review.
By Richards DM, Deeks JJ, Sheldon TA, Shaffer JL.

No. 2
Diagnosis, management and screening of early localised prostate cancer.
A review by Selley S, Donovan J, Faulkner A, Coast J, Gillatt D.

No. 3
The diagnosis, management, treatment and costs of prostate cancer in England and Wales.
A review by Chamberlain J, Melia J, Moss S, Brown J.

No. 4
Screening for fragile X syndrome.
A review by Murray J, Cuckle H, Taylor G, Hewison J.

No. 5
A review of near patient testing in primary care.

No. 6
Systematic review of outpatient services for chronic pain control.
By McQuay HJ, Moore RA, Eccleston C, Morley S, de C Williams AC.

No. 7
Neonatal screening for inborn errors of metabolism: cost, yield and outcome.

No. 8
Preschool vision screening.
A review by Snowdon SK, Stewart-Brown SL.

No. 9
Implications of socio-cultural contexts for the ethics of clinical trials.
A review by Ashcroft RE, Chadwick DW, Clark SRL, Edwards RHT, Frith L, Hutton JL.

No. 10
A critical review of the role of neonatal hearing screening in the detection of congenital hearing impairment.
By Davis A, Bamford J, Wilson I, Ramkalawan T, Forshaw M, Wright S.

No. 11
Newborn screening for inborn errors of metabolism: a systematic review.

No. 12
Routine preoperative testing: a systematic review of the evidence.
By Munro J, Booth A, Nicholl J.

No. 13
Systematic review of the effectiveness of laxatives in the elderly.
By Petticrew M, Watt I, Sheldon T.

No. 14
When and how to assess fast-changing technologies: a comparative study of medical applications of four generic technologies.
A review by Mowatt G, Bower DJ, Brehn JA, Cairns JA, Grant AM, McKee I.

Volume 2, 1998

No. 1
Antenatal screening for Down’s syndrome.
A review by Wald NJ, Kennard A, Hackshaw A, McGuire A.

No. 2
Screening for ovarian cancer: a systematic review.
By Bell R, Petticrew M, Luengo S, Sheldon TA.

No. 3
Consensus development methods, and their use in clinical guideline development.

No. 4
A cost-utility analysis of interferon beta for multiple sclerosis.

No. 5
Effectiveness and efficiency of methods of dialysis therapy for end-stage renal disease: systematic reviews.
By MacLeod A, Grant A, Donaldson C, Khan I, Campbell M, Daly C, et al.

No. 6
Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model.

No. 7
Antimicrobial prophylaxis in colorectal surgery: a systematic review of randomised controlled trials.
By Song F, Glenny AM.

No. 8
Bone marrow and peripheral blood stem cell transplantation for malignancy.
A review by Johnson PWM, Simnett SJ, Sweetenham JW, Morgan GJ, Stewart LA.

No. 9
Screening for speech and language delay: a systematic review of the literature.
By Law J, Boyle J, Harris F, Harkness A, Nye C.

No. 10
By Sculpher MJ, Petticrew M, Kelland JL, Elliott RA, Holdright DR, Buxton MJ.

No. 11
Detection, adherence and control of hypertension for the prevention of stroke: a systematic review.
By Ebrahim S.

No. 12
Postoperative analgesia and vomiting, with special reference to day-case surgery: a systematic review.
By McQuay HJ, Moore RA.

No. 13
Choosing between randomised and nonrandomised studies: a systematic review.
By Britton A, McKee M, Black N, McPherson K, Sanderson C, Bain C.

No. 14
Evaluating patient-based outcome measures for use in clinical trials.
A review by Fitzpatrick R, Davey C, Buxton MJ, Jones DR.
No. 15  
Ethical issues in the design and conduct of randomised controlled trials.  
A review by Edwards SJL, Lilford RJ, Braunholtz DA, Jackson JC, Hewison J, Thornton J.

No. 16  
Qualitative research methods in health technology assessment: a review of the literature.  
By Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P.

No. 17  
The costs and benefits of paramedic skills in pre-hospital trauma care.  
By Nicholl J, Hughes S, Dixon S, Turner J, Yates D.

No. 18  
Systematic review of endoscopic ultrasound in gastro-oesophageal cancer.  

No. 19  
Systematic reviews of trials and other studies.  
By Sutton AJ, Abrams KR, Jones DR, Sheldon TA, Song F.

No. 20  
Primary total hip replacement surgery: a systematic review of outcomes and modelling of cost-effectiveness associated with different prostheses.  

Volume 3, 1999

No. 1  
Informed decision making: an annotated bibliography and systematic review.  

No. 2  
Handling uncertainty when performing economic evaluation of healthcare interventions.  
A review by Briggs AH, Gray AM.

No. 3  
The role of expectancies in the placebo effect and their use in the delivery of health care: a systematic review.  

No. 4  
A randomised controlled trial of different approaches to universal antenatal HIV testing: uptake and acceptability.  

No. 5  
Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review.  
By Ukoumunne OC, Lilford MC, Chinn S, Sterne JAC, Burney PGJ.

No. 6  
Assessing the costs of healthcare technologies in clinical trials.  
A review by Johnston K, Buxton MJ, Jones DR, Fitzpatrick R.

No. 7  
Cooperatives and their primary care emergency centres: organisation and impact.  
By Hallam L, Henthorne K.

No. 8  
Screening for cystic fibrosis.  
A review by Murray J, Cuckle H, Taylor G, Littlewood J, Hewison J.

No. 9  
A review of the use of health status measures in economic evaluation.  
By Brazier J, Deverill M, Green C, Harper R, Booth A.

No. 10  
A review by Billingham LJ, Abrams KR, Jones DR.

No. 11  
Antenatal and neonatal haemoglobinopathy screening in the UK: review and economic analysis.  
By Zeuner D, Ades AE, Karmou J, Brown J, Dezateux C, Anionwu EN.

No. 12  
Assessing the quality of reports of randomised trials: implications for the conduct of meta-analyses.  

No. 13  
‘Early warning systems’ for identifying new healthcare technologies.  
By Robert G, Stevens A, Gabbay J.

No. 14  
A systematic review of the role of human papillomavirus testing within a cervical screening programme.  

No. 15  
Near patient testing in diabetes clinics: appraising the costs and outcomes.  
By Griev T, Beech R, Vincent J, Mazurkievic J.

No. 16  
Positron emission tomography: establishing priorities for health technology assessment.  
A review by Robert G, Milne R.

No. 17 (Pt 1)  
The debridement of chronic wounds: a systematic review.  
By Bradley M, Cullum N, Sheldon T.

No. 17 (Pt 2)  
Systematic reviews of wound care management: (2) Dressings and topical agents used in the healing of chronic wounds.  
By Bradley M, Cullum N, Nelson EA, Petticrew M, Sheldon T, Torgerson D.

No. 18  
A systematic literature review of spiral and electron beam computed tomography: with particular reference to clinical applications in hepatic lesions, pulmonary embolus and coronary artery disease.  

No. 19  
What role for statins? A review and economic model.  

No. 20  
Factors that limit the quality, number and progress of randomised controlled trials.  
A review by Prescott RJ, Counsell CE, Gillespie WJ, Grant AM, Russell IT, Kiauka S, et al.

No. 21  
Antimicrobial prophylaxis in total hip replacement: a systematic review.  
By Glenn AM, Song P.

No. 22  
Health promoting schools and health promotion in schools: two systematic reviews.  
By Lister-Sharp D, Chapman S, Stewart-Brown S, Sowden A.

No. 23  
Economic evaluation of a primary care-based education programme for patients with osteoarthritis of the knee.  

Volume 4, 2000

No. 1  
The estimation of marginal time preference in a UK-wide sample (TEMPUS) project.  
A review by Cairns JA, van der Pol MM.

No. 2  
Geriatric rehabilitation following fractures in older people: a systematic review.  
No. 3  Screening for sickle cell disease and thalassaemia: a systematic review with supplementary research.
By Davies SC, Cronin E, Gill M, Greengross P, Hickman M, Normand C.

No. 4  Community provision of hearing aids and related audiology services.
A review by Reeves DJ, Alborz A, Hickson FS, Bamford JM.

No. 5  False-negative results in screening programmes: systematic review of impact and implications.
By Petticrew MP, Sowden AJ, Lister-Sharp D, Wright K.

No. 6  Costs and benefits of community postnatal support workers: a randomised controlled trial.
By Morrell CJ, Spiby H, Stewart P, Walters S, Morgan A.

No. 7  Implantable contraceptives (subdermal implants and hormonally impregnated intrauterine systems) versus other forms of reversible contraceptives: two systematic reviews to assess relative effectiveness, acceptability, tolerability and cost-effectiveness.

No. 8  An introduction to statistical methods for health technology assessment.
A review by White SJ, Ashby D, Brown PJ.

No. 9  Disease-modifying drugs for multiple sclerosis: a rapid and systematic review.
By Clegg A, Bryant J, Milne R.

No. 10  Publication and related biases.
A review by Song F, Eastwood AJ, Gilbody S, Dudley L, Sutton AJ.

No. 11  Cost and outcome implications of the organisation of vascular services.
By Michaels J, Brazier J, Palfreyman S, Shackley P, Slack R.

No. 12  Monitoring blood glucose control in diabetes mellitus: a systematic review.
By Coster S, Guillford MC, Seed PT, Powrie JK, Swaminathan R.

No. 13  The effectiveness of domiciliary health visiting: a systematic review of international studies and a selective review of the British literature.

No. 14  The determinants of screening uptake and interventions for increasing uptake: a systematic review.

No. 15  The effectiveness and cost-effectiveness of prophylactic removal of wisdom teeth.
A rapid review by Song F, O’Meara S, Wilson P, Golder S, Kleijnen J.

No. 16  Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women’s views.

No. 17  A rapid and systematic review of the effectiveness and cost-effectiveness of the taxanes used in the treatment of advanced breast and ovarian cancer.
By Lister-Sharp D, McDonagh MS, Khan KS, Kleijnen J.

No. 18  Liquid-based cytology in cervical screening: a rapid and systematic review.
By Payne N, Chilcott J, McGooagan E.

No. 19  Randomised controlled trial of non-directive counselling, cognitive–behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care.

No. 20  Routine referral for radiography of patients presenting with low back pain: is patients’ outcome influenced by GPs’ referral for plain radiography?
By Kerry S, Hilton S, Patel S, Dundas D, Rink E, Lord J.

No. 21  Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration.
By O’Meara S, Cullum N, Majid M, Sheldon T.

No. 22  Using routine data to complement and enhance the results of randomised controlled trials.
By Lewsey JD, Leyland AH, Murray GD, Boddy FA.

No. 23  Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review.
By Meads A, Cummins C, Jolly K, Stevens A, Burls A, Hyde C.

No. 24  Outcome measures for adult critical care: a systematic review.
By Hayes JA, Black NA, Jenkinson C, Young JD, Rowan KM, Daly K, et al.

No. 25  A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding.
By Fairbank L, O’Meara S, Renfrew MJ, Woolridge M, Sowden AJ, Lister-Sharp D.

No. 26  Implantable cardioverter defibrillators: arrhythmias. A rapid and systematic review.
By Parkes J, Bryant J, Milne R.

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<td>Professor Imti Choonara, Professor in Child Health, Academic Division of Child Health, University of Nottingham</td>
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<td>Professor John Geddes, Professor of Epidemiological Psychiatry, University of Oxford</td>
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<td>Mrs Barbara Geggains, Non-Executive Director, Geggains Management Ltd</td>
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<td>Mrs Sharon Hart, Consultant Pharmaceutical Adviser, Reading</td>
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<td>Dr Jonathan Karnon, Senior Research Fellow, Health Economics and Decision Science, University of Sheffield</td>
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<tr>
<td>Dr Yoon Loke, Senior Lecturer in Clinical Pharmacology, University of East Anglia</td>
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<tr>
<td>Ms Barbara Meredith, Lay Member, Epsom</td>
</tr>
<tr>
<td>Dr Andrew Prentice, Senior Lecturer and Consultant Obstetrician &amp; Gynaecologist, Department of Obstetrics &amp; Gynaecology, University of Cambridge</td>
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<td>Dr Frances Rothblat, CPMP Delegate, Medicines &amp; Healthcare Products Regulatory Agency, London</td>
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<td>Dr Martin Shelly, General Practitioner, Leeds</td>
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<td>Mrs Katrina Simister, Assistant Director New Medicines, National Prescribing Centre, Liverpool</td>
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<td>Dr Richard Tiner, Medical Director, Medical Department, Association of the British Pharmaceutical Industry, London</td>
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### Therapeutic Procedures Panel

**Members**

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Professor Matthew Cooke, Professor of Emergency Medicine, Warwick Emergency Care and Rehabilitation, University of Warwick</td>
</tr>
<tr>
<td>Mr Mark Emberton, Senior Lecturer in Oncological Urology, Institute of Urology, University College Hospital</td>
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<tr>
<td>Professor Paul Gregg, Professor of Orthopaedic Surgical Science, Department of General Practice and Primary Care, South Tees Hospital NHS Trust, Middlesbrough</td>
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<tr>
<td>Ms Maryann L Hardy, Lecturer, Division of Radiography, University of Bradford</td>
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<tr>
<td>Dr Simon de Lusignan, Senior Lecturer, Primary Care Informatics, Department of Community Health Sciences, St George’s Hospital Medical School, London</td>
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<tr>
<td>Dr Peter Martin, Consultant Neurologist, Addenbrooke’s Hospital, Cambridge</td>
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<tr>
<td>Professor Neil McIntosh, Edward Clark Professor of Child Life &amp; Health, Department of Child Life &amp; Health, University of Edinburgh</td>
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<tr>
<td>Professor Jim Neilson, Professor of Obstetrics and Gynaecology, Department of Obstetrics and Gynaecology, University of Liverpool</td>
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<tr>
<td>Dr John C Bumsford, Consultant Physician, Directorate of Medical Services, North Bristol NHS Trust</td>
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<tr>
<td>Dr Karen Roberts, Nurse Consultant, Queen Elizabeth Hospital, Gateshead</td>
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<tr>
<td>Dr Vimal Sharma, Consultant Psychiatrist/Hon. Senior Lecturer, Mental Health Resource Centre, Cheshire and Wirral Partnership NHS Trust, Wallasey</td>
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<td>Professor Scott Weich, Professor of Psychiatry, Division of Health in the Community, University of Warwick</td>
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### Disease Prevention Panel

**Members**

<table>
<thead>
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<tr>
<td>Dr Elizabeth Fellow-Smith, Medical Director, West London Mental Health Trust, Middlesex</td>
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<td>Mr Ian Flack, Director PPI Forum Support, Council of Ethnic Minority Voluntary Sector Organisations, Stratford</td>
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<td>Dr John Jackson, General Practitioner, Newcastle upon Tyne</td>
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<tr>
<td>Mrs Veronica James, Chief Officer, Horsham District Age Concern, Horsham</td>
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<td>Professor Mike Kelly, Director, Centre for Public Health Excellence, National Institute for Health and Clinical Excellence, London</td>
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<td>Professor Yi Mien Koh, Director of Public Health and Medical Director, London NHS (North West London Strategic Health Authority), London</td>
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<td>Mrs Jeanett Martin, Director of Clinical Leadership &amp; Quality, Lewisham PCT, London</td>
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<td>Dr Chris McCall, General Practitioner, Dorset</td>
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<tr>
<td>Dr Carol Tannahill, Director, Glasgow Centre for Population Health, Glasgow</td>
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<td>Professor Margaret Thorogood, Professor of Epidemiology, University of Warwick, Coventry</td>
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<td>Dr Ewan Wilkinson, Consultant in Public Health, Royal Liverpool University Hospital, Liverpool</td>
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Mrs Sheila Clark, Chief Executive, St James’s Hospital, Portsmouth

Mr Richard Copeland, Lead Pharmacist: Clinical Economy/Interface, Wansbeck General Hospital, Northumberland

Dr David Pencheon, Director, Eastern Region Public Health Observatory, Cambridge

Dr Ken Stein, Senior Clinical Lecturer in Public Health, Director, Peninsula Technology Assessment Group, University of Exeter, Exeter

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<td>Professor Douglas Altman, Professor of Statistics in Medicine, Centre for Statistics in Medicine, University of Oxford</td>
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<tr>
<td>Professor John Bond, Director, Centre for Health Services Research, University of Newcastle upon Tyne, School of Population &amp; Health Sciences, Newcastle upon Tyne</td>
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<tr>
<td>Professor Andrew Bradbury, Professor of Vascular Surgery, Solihull Hospital, Birmingham</td>
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<td>Mr Shaun Brogan, Chief Executive, Ridgeway Primary Care Group, Aylesbury</td>
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<td>Mrs Stella Burnside OBE, Chief Executive, Regulation and Improvement Authority, Belfast</td>
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<td>Ms Tracy Bury, Project Manager, World Confederation for Physical Therapy, London</td>
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<td>Professor Lain T Cameron, Professor of Obstetrics and Gynaecology and Head of the School of Medicine, University of Southampton</td>
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<td>Dr Christine Clark, Medical Writer &amp; Consultant Pharmacist, Rossendale</td>
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<td>Professor Collette Clifford, Professor of Nursing &amp; Head of Research, School of Health Sciences, University of Birmingham, Edgbaston, Birmingham</td>
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<td>Professor Barry Cookson, Director, Laboratory of Healthcare Associated Infection, Health Protection Agency, London</td>
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<td>Dr Carl Counsell, Clinical Senior Lecturer in Neurology, Department of Medicine &amp; Therapeutics, University of Aberdeen</td>
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<tr>
<td>Professor Howard Cuckle, Professor of Reproductive Epidemiology, Department of Paediatrics, Obstetrics &amp; Gynaecology, University of Leeds</td>
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<td>Dr Katherine Darton, Information Unit, MIND – The Mental Health Charity, London</td>
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<td>Professor Carol Dezateux, Professor of Paediatric Epidemiology, London</td>
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<td>Dr Keith Dodd, Consultant Paediatrician, Derby</td>
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<td>Mr John Dunnin, Consultant Cardiothoracic Surgeon, Cardiothoracic Surgical Unit, Papworth Hospital NHS Trust, Cambridge</td>
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<td>Professor Gene Feder, Professor of Primary Care Research &amp; Development, Centre for Health Sciences, Barts &amp; The London Queen Mary’s School of Medicine &amp; Dentistry, London</td>
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<td>Mr Leonard R Fenwick, Chief Executive, Newcastle upon Tyne Hospitals NHS Trust</td>
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<td>Mrs Gillian Fletcher, Antenatal Teacher &amp; Tutor and President, National Childbirth Trust, Henfield</td>
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<td>Professor Jayne Franklyn, Professor of Medicine, Department of Medicine, University of Birmingham, Queen Elizabeth Hospital, Edgbaston, Birmingham</td>
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<td>Dr Neville Goodman, Consultant Anaesthetist, Southmead Hospital, Bristol</td>
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<td>Professor Allen Hutchinson, Director of Public Health &amp; Deputy Dean of SchHARR, Department of Public Health, University of Sheffield</td>
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<td>Professor Peter Jones, Professor of Psychiatry, University of Cambridge, Cambridge</td>
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<td>Professor Stan Kaye, Cancer Research UK Professor of Medical Oncology, Section of Medicine, Royal Marsden Hospital &amp; Institute of Cancer Research, Surrey</td>
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<td>Dr Duncan Keeley, General Practitioner (Dr Burch &amp; Partners), The Health Centre, Thame</td>
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<td>Dr Donna Lamping, Research Degrees Programme Director &amp; Reader in Psychology, Health Services Research Unit, London School of Hygiene and Tropical Medicine, London</td>
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<td>Mr George Levy, Chief Executive, Motor Neurone Disease Association, Northampton</td>
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<td>Professor Julian Little, Professor of Human Genome Epidemiology, Department of Epidemiology &amp; Community Medicine, University of Ottawa</td>
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<td>Professor Rajan Madhok, Consultant in Public Health, South Manchester Primary Care Trust, Manchester</td>
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<td>Professor Alexander Markham, Director, Molecular Medicine Unit, St James’s University Hospital, Leeds</td>
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<td>Dr Andrew Mortimore, Public Health Director, Southampton City Primary Care Trust, Southampton</td>
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<td>Dr Sue Moss, Associate Director, Cancer Screening Evaluation Unit, Institute of Cancer Research, Sutton</td>
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<td>Mrs Julietta Patrick, Director, NHS Cancer Screening Programmes, Sheffield</td>
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<td>Professor Robert Peveler, Professor of Liaison Psychiatry, Royal South Hants Hospital, Southampton</td>
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<td>Professor Chris Price, Visiting Professor in Clinical Biochemistry, University of Oxford</td>
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<td>Professor William Rosenberg, Professor of Hepatology and Consultant Physician, University of Southampton, Southampton</td>
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<td>Professor Peter Sandercock, Professor of Medical Neurology, Department of Clinical Neurosciences, University of Edinburgh</td>
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<td>Dr Eamonn Sheridan, Consultant in Clinical Genetics, Genetics Department, St James’s University Hospital, Leeds</td>
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<td>Professor Ala Szczepura, Professor of Health Service Research, Centre for Health Services Studies, University of Warwick</td>
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<td>Dr Ross Taylor, Senior Lecturer, Department of General Practice and Primary Care, University of Aberdeen</td>
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<td>Mrs Joan Webster, Consumer member, HTA – Expert Advisory Network</td>
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E Loveman, GK Frampton and AJ Clegg

April 2008