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Abstract

The clinical and cost-effectiveness of patient education models for diabetes: a systematic review and economic evaluation

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Objectives: To assess the clinical effectiveness and cost-effectiveness of educational interventions for patients with diabetes, compared with usual care or other educational interventions.
Data sources: Electronic databases, reference lists and experts were all consulted in this study. Sponsor submissions to the National Institute of Clinical Excellence were also reviewed.
Review methods: Electronic databases were searched, references of all retrieved articles were checked for relevant studies, and experts were contacted for advice and peer review and to identify additional published and unpublished references. Randomised clinical trials (RCTs) and controlled clinical trials (CCTs) were included if they fulfilled pre-specified criteria, among which was follow-up from inception ≥ 12 months. Data were synthesised through a narrative review because the diversity of studies prevented a meta-analysis.
Results: Twenty-four studies (18 RCTs and six CCTs) that compared education with either a control group or with another educational intervention were included. The quality of reporting and methodology was generally found to be poor by today's standards. As part of treatment intensification, education in Type 1 diabetes (four studies) resulted in significant and long-lasting improvements in metabolic control and reductions in complications. In Type 2 diabetes (16 studies) a diversity of educational programmes did not yield consistent results on measures of metabolic control. Inconsistent results on metabolic control were also found in studies of diabetes of either type (four studies), with studies of lower quality producing significant effects. Few studies evaluated quality of life. Economic evaluations comparing education with usual care or other educational interventions were not identified.
Conclusions: Education as part of intensification of treatment produces improvement in diabetic control in Type 1 diabetes. Mixed results in Type 2 diabetes mean that no clear characterisation is possible as to what features of education may be beneficial. Cost analysis and information from sponsor submissions indicated that where costs associated with patient education were in the region of £500–600 per patients, the benefits over time would have to be very modest to offer an attractive cost-effectiveness profile. Further research should focus on RCTs with clear designs based on explicit hypotheses and with a range of outcomes evaluated after long follow-up intervals.

Contents

List of abbreviations

AADE	American Association of Diabetes Educators
ACD	Association of Clinical Diabetologists
ADA	American Diabetes Association
ANCOVA	covariance analysis
ANOVA	analysis of variance
APT	Automated Psychological Test
BDA	British Diabetic Association (former name for Diabetes UK)
BDI	Beck Depression Inventory
BG	blood glucose
BGSM	blood glucose self-monitoring
BMI	body mass index
BMJ	British Medical Journal
BP	blood pressure
BDTTP	basic diabetes treatment and training programme
CCT	controlled clinical trial
CdR	Condotte di Referimento
CRD	Centre for Reviews and Dissemination
CUA	cost-utility analysis
CVD	cardiovascular disease
DAFNE	dose adjustment for normal eating
DCCT	Diabetes Control and Complications Trial
DES	diabetes education session
DKA	diabetic ketoacidosis
DKNA	Diabetes Knowledge Scale – form A
DLAY	Diabetes Look After Yourself
DQOL	diabetes quality of life measure
DSN	diabetes specialist nurse
DTTP	Diabetes Treatment and Teaching Programmes
D(UK)	Diabetes UK
EQ-5D	EuroQol health state classification questionnaire
ESRD	end-stage renal disease
ETDRS	Early Treatment Diabetic Retinopathy Study
FBG	fasting blood glucose
FF	friends and family
FHQ	Food Habits Questionnaire
FPG	fasting plasma glucose
GFR	glomerular filtration rate
GHb	glycated haemoglobin
HbA_{1c}	glycated haemoglobin A1c
HDL	high-density lipoprotein
Hypo	hypoglycaemic episode
ICT	intensified conventional treatment
IDDM	insulin-dependent diabetes mellitus

IDTTP	intensive diabetes treatment and training programme
ITT	intention-to-treat
LDL	low-density lipoprotein
MANOVA	multivariate analysis of variance
MRC	Medical Research Council
N/A	not applicable
NICE	National Institute for Clinical Excellence
NIDDM	non-insulin-dependent diabetes mellitus
NR	not reported
NS	not statistically significant
OHA	oral hypoglycaemic agent
OO	one-to-one
Pt(s)	patient(s)
QALY	quality-adjusted life-year
QoL	quality of life
QWB	quality of well-being scale
RCT	randomised controlled trial
SD	standard deviation
SDIS	Stockholm Diabetes Intervention Study
SE	standard error
SEM	standard error of mean
SF-36	Short-Form 36 Health Status Questionnaire
SG	standard gamble
SMBG	self-monitoring of blood glucose
TTO	time trade-off
UAER	urinary albumin excretion rate
UGSM	urine glucose self-monitoring
UKPDS	United Kingdom Prospective Diabetes Study
VAS	visual analogue scale
WESDR	Wisconsin Epidemiologic Study of Diabetic Retinopathy
YHEC	York Health Economics Consortium

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

Description of the proposed service

This systematic review examines the clinical and cost-effectiveness of patient education models for adults with Type 1 or Type 2 diabetes.

Epidemiology and background

Diabetes mellitus (diabetes) is characterised by a state of chronic hyperglycaemia (raised blood sugar). There are two main types of diabetes: Type 1 and Type 2. Type 1 diabetes is an autoimmune condition involving a process of destruction of the beta cells of the pancreas, leading to severe insulin deficiency. About one-fifth of patients with diabetes in England and Wales have Type 1 diabetes. Type 2 diabetes is characterised by insulin resistance and relative insulin deficiency and is linked to being overweight or obese, and to physical inactivity. Type 2 diabetes primarily affects people aged over 40 years. The basic target in the treatment of diabetes is the normalisation of blood glucose levels. Poor control of diabetes can in the short term result in diabetic ketoacidosis, a serious and potentially fatal condition, and in the long term can increase the risk of complications such as diabetic retinopathy and nephropathy. However, studies have shown that good diabetic control is associated with a reduced risk of these complications. Diabetic control is affected by both lifestyle factors such as diet, and by pharmacological treatments, and the management of diabetes is largely the responsibility of patients. A key component in empowering patients to manage their own diabetes is education.

Education of patients with diabetes is considered a fundamental aspect of diabetes care and aims to empower patients by improving knowledge and skills. Structured educational programmes for diabetes self-management are often multifaceted interventions providing patients with information not only about diabetes but also management issues such as diet, exercise, self-monitoring of blood glucose and medication use.

Methods

A systematic review of the literature and an economic evaluation were undertaken.

Data sources

Electronic databases were searched, including the Cochrane Library, MEDLINE, EMBASE, PubMed, Science Citation Index, Web of Science Proceedings, DARE and HTA databases, PsychINFO, CINAHL, NHS Economic Evaluation Database and EconLit. References of all retrieved articles were checked for relevant studies, and experts were contacted for advice and peer review and to identify additional published and unpublished references. Sponsor submissions to the National Institute for Clinical Excellence were reviewed.

Study selection

Studies were included if they fulfilled the following criteria:

- Interventions: educational interventions compared with usual care or another educational intervention.
- Participants: adults with Type 1 or 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 $\geq$12 months from inception of intervention.
- Design: randomised clinical trials (RCTs), and controlled clinical trial (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 language or available only as abstracts were excluded.

Titles and abstracts were checked by two reviewers. Full texts of selected studies were assessed for

inclusion by one reviewer and checked by a second. Differences in opinion were resolved through discussion.

Data extraction and quality assessment

Data extraction and quality assessment were undertaken by one reviewer and checked by a second, with any disagreement resolved through discussion involving a third reviewer if necessary. The quality of included studies was assessed in accordance with Centre for Reviews and Dissemination Report 4.

Data synthesis

Data on clinical effectiveness were synthesised through a narrative review with tabulation of results from included studies. Studies were too diverse to be combined in a meta-analysis. Cost-effectiveness analyses were reported in a narrative review.

Number and quality of studies

Searches identified 24 studies comparing education with either a control group or with another educational intervention. These were 18 RCTs and six CCTs. Four studies included adults with Type 1 diabetes, 16 studies included adults with Type 2 diabetes and four studies included adults with either Type 1 or Type 2 diabetes. The quality of reporting and methodology of the studies was generally poor by today's standards with only two RCTs reporting adequate randomisation procedures and none demonstrating adequate allocation concealment.

Economic evaluations

Literature searches identified only two studies reporting cost-effectiveness results: one cost-utility analysis and one cost-effectiveness analysis using intermediate outcomes only.

Summary of benefits

Studies of education in Type 1 diabetes suggest that education programmes offered as a part of intensified treatment interventions can result in significant and long-lasting improvements in metabolic control and reductions in complications. These are studies in which education is part of a package of care also including treatment changes (for example diet and insulin) and therefore it is not possible to draw conclusions about potential effects of education *per se* in Type 1 diabetes.

Diverse educational programmes in Type 2 diabetes did not yield consistent results. Although some trials reported significant improvements in metabolic control and/or quality of life or other psychological outcomes, many others did not report significant effects of educational interventions. No clear characterisation is possible as to what features of education may be beneficial in this patient group.

Studies that included patients with either Type 1 or Type 2 diabetes also produced mixed results with only poorer quality studies reporting significant effects.

Costs

Literature searches identified a small number of studies offering cost data in relation to patient education models. These were all studies undertaken outside the UK and they covered a variety of methodologies. We are not able to generalise from these studies as to the cost-effectiveness of patient education models. Patient education models will predominantly consist of direct costs for resource inputs to particular education packages, for example staff time (diabetes specialist nurse, dietitian and/or consultant) and education materials. The Dose Adjustment for Normal Eating (DAFNE) intervention is estimated to cost approximately £545 per person attending.

Costs per life year gained

Owing to the absence of accurate data on health outcomes, we are not able to provide cost-effectiveness summary statistics. The evidence base does indicate that improved glycaemic control is likely to have a positive impact on the incidence of long-term diabetic complications. Therefore, where the costs associated with patient education are assumed to be in the region of £500–600 per patient, the benefits over time would have to be very modest to offer an attractive cost-effectiveness profile for the intervention. The submission from the DAFNE study group predicts a scenario in which the DAFNE intervention results in cost savings and added health benefits over time, when compared with usual practice.

Implications

The main implication for the NHS would be staff time, particularly of diabetes specialist nurses, but also dietitians. Provision of increased education

may be hindered by a shortage of trained specialist nurses, which will take some years to resolve.

Future research needs

The paucity of high-quality trials that have tested education *per se* in diabetes reveals a need for more research. Such research should focus on RCTs with clear designs based on explicit hypotheses and with a range of outcomes evaluated after long follow-up intervals. In order to draw conclusions about the effects of education alone, such trials should manipulate only education rather than confounding education with other factors.

Chapter 1

Aim of the review

The main aim of this review is to assess the clinical effectiveness and cost-effectiveness of educational interventions for patients with diabetes, compared with usual care or other educational interventions. Potential benefits include improved control of blood glucose (BG) levels as reflected in glycated haemoglobin (HbA_{1c}), fewer short- and long-term complications of diabetes, better self-care and improved quality of life (QoL) or well-being. Education may also lead to improved knowledge of diabetes, although this may not necessarily affect outcomes. The review does not cover educational interventions aimed at preventing Type 2 diabetes. (The HTA programme has commissioned a review of interventions targeted at weight loss in people with obesity and some included studies have looked at Type 2 diabetes.)

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 the pathological mechanisms:

- Type 1 diabetes is a condition in which most or all of the insulin-producing cells in the pancreas have been destroyed, usually due to an auto-immune process. Patients with Type 1 diabetes are 'insulin dependent' and need insulin for survival; it was formerly called insulin-dependent diabetes mellitus (IDDM).[1]

  Type 1 diabetes generally appears before age 40 years[2] and is most often diagnosed in children and adolescents under age 15, but it can occur at any age. The onset of the disease is usually fairly rapid, although the underlying process may be slower.
- 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 mellitus (NIDDM).[1]

  Type 2 diabetes primarily affects people over age 40 years, and tends to have a more gradual onset.[2] Type 2 diabetes may be found incidentally, for example at routine health checks.

  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. It is now being seen at younger ages.[3,4]

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 include increased thirst, increased urination, extreme tiredness, weight loss, genital itching and blurred vision. These symptoms are usually more pronounced in Type 1 diabetes.[2] Type 2 diabetes may 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 acid–base balance. Ketoacidosis requires prompt hospital treatment, and can result in coma and occasionally death. Ketoacidotic coma is more common in Type 1 diabetes. This is the most common cause of death for people with diabetes under the age of 20.[2]
- Hypoglycaemia: means that BG has fallen too low. This is chiefly caused by the inadequacy of current methods of insulin delivery, but can also be also due to too high a dose of oral hypoglycaemic agents (OHAs), inadequate food intake or sudden or sustained exercise, and it can occur without any apparent cause. It is not seen in patients controlled by diet alone. Early symptoms 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. For a small proportion of patients hypoglycaemic coma can occur frequently enough to be incapacitating.

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.[2] Nephropathy may be in decline at least in Type 1 diabetes, but kidney disease may develop in 20–25% of people with diabetes and may progress to kidney failure.[2] 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 2–3-fold higher risk of coronary heart disease in men and a 4–5-fold increased risk in premenopausal women.[2] Stroke risk is increased 2–3-fold.[2]

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. Diabetes also increases the risk of congenital malformations (both fatal and non-fatal) in babies of women with diabetes.

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.[5] The main cause of death is heart disease.[6–8]

Management

The first goal in the treatment of diabetes is the normalisation of BG levels. There is good evidence to show that tight control of BG and blood pressure (BP) can prevent or delay diabetic complications [United Kingdom Prospective Diabetes Study (UKPDS)[9] and Diabetes Control and Complications Trial (DCCT),[10] see Appendix 4]. BG 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. In Type 1 diabetes the balance between insulin, food, and exercise must be maintained if hypoglycaemia is to be avoided. Exercise helps overweight patients with Type 2 diabetes bring their weight under control. Exercise can be used as a mechanism for glycaemic control, particularly in patients who are not taking insulin. Exercise will increase insulin sensitivity, hence reducing insulin resistance.

Insulin therapies and regimens vary. Depending upon the goals of therapy, the frequency of insulin dosing can vary. Recent evidence that tight control of BG levels can prevent or delay serious complications has led to regimens that involve more complex patterns of daily insulin treatment. Insulin pumps may be used to provide insulin on a more continuous basis with boluses at meal times.

Oral hypoglycaemic agents are often prescribed in Type 2 diabetes. Most of these are sulphonylureas. These sensitise the insulin-secreting cells and may upregulate insulin receptors and increase their number.[1] Biguanides also reduce BG by another mechanism, which shows little dependence on the residual effectiveness of insulin-secreting cells.[1] Other oral agents, such as the glitazone drugs, are available and are used as an adjunct to sulphonylureas and biguanides. Sometimes, insulin and biguanide drugs are used in combination (e.g. for obese patients).

Incidence and prevalence

Diabetes is one of the most common chronic disorders, but estimates of incidence and prevalence vary. Diabetes UK [D(UK)] estimates that about 1.4 million people in the UK today have diagnosed diabetes. It is thought that at least 1 million more have diabetes, but have not been diagnosed,[11] although some suggest that this may be an overestimate.[12] The Audit Commission

TABLE 1 *Prevalence of insulin- and non-insulin-treated diabetes per 1000 patients, by age and gender in 1998*

Diabetes	Age (years)	0–4	5–15	16–24	25–34	35–44	45–54	55–64	65–74	75–84	85+
Insulin-treated	Males Rate/1000	0.2	1.7	3.5	4.6	6.2	7.2	10	13.3	10.9	6.8
	Females Rate/1000	0.3	1.9	3.2	4.3	5.2	5.7	9.4	12.1	9.4	5.9
Non-insulin-treated	Males Rate/1000	0	0	0.2	0.6	3.6	11.8	30.5	47.5	47.4	43.1
	Females Rate/1000	0	0	0.2	0.6	2.8	7.9	20.3	35.7	37.1	33.8

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estimated that diabetes affects about 3% of the population, not including those who are undiagnosed.[13] The number of patients with diagnosed diabetes has been increasing significantly in recent years in the UK and worldwide. It has been estimated that the number of people with diabetes will rise from 1.4 million to 3 million by 2010.[13]

- Type 1: the incidence of Type 1 diabetes varies greatly worldwide from as high as 35 per 100,000 in some Scandinavian countries to 2 per 100,000 in Japan. The incidences in Scandinavia and the UK are higher than those in France and Italy.[1]

  If approximately 3% of the population have diabetes and 10–25% of these have Type 1 diabetes, then based on 1999 population estimates about 158,000–395,000 people in England and Wales have Type 1 diabetes.
- Type 2: this form is far more common than Type 1, but estimates for the proportion of people with diabetes who have Type 2 varies from 75 to 90%.[2] The Audit Commission estimates that over 80% of cases are Type 2, with over 1 million people diagnosed in the UK.[13]

  If approximately 3% of the population has diabetes, then based on 1999 population estimates and assuming that between 75 and 90% of patients with diabetes have Type 2, about 1,185,500–1,422,600 people in England and Wales have Type 2 diabetes.

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.

Diabetes is more common in older people. Diabetes may affect as many as 6% of people aged 65 and over.[2] The average age of diagnosis is about 52 in people without a family history and 51 in people with a family history.

Diabetes is slightly more common in men than women. Diabetes seems to remove women's natural protection against heart disease and stroke before the menopause.

Diabetes, especially Type 2, tends to run in families. There is some suggestion, however, that concordance between twins might also arise from shared environments, especially foetal environment.

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

Current service provision

The long-term care required for people with diabetes is organised in different ways in different areas. Traditionally, most patients have been treated in a hospital diabetes clinic. However, with increasing 'shared care', the care of more patients is being shared between hospitals and general practice teams, although this applies mainly to Type 2 diabetes. There are a number of different models for shared care, with varying degrees of involvement from primary care teams. In some areas there are district diabetes centres that are devoted to the care of patients with diabetes throughout the district.

Irrespective of whether patients are cared for in primary care or by a hospital team, it is generally thought that the best care requires a group of

health care professionals including consultant physician, diabetes specialist nurse (DSN), dietitian, podiatrist, general practitioner (GP) and practice nurse. The skills of clinical psychologists, ophthalmologists, nephrologists, neurologists, vascular and orthopaedic surgeons, obstetricians, midwives and other specialists may be called on as necessary.

The goals of management for patients with diabetes include optimisation of BG control, prevention of immediate complications and prevention of long-term complications. The details of management goals should be set by patients and professionals in consultation.

Education

Education of patients with diabetes is considered a fundamental aspect of diabetes care. 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. 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.

D(UK)[14] has produced a list of educational needs at initial diagnosis. Patients should be instructed about the nature of the condition and its treatment, be given advice on adapting lifestyle and be given counselling on the implications of diabetes. Education, however, needs to continue beyond initial diagnosis and to involve access to team members as needed.

DSNs play an important role in providing care. They educate, advise and counsel people with diabetes about all aspects of living with diabetes. They are usually based at a hospital clinic or diabetes centre but also liaise with general practices and visit patients in their homes.

Practice nurses also provide education and advice and work to coordinate care among members of the team. They can also provide social and psychological support for patients and families.

For patients treated with insulin, monitoring BG levels is necessary to try to maintain levels as consistently near normal as possible.[9,10] BG can be checked by means of a simple blood test or, indirectly, 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.

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. Patients must also be aware of the necessity to monitor for complications such as diabetic retinopathy and see that they are regularly screened for these complications.

Recommendations on education from advisory bodies

The National Service Framework has recently published recommendations for standards in diabetes care.[15] Standard 3 states that all patients with diabetes will receive a service that encourages partnership in decision making, supports them in managing their diabetes and helps them to adopt and maintain a healthy lifestyle. It goes on to state that the provision of information, education and psychological support that facilitates self-management is the cornerstone of diabetes care and that structured education should be tailored to the needs of the individual and include skills-based approaches. Such education should be rooted in principles of adult learning, including an appropriate mix of "didactic information giving, active learning, problem-based learning and skills development, as well as group teaching sessions". However, the word 'appropriate' is not defined.

The National Institute for Clinical Excellence (NICE) guidelines for Type 2 diabetes recommend that patients with diabetes should be offered education on an ongoing basis, and that different approaches should be used until there is more certainty about the most effective methods. Their review of the evidence shows that educational provision is better than no provision, and that it is unclear which type of education (e.g. didactic, patient-centred, computer-assisted) has the most impact on outcomes such as metabolic control or knowledge scores. The report points out that many of the reported interventions have been poorly described, without clear evidence of underlying psychological, behavioural or educational theory. Furthermore, follow-up periods have been short, and the patients in the studies have been somewhat heterogeneous.

The Audit Commission report on diabetes services[13] also comes out strongly in favour of

provision of education for all patients with diabetes, and outlines some features of high-quality provision:

- a structured programme, including a written curriculum
- multidisciplinary delivery (including podiatrists and dietitians)
- varied modes of delivery (including both group and one-to-one sessions)
- access for newly diagnosed and established patients
- continuous assessment and a programme for established patients according to their needs
- access to all patients, regardless of who delivers care
- built-in evaluation of each patient's knowledge and self-care.

Various professional bodies have published recommendations for both the infrastructure and the content of diabetes education programmes. For instance, diabetes organisations in the USA recently published national standards for diabetes self-management education[16] in which basic organisational goals were outlined and references were made to detailed curricula available from the American Diabetes Association (ADA) and the American Association of Diabetes Educators (AADE). Similarly, the AADE has published a position statement on the scope of practice and diabetes educators and standards of practice for diabetes educators.[17] A similar formalisation of goals for diabetes care including education is included in the guides to diabetes mellitus from the European Diabetes Policy Group.[18]

Finally, the D(UK) website (www.diabetes.org.uk) advises patients that they should be offered a programme of care "that suits you", and they should be offered education initially (on diagnosis) and on an ongoing basis. There is an emphasis on the diabetes care team working in tandem with the patient and allowing shared decisions of care, based on knowledge and agreed management goals for each individual. A page entitled "your responsibilities" also states that it is the responsibility of each patient to learn about their diabetes and to know how to manage the disease, and when to ask for help.

Thus, there can be little doubt that education is seen to be a pivotal part of the management strategy for all patients with diabetes. However, there is much less agreement as to the best methods by which this can be achieved, owing to an apparent paucity of rigorous research on the subject.

How effectively is diabetes education being provided at present?

The Audit Commission report (2000)[13] found rather variable provision in the nine hospital trusts that they visited, with a particular lack of emphasis on evaluation of the services that were provided. Only five of the trusts had a structured programme, with a written curriculum, and the majority did not involve podiatrists routinely, despite the recognised importance of foot care. Because the nine hospital trusts in this report were chosen to be broadly representative of the range of hospital services available for patients with diabetes across the country, it is likely that the situation described above applies generally. The provision of educational services in general practice was not surveyed in the same detail in this report, and could well be even less comprehensive because of the lack of necessary skills and facilities. Probably most GPs would expect educational services to be provided by their local district general hospital, but this might prove a problem where patients with diabetes are routinely discharged back to GP care.

Examples of currently available education programmes

It is thought that most patients with diabetes in England and Wales are offered education, at least at the time of diagnosis. Some examples of programmes that are available are detailed below, but these may not have had formal evaluation. In addition, the extent to which these programmes are representative of current programmes across the NHS is unknown and these may reflect 'best practice'.

The Diabetes and Endocrine Centre of the Royal Bournemouth Hospital has structured education programmes for patients with Type 1 and Type 2 diabetes. They report that the majority of patients with Type 2 diabetes take up the offer of education, but that uptake is more limited for Type 1 patients – often owing to work commitments. Nevertheless, 70% of newly diagnosed patients with Type 1 diabetes since 1999 have gone through the education programme.

The programme for Type 1 diabetes comprises four afternoon sessions of approximately 4 hours each, led either by a consultant physician or by a DSN, with input from a dietitian. Sessions are a mixture of didactic teaching and practical sessions (e.g. taking a meal together in the hospital canteen and estimating carbohydrate intake), and cover management of diabetes including exercise and nutrition, why good control is important, development of complications and injection techniques.

The programme for Type 2 diabetes is known as the Focus Education Programme and consists of four group education sessions lasting 1.5 hours each. These sessions are run by a DSN, with input from a consultant physician, a podiatrist and a nutritionist. Friends and relatives of the patient are encouraged to attend. Topics covered include 'what is diabetes?', monitoring, healthy eating and complications. The fourth session is an optional in-depth workshop on food labelling, cooking hints and shopping tips.

A similarly structured education programme is available to all new referrals to the local diabetes centre in St Helens and Knowsley. The programme consists of 1 hour per week of either individual and group education for five consecutive weeks. These sessions are run by the diabetes specialist nursing team and dietitians. Topics covered include 'what is diabetes?', control and complications, diet and exercise and medications.

A structured education programme for Type 1 diabetes is currently available in a number of hospitals across England as part of an evaluation. The Dose Adjustment for Normal Eating (DAFNE) group educational programme incorporates skills based training to teach flexible insulin adjustment to match carbohydrate in a free diet on a meal by meal basis. The programme is based on the Diabetes Treatment and Teaching Programmes (DTTP). Developed in Europe in the 1970s, these are often referred to as the Geneva–Düsseldorf models of education and consist of intensive training for patients with Type 1 diabetes.

The programme consists of 5 days of intensive structured training delivered to groups of 6–8 patients. Topics covered include the estimation of the carbohydrate content of meals and participants are taught skills of insulin dose adjustment. The definitive aim of the programme is to achieve patient autonomy. The course is taught by two or three educators (DSNs and dietitians) in each centre. DAFNE is currently undergoing a process of evaluation in England and more details can be found in Appendix 4 and also in Chapter 9.

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 of the context of treatment modifications. For all of 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. We have therefore adopted a pragmatic approach in assessing the efficacy of education for diabetes, and have included packages of care wherein education is only one component. The methodology for the review is detailed in Chapter 3.

The educational interventions considered in this review are all aimed at educating adults with Type 1 or 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 Chapter 3). This review has subdivided the interventions into three groups: interventions for Type 1 diabetes, interventions for Type 2 diabetes and interventions aimed at either Type 1 or Type 2 diabetes.

Interventions for Type 1 diabetes

These interventions all attempt to educate patients on a wide range of topics related to diabetes self-management, including diet, self-monitoring of blood glucose (SMBG), the effects of insulin and exercise.

Interventions for Type 2 diabetes

These trials fell 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).

Interventions for patients with either Type 1 or Type 2 diabetes

These trials also 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).

Owing to the differences in the interventions within each of these groups, more detailed descriptions will be given with the assessment of clinical effectiveness (see Chapters 4–6).

Chapter 3
Methods

Methods for reviewing effectiveness

The methods for reviewing evidence of clinical effectiveness and the economic evaluation are described in the research protocol (Appendix 1). Expert comments were obtained from the review advisory group. Although many helpful comments were received relating to the general content of the research protocol and the included outcomes, there were none that identified specific problems with the methods of the review. Some experts expressed reservations about the focus on controlled trials for the evaluation of what is often a complex intervention, but a review which included all forms of evidence, for example from observational and qualitative studies, would not have been possible within the time and resource constraints for this review and randomised controlled trial (RCT) evidence is usually the most reliable.

The methods outlined in the protocol are summarised below.

Search strategy

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

Studies identified by the search strategy were assessed for inclusion through three stages. The titles of all identified studies were screened by one reviewer and checked by a second reviewer. Abstracts were then screened by two independent reviewers and full-text versions of relevant papers were retrieved. Inclusion criteria were applied by one reviewer and checked by a second reviewer, any differences being resolved through discussion. Owing to the number of eligibility criteria for the review, an inclusion worksheet was utilised for the purpose of applying the inclusion criteria, which can be found in Appendix 3. Data were extracted by one reviewer using a standard data extraction form and checked by a second reviewer. At each stage, any differences in opinion were resolved through discussion. Studies excluded from the review of clinical effectiveness are listed in Appendix 4.

Inclusion and exclusion criteria

Design

RCTs and controlled clinical trials (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.

Intervention

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 include 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 education is delivered (e.g. in person, by computer)
- group or individual
- length of intervention (length and number of sessions)
- target audience (e.g. Type 1, Type 2 or both; newly diagnosed)
- didactic or interactive instruction
- training for the educators.

Educational interventions that were not described in sufficient detail to replicate were not included.

Participants

Participants should have been diagnosed with Type 1 or 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. In some cases the types of diabetes were not clearly defined in trials, in which case these were treated as a separate sub-group of trials. Participants should have been described as 'adults' or a minimum of 80% of participants should be 18 years of age or older.

Quality assessment

The quality of included trials was assessed using criteria recommended by the NHS Centre for Reviews and Dissemination (CRD) (University of York) (Appendix 5).[19] Economic evaluations were assessed using a modified version of the criteria recommended by Drummond and Jefferson.[20] Quality criteria were applied by one reviewer and checked by a second reviewer. Any disagreements were resolved through discussion.

Some changes, additions or points of clarification were made to the methods discussed in the original protocol and these are outlined below:

- As they did not assess patient education *per se*, interventions that were primarily evaluations of patient case management were not included.
- Studies that were available only as unpublished master's theses or doctoral dissertations were not included.

Outcomes considered within clinical effectiveness sections

A range of outcomes has been assessed by the included trials. For ease of understanding these outcomes 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. These outcomes are important indicators of self-management success and serve as surrogate indicators of the risk of long-term complications.

Glycated haemoglobin (GHb) (e.g. HbA_{1c}) is a measure that reflects glucose levels in the blood over a relatively long interval (2–3 months), 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.

Body mass index (BMI) and weight are measures of obesity, which is related to the development of problems in glycaemic control initially and is another risk factor for the development of cardiovascular disease.

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) 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 general deterioration of health or diabetic status.

Episodes of hypoglycaemia or ketoacidosis: patients may have too little glucose in the system or too much. Both of these complications have been discussed previously.

Retinopathy and nephropathy are long-term complications associated with long-term poor regulation of BG. Neuropathy can be an acute or long-term complication.

Rates of hospital admission are an indication of the general health of patients and whether BG is under control.

QoL 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.

Some of the studies assessed these variables with instruments that were not validated. Results using non-validated instruments were not data extracted and will not be discussed. Although there may be some merit in such measures, without formal validation instruments may not be measuring what they claim to measure.

QoL has been measured with a number of validated instruments. These instruments are designed to indicate changes in how patients perceive their QoL. Some instruments are disease-

specific to assess QoL in relation to diabetes whereas others are generic measures.

Measures considered under cognitive 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 included studies are described in more detail in Appendix 6.

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 are randomly assigned to intervention and control groups (RCTs). In this review, CCTs are also considered as long as a control group is evaluated concurrently with the intervention group. Although many studies of diabetes interventions have used designs that have not employed a control group and have 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. These differences cannot be attributed to the intervention and cannot be evaluated in uncontrolled designs.

In addition, it is important that statistical comparisons are made between the intervention and control groups rather than considering within-group changes from baseline. If within-group changes are reported they may reflect not only the effect of an intervention, but also the effect of being in a study or some other factor that is co-varying with the intervention. For instance, changes from baseline in both intervention and control groups suggest something of this sort is occurring. 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. Patients with Type 1 diabetes may have a 'honeymoon period' and may even be able to stop insulin injections for a time, after which control deteriorates again. In designs in which both intervention and control patients might be expected to exhibit changes in variables, it is desirable to use statistical methods that detect relative changes (e.g. interactions between treatment condition and time). Similarly, 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.

Chapter 4

Effectiveness of interventions for Type 1 diabetes

Background

Diabetes treatment aims to maintain BG levels as close as possible to non-diabetic levels and to reduce cardiovascular risk factors including obesity, hypertension, smoking and high blood lipid levels. In addition, patients should have regular ophthalmological and podiatric examinations and maintain appropriate foot care. Most studies of educational interventions have these treatment goals in mind and have measured one or more related variables. In addition, there is a growing awareness of the importance of patients' QoL and a few studies have measured QoL or other more specific indicators of attitudes or psychological well-being.

Trials of self-management interventions

Quantity and quality of evidence

Four studies considering education for patients with Type 1 diabetes met the inclusion criteria for the review (see *Table 2* and Appendix 7). Two of the included studies were RCTs,[21,22] and two were CCTs.[23,24] Only one of the studies was truly a test of an educational intervention.[22] The other three tested the effects of intensified insulin treatment that involved an educational component. Therefore, in three of the studies the effects of education are confounded with the effects of intensified insulin treatment.

The study sample size in the RCTs varied from 37 participants between four study groups in the Terent trial,[22] to 102 between two groups in the Reichard trial.[21] Sample sizes in the CCTs were 181 for three groups in the Starostina trial[24] and 300 between three groups in the Mühlhauser trial.[23] All trials except the Terent were carried out in secondary care. Duration of diabetes across the four included trials ranged from 5[23] to 18 years,[21] with the mean ages of participants being approximately 28 years in all studies. The length of follow-ups from inception of the trial were 12 months,[23] 18 months,[22] 24 months[24] and 10 years in the Stockholm Diabetes Intervention Study (SDIS).[21]

The quality of reporting and methodology of the included studies was generally poor by today's standards (*Tables 3* and *4*). The method of randomisation was unknown in both RCTs, and an attempt at concealment of allocation was made in one.[21] The similarity of groups at baseline and the eligibility criteria were reported in all four included trials. No trial reported analysis by intention-to-treat (ITT).

Description of the intervention

All of these studies involved a full self-management approach to education meaning that they attempted to educate on a wide range of topics related to diabetes self-management. However, the degree of detail in describing the educational interventions varied among reports. In some cases certain assumptions have been made about the nature of the interventions based on reported outcomes or on vague descriptions.

In the one study that specifically assessed the effect of education alone,[22] four groups were randomised. Two groups received a multifaceted education programme consisting of six, 1-hour sessions within 1 month. These were individual sessions that covered the relation between food and BG, insulin and urinary glucose excretion, hypoglycaemic and hyperglycaemic episodes, foot care, injections and urine testing. One of the educated groups and another group not having received the education were also taught about SMBG in an additional session. The groups performing SMBG were "encouraged to change their insulin doses to achieve preprandial values below 7 mmol/l and postprandial values below 10 mmol/l". A final group continued with usual care. The providers for this study were a physician and a dietitian.

Three studies were designed to test the effects of intensified treatment. These interventions relied on education to help patients understand the relationship between eating and insulin. The theory behind these interventions (and the SMBG groups in the Terent study) is that normal metabolic regulation is a constant interplay between food consumption, energy requirements and insulin production. Therefore, these interventions focused on educating patients about

TABLE 2 *Included studies of self-management education interventions for Type 1 diabetes*

Reference	Intervention	Participants	Duration of intervention	Timing of evaluation
Reichard *et al.*, (multiple publications), 1988–96[21] (SDIS) RCT	Two groups: 1. Self-management education with intensified treatment. Physician provided 2 sessions of education to individuals or pairs of 2–3 h. Regular contact over study period via telephone. 2. Usual care: instructed to use SMBG and visited clinic every 4 months, many had frequent contact over study period	102 patients	2 initial education sessions then phone calls every 2 weeks initially, later as required	1.5 years 3 years 5 years 7.5 years 10 years
Terent *et al.*, 1985[22] RCT	Four groups: 1. Self-management education + SMBG 2. Self-management education 3. SMBG 4. Usual care Groups 1 and 2 provided by physician and dietitian for 6 hourly lessons during 1 month. SMBG groups had additional session. Then seen every 3rd month Group 4 seen in clinic every 3rd month	37 patients	1 month	18 months
Mühlhauser *et al.*, 1987[23] (Geneva–Düsseldorf model) CCT	Three groups: 1. Self-management education with intensified treatment. Group education over 5 days, run by DSNs. 2. Self-management education with simple rules for insulin adjustment but 'conventional treatment'. Group education over 4 days, run by DSNs. 3. Usual care. Under care of physician	300 patients	4–5 days	12 months
Starostina *et al.*, 1994[24] (Geneva–Düsseldorf model) CCT	Three groups: 1. Self-management education with intensified treatment + SMBG 2. Self-management education with intensified treatment + urine testing 3. Usual care Groups 1 and 2, 5-day group education provided by 2 physicians Group 3 no details	181 patients	5 days	12 months 24 months

SDIS, Stockholm Diabetes Intervention Study; SMBG, self-monitoring of blood glucose, in which patients are taught how to take a blood sample and test the glucose level.

TABLE 3 *Quality assessment of RCTs of education for Type 1 diabetes*

Study	Randomisation	Concealment of allocation	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values
Reichard *et al.*, 1988–96[21]	Partial	Inadequate	Reported	Yes	Adequate	Partial	Inadequate	Adequate
Terent *et al.*, 1985[22]	Unknown	Unknown	Reported	Yes	Adequate	Partial	N/A	N/A
Not applicable.								

TABLE 4 *Quality assessment of CCTs of education for Type 1 diabetes*

Study	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values	Representativeness
Mühlhauser *et al.*, 1987[23]	Reported	Yes	Unknown	Partial	Unknown	Partial	Yes
Starostina *et al.*, 1994[24]	Reported	Yes	Unknown	Partial	Unknown	Adequate	No

metabolic processes and how to regulate the relation between eating, exercise and insulin doses. Contrary to a set regimen for insulin doses, the goal was to help patients learn how to self-treat with generally more frequent insulin doses that were specifically related to variations in eating. This method of constant patient self-regulation of insulin doses is designed to mimic more closely the natural regulation of insulin production in people who do not have diabetes. Patients were taught to self-monitor glucose levels and to self-adjust insulin doses in relation to their energy consumption and energy demands. In one study[21] goals for BG were set individually with an overall goal to reduce HbA_{1c} to 7%. The two other studies used the Geneva–Düsseldorf model for patient education and self-regulation. In one of these studies there was a comparison between self-monitoring using BG and using urine glucose and in these two studies the potential for liberalising diet was emphasised in relation to self-monitoring and insulin adaptation. The SDIS study also included education on microvascular complications.

The SDIS programme was provided by a physician in two sessions of 2 and 3 hours. These patients were seen in the clinic every 2 months and had frequent face-to-face and telephone contact with the physician (continuous tutoring on demand). The control group were advised to monitor their BG and visited the clinic every fourth month. This intervention lasted for 7.5 years with an additional follow-up at 10 years. This study was essentially an individual intervention, rather than a group one, although the initial education was reported to sometimes be given in pairs.

The two Geneva–Düsseldorf modelled programmes[23,24] were based on a 5-day inpatient group training. The Mühlhauser study[23] involved one group based on the Geneva–Düsseldorf model [intensive diabetes treatment and teaching programme (IDTTP)] and another group [basic diabetes treatment and training programme (BDTTP)] who were trained over 4 days and used urine self-monitoring using locally available materials (Romania). The IDTTP group were explicitly trained in intensified insulin treatment whereas the BDTTP group were instructed on simple rules for self-adjustment of insulin but were described as having conventional insulin therapy. In the Starostina study,[24] one group self-monitored BG (BGSM) and another self-monitored using urine glucose (UGSM). In one study[23] the education was provided by nurses and in the other[24] by physicians. The control group patients received usual care by their physicians (no self-adjustment of insulin doses and usual strict diet recommendations).

TABLE 5 *GHb (%) findings from studies of adults with Type 1 diabetes*[a]

Reference	*n*	Time point	Intervention(s) (mean % ± SEM unless stated otherwise)			Control	Differences between groups
Reichard, *et al.*, 1988–96[21] (SDIS) RCT	Initial total: 102	Baseline	9.5			9.4	
	3 y = 97	18 months	7.5 (from graph)			9.0 (est.)	$p < 0.01$
	5 y = 96	3 y	7.4 (0.1)			9.0 (0.2)	$p < 0.01$
	7.5 y = 89	5 y	7.2 (0.1)			8.7 (0.1)	$p < 0.01$
	10 y = 43	7.5 y	7.1 (0.7)			8.5 (0.7)	$p < 0.01$
		10 y	7.2 (0.6)			8.3 (1.0)	$p < 0.01$
Terent *et al.*, 1985[22] RCT	Initial total: 37 (10/8/9/10)	Baseline	Education + SMBG	SMBG alone	Education alone		
	In analysis: 37 (10/8/9/10)	12 months	12.3 (SD 3.2)	11.8 (SD 1.4)	11.2 (SD 2.0)	11.2 (SD 2.3)	
		18 months	11.0 (SD 2.6)	10.8 (SD 1.0)	9.9 (SD 2.5)	9.5 (SD 3.2)	NS
			10.2 (SD 1.9)	9.8 (SD 3.0)	10.2 (SD 2.1)	10.4 (SD 2.1)	NS
Mühlhauser, *et al.*, 1987[23] CCT	Initial total: 300 (100/100/100)	Baseline	IDTTP	BDTTP			
		12 months	12.3 (0.2)	11.7 (0.2)		12.5 (0.2)	IDTTP: Control $p < 0.01$ IDTTP: BDTTP $p < 0.01$
	In analysis: 287 (98/92/93)		9.3 (from graph)	11.2 (from graph)		12.8 (from graph)	
Starostina, *et al.*, 1994[24] CCT	Initial total: 181 (61/60/60)	Baseline	UGSM	BGSM			
		12 months	12.5 (0.2)	12.6 (0.2)		12.2 (0.2)	
		24 months					
	In analysis: 165 (55/52/58)		9.4 (0.2)	9.3 (0.2)		12.3 (0.2)	Not tested
			9.2 (0.2)	9.2 (0.2)		No data	Not tested

[a] Values may represent HbA_1 or HbA_{1c} (see individual data extraction in Appendix 7 for details).
SEM, standard error of mean; IDTTP, intensive diabetes treatment and teaching programme, a 5-day training with intensified insulin treatment; BDTTP, basic diabetes treatment and training programme, a 4-day training with simple rules for self-adjustment of insulin; UGSM, urine glucose self-monitoring; BGSM, BG self-monitoring; SD, standard deviation; NS, not statistically significant.

Assessment of effectiveness

Outcomes reflecting diabetic control

Table 5 shows the results for GHb for the four studies in Type 1 diabetes. Results are shown with RCT findings preceding CCT findings. Within these groups the results from the largest trials are shown first succeeded by other trials in descending order. The size of the study at the start is shown and the number of patients included in the analyses is indicated with the corresponding results. These conventions will apply throughout the report.

The SDIS followed patients for 7.5 years during the study with a final post-study follow-up at 10 years. The intervention group demonstrated consistently lower HbA_{1c} levels at all points ranging from 1.6% lower to 1.1% lower, p values < 0.01. It should be noted that there was attrition across the evaluation points, but substantial losses were not seen until the 10-year follow-up. At this last assessment point it may be that a non-representative group of patients remained available for evaluation, that is, those most concerned about their illness, or those more interested in education. The decreasing HbA_{1c} levels in the control group over time may also reflect that the least motivated participants were dropping out of the trial. It should also be noted that this study involved more clinic visits for the intervention group and allowed for telephone consultation for the intervention group on demand for the 7.5 years of the study. Therefore, it may be that to achieve these long-lasting results requires some continuous level of contact. However, between the 7.5- and 10-year evaluations the intervention participants returned to routine care.

The Terent study[22] is the only one designed to test an effect of education specifically. There were no significant differences in HbA_1 between groups in this study, but it was a very small study. There is therefore no indication that this educational intervention had any effect on HbA_1. The education provided in this study was relatively brief with relatively long follow-ups (11 and 17 months) without additional intervention. Interestingly, the two groups who were trained to self-monitor BG and were advised to self-regulate their insulin also showed no signs of metabolic improvement over the control group. However, the SMBG training was brief, consisting of only a single session.

In the Mühlhauser study,[23] the group receiving the 5-day training programme and explicitly intensified treatment (IDTTP) had lower HbA_1 levels than either the control group or the group receiving the 4-day programme (BDTTP) and conventional insulin treatment. In the Starostina study[24] the intervention groups appear to have lower HbA_1 levels than the control group; however, between-group comparisons were not conducted. Both of these studies were CCTs.

Based on the SDIS and Mühlhauser results, it appears that educationally based intensive treatment interventions can have long-lasting beneficial effects on HbA_1.

BP

Only one trial reported BP as an outcome. The SDIS reported lower systolic and diastolic BP in the intervention group at both 3- and 5-year follow-ups, but the differences were not compared statistically. At 10 years systolic BP was lower in intervention patients (124.9) than in control patients (132.2), $p < 0.05$. The diastolic BP in intervention patients (74.1) was also marginally lower than in control patients (77.3), $p = 0.085$. However, it should be noted that there was considerable attrition at the 10-year follow-up and that systolic BP was higher at baseline in the patients remaining in the control group.

BMI

Reduction of body weight is often not a treatment goal for Type 1 diabetes, but excessive increase in body weight may be due to overinsulinisation and frequent hypoglycaemia. None of the three studies[23–25] reporting BMI demonstrated reduced BMI in their intervention groups. At the 12-month evaluation, the Mühlhauser study reported significantly higher BMI in their IDTTP group (23.3) than in the BDTTP (22.6) or control (22.4) groups ($p < 0.05$), despite similar body composition at baseline. A similar finding occurred with higher BMIs in the intervention groups than the control group in the Starostina study, but between-group comparisons were not performed. Intensive treatment may result in weight gain but these do not appear to be large effects.

Outcomes reflecting diabetic end-points

Ideally, interventions should help to prevent the complications associated with diabetes. These may be short-term as in hypoglycaemic episodes or long-term as in retinopathy or neuropathy.

Hypoglycaemic episodes

Table 6 shows the reported hypoglycaemic episodes during the intervention period in the Type 1 studies.

A concern when patients are self-regulating their insulin doses and often increasing the doses or frequency of doses is that their BG may fall too low, resulting in a hypoglycaemic episode. The DCCT, an influential large trial of the effects of intensive treatment, concluded that there was an increased risk of hypoglycaemia with this method of treatment.[26]

In the SDIS, the intervention group had a consistently higher percentage of patients with at least one hypoglycaemic episode. These differences were significant at all points except at the 10-year follow-up. The high proportions of patients with hypoglycaemia may be misleading as the figures reported at each follow-up are cumulative. It appears that most of the additional hypoglycaemic episodes in the intervention group occur in the first 3 years, after which there is little if any difference between the groups. Two of the studies reported no significant differences in hypoglycaemic episodes between study groups,[22,23] although the Mühlhauser study did report that their IDTTP intensive treatment group had significantly more patients who had at least one hypoglycaemic episode than their control group. The IDTTP group also had more patients with a history of severe hypoglycaemia at baseline, but this difference was not reported to be significant. Another study[24] reported fewer hypoglycaemia cases in the intervention groups than in the control group at 12 months, but did not statistically test this difference.

Across the studies there is a suggestion that hypoglycaemic episodes may be more frequent in the first few years of intensified treatment.

TABLE 6 *Episodes of hypoglycaemia from studies of adults with Type 1 diabetes*

Study	Outcome	*n*	Time point	Intervention	Control	Differences between groups
Reichard *et al.*, 1988–96[21] (SDIS) RCT	Hypoglycaemic episodes (% of patients with at least one episode)	Initial total: 102 3 y = 97 5 y = 96 7.5 y = 89 10 y = 43	Baseline	NR	NR	
			18 months	48%	22%	$p < 0.01$
			3 y	57%	23%	$p < 0.01$
			5 y	77%	56%	$p < 0.05$
			7.5 y	80%	58%	$p < 0.05$
			10 y	86%	73%	NS
Terent *et al.*, 1985[22] RCT	Hypoglycaemic episodes	Initial total 37 (10/8/9/10) In analysis: 37 (10/8/9/10)		Education + SMBG / SMBG alone	Education alone	
			Baseline	NR	NR	
			12 months	7 in SMBG groups	14 in non-SMBG groups	NS
Mühlhauser *et al.*, 1987[23] CCT	Hypoglycaemic episodes (total no. of patients with at least one episode)	Initial total: 300 (100/100/100) In analysis: 287 (98/92/97)		IDTTP	BDTTP	
			Baseline	NR	NR	NR
			12 months	12	5	6 IDTTP: control $p < 0.05$
Mühlhauser *et al.*, 1987[23] CCT	Hypoglycaemic episodes (total no. of episodes)	Initial total: 300 (100/100/100) In analysis: 287 (98/92/97)		IDTTP	BDTTP	
			Baseline	NR	NR	NR
			12 months	27	5	9 NS
Starostina *et al.*, 1994[24] CCT	Hypo-glycaemia (cases)	Initial total: 181 (61/60/60) In analysis: 165 (55/52/58)		UGSM	BGSM	
			Baseline	2	6	6
			12 months	2	6	8 Not tested
			24 months	8	4	No data Not tested

NR, not reported.

Ketoacidosis

The frequency of diabetic ketoacidosis (DKA) should be reduced by effective treatments and in particular treatments that seek to more closely match insulin dose with metabolic requirements. *Table 7* shows the reported ketoacidotic incidents during the intervention period in the Type 1 studies.

Two studies tested for statistical differences between groups in ketoacidotic incidents. The Terent study reported no significant differences between the education plus SMBG group and the education group, but was likely underpowered. The Mühlhauser study reported that the control group had more patients with DKA and more episodes of DKA than either of the intervention groups.

There is a suggestion that ketoacidotic incidents may be less frequent in the intervention groups, although the evidence is limited.

Hospital admissions

One desirable outcome from a diabetes intervention would be reduction in hospitalisation. This would be indicative of better health.

Two studies reported hospital admission rates, but the Starostina study did not test for between-group differences. The Mühlhauser study reported that fewer patients were hospitalised in the intervention groups (IDTTP, 42; BDTTP, 57) than the control group (84), $p < 0.01$. There were also lower total hospital admissions and days admitted in the intervention groups (IDTTP, 67 admissions/630

TABLE 7 *Incidents of ketoacidosis from studies of adults with Type 1 diabetes*

Study	Outcome	*n*	Time point	Intervention	Control	Differences between groups
Reichard *et al.*, 1988–96[21]	DKA (no. of patients experiencing 1 episode)	Initial total: 102	Baseline	NR	NR	
		7.5 y = 89	7.5 y	1	2	Not tested
		10 y = 43				
RCT			10 y	1	4	Not tested
Terent *et al.*, 1985[22]	DKA	Initial total 37 (10/8/9/10)		Education + SMBG	SMBG alone	Education alone
		In analysis:				
RCT		37 (10/8/9/10)	Baseline	NR	NR	
			12 months	2	3	NS
Mühlhauser *et al.*, 1987[23]	DKA (no. of patients with at least one episode)	Initial total: 300 (100/100/100)		IDTTP	BDTTP	
			Baseline	NR	NR	NR
CCT		In analysis: 287 (98/92/97)	12 months	2	3	13	IDTTP: control, $p < 0.01$ BDTTP: control, $p < 0.05$
Mühlhauser *et al.*, 1987[23]	DKA (total no. of episodes)	Initial total: 300 (100/100/100)		IDTTP	BDTTP	
			Baseline	NR	NR	NR
CCT		In analysis: 287 (98/92/97)	12 months	2	4	16	IDTTP: control, $p < 0.01$ BDTTP: control, $p < 0.05$
Starostina *et al.*, 1994[24]	DKA (cases)	Initial total: 181 (61/60/60)		UGSM	BGSM	
			Baseline	9	10	17	
CCT		In analysis: 165 (55/52/58)	12 months	1	0	16	Not tested
			24 months	0	0		Not tested

days; BDTTP, 100 admissions/967 days; control, 173 admissions/1447 days), p values < 0.01. In addition, hospitalisation was lower in the IDTTP group (5-day education) than in the BDTTP group (4-day education), p values < 0.05. Care is needed in the interpretation of data on hospitalisations, as little detail is reported as to the cause for the hospital stay. However, these results suggest that patients who are intensively self-treating require less hospital treatment than control patients.

Long-term complications

The rates of other complications were reported only in the SDIS as this was the only study with a sufficiently long follow-up. These complications were followed in detail and all reported outcomes can be seen in the data extraction form for this study in Appendix 7. Representative outcomes are reported here.

Retinopathy

The percentage of patients who demonstrated serious retinopathy was significantly lower in the intervention group at both 7.5 years (27%) and 10 years (33%) than the control group (52 and 63%, respectively), p values < 0.01. Mean retinopathy levels (using a 12 grade scale, 0.5–6.0) are shown in *Table 8*.

Differences in mean retinopathy level between the intervention and control groups did not become statistically significant until after 5 years of follow-up.

TABLE 8 *Mean (SEM) retinopathy level in SDIS trial*

Time	Intervention	Control	Difference between groups
Baseline	2.4 (0.1)	2.6 (0.1)	
18 months	2.8 (0.2)	3.2 (0.2)	
3 years	3.2 (0.2)	3.6 (0.2)	NS
5 years	3.5 (0.2)	4.1 (0.2)	$p < 0.05$

TABLE 9 *Mean (SEM) UAER and GFR rates in SDIS trial*

Parameter	Time point	Intervention	Control	Difference between groups
Mean UAER levels (μg/min)	Baseline for 3 y	1.3 (0.1)	1.4 (0.1)	
	3 y[a]	1.3 (0.1)	1.6 (0.1)	$p < 0.05$
	Baseline for 5 y	55.7 (26.7)	74.3 (31.0)	
	5 y	46.0 (26.1)	239.9 (129.7)	$p < 0.05$
	Baseline for 7.5 y	56 (175)	63 (206)	
	7.5 years	45 (110)	119 (219)	$p < 0.05$
GFR (ml/min)	Baseline	122	126	
	3 years	115 (3)	119 (3)	Not tested
	5 years	112 (3)	115 (4)	Not tested
	7.5 years	109 (19)	110 (27)	NS
	10 years	110 (18)	109 (25)	NS

[a] Appears to use a different scale from that used at 5 and 7.5 years, although reported to be μg/min.

TABLE 10 *Number (percentage) of patients who exhibited neuropathy in the SDIS trial*

Time points	Intervention	Control	Difference between groups
Baselines (5 y/7.5 y/10 y)	13/5 (12)/ 2	17/8 (17)/16	
5 y	16	34	$p < 0.01$
7.5 y	6 (14%)	13 (28%)	NS
10 y	14%	32%	$p < 0.05$

Nephropathy

Nephropathy was assessed by 24-hour urinary excretion of albumin (UAER) and by glomerular filtration rate (GFR). These results are shown in *Table 9*.

The UAER was significantly higher in the control group than in the intervention group at 3, 5 and 7.5 years. At the end of the trial (7.5 years), only one patient from the intervention group had UAER levels >200 μg/min compared with nine patients in the control group, $p = 0.01$. Although the mean GFR did not significantly differ between the groups, by 7.5 years six control patients developed a GFR below the normal range whereas none of the intervention patients did, $p = 0.02$.

Neuropathy

Neuropathy was primarily assessed by self-reports from patients. However, nerve conduction velocities were also measured and these results can be found on the data extraction form in Appendix 7. The number of patients who exhibited neuropathy is shown in *Table 10*.

Variable results with regard to the presence of neuropathy can be attributed to the differing number of patients remaining in the evaluation at different time points. At the official end of the trial (7.5 years) there were no significant differences in neuropathy between intervention and control groups. However, at the 10-year follow-up (2.5 years after the trial had ended), among those patients who were available for evaluation there were significantly more patients with neuropathy among the control patients.

Outcomes reflecting QoL and cognitive measures

QoL was not assessed using validated measures in any of the included Type 1 studies. Knowledge was assessed with validated instruments in two studies

TABLE 11 *Knowledge of diabetes from studies of adults with Type 1 diabetes*

Reference	*n*	Time point	Intervention (mean score ± SEM)		Control	Differences between groups
Mühlhauser *et al.*, 1987[23]	Initial total: 300		IDTTP	BDTTP		
	(100/100/100)	Baseline	16 (1)	17 (1)	16 (1)	
CCT	In analysis: 287					
	(98/92/93)	12 months	32 (1)	26 (1)	24 (1)	IDTTP: control, $p < 0.01$ BDTTP: control, $p < 0.01$ IDTTP: BDTTP, $p < 0.05$
Starostina *et al.*, 1994[24]	Initial total: 181 (61/60/60)	Baseline	UGSM 11 (0.1)	BGSM 11 (0.1)	11 (1)	
CCT	In analysis: 165	12 months	25 (1)	26 (1)	11 (1)	Not tested
	(55/52/58)	24 months	25 (1)	26 (1)	No data	

and the results are shown in *Table 11*. A fuller description of the measures used in these two studies can be found in Appendix 6.

In the Mühlhauser study, knowledge scores were higher in the two intervention groups than in the control group and were higher in the IDTTP group than in the BDTTP group. Although knowledge was apparently greater in the intervention groups of the Starostina study, differences from the control group were not statistically tested.

Increased knowledge is undoubtedly a desirable outcome that should reflect greater ability to take part in one's own care and greater confidence in self-care. However, there is little evidence that knowledge alone predicts better metabolic outcomes or reduced complications (e.g. Glasgow and Osteen[27]).

Summary of results from studies in Type 1 diabetes

Three included studies tested interventions that were built on a foundation of education, but that fundamentally were intensified treatment programmes. These interventions focused on helping patients learn the relation between eating and insulin requirements. The goal was to help patients to self-regulate their insulin intake and generally to take more doses of insulin during the day to more closely mimic the non-diabetic state.

The SDIS trial may be of most value in that it was an RCT that continued for a sufficiently long period to assess not only mediating control variables, but also long-term complications. This trial was based on the belief that education provides the means for patients to learn to self-regulate their insulin. The initial training in this trial was less intensive than those based on the Geneva–Düsseldorf model, but high levels of ongoing face-to-face and telephone contact were available to patients meaning that for a long period they were effectively receiving individualised education. The mean contact per patient in the intervention group was 45 minutes/month compared with an average of 10 minutes/month for the control group. Between 3 and 5 years after the start of the study the contact time no longer statistically differed between groups. Therefore, it seems that this study involved on-going education for approximately 3–4 years. This level of individualised contact with patients is not likely to be supportable in most usual care settings.

The SDIS study demonstrated that significant reductions in HbA_{1c}, retinopathy, nephropathy and neuropathy could be achieved. Reductions in HbA_{1c} were long-lasting. The differences in complications generally were not evident until several years into the study, demonstrating the importance of long follow-ups for these kinds of studies. However, similar to the Mühlhauser study, the intervention group had more hypoglycaemic episodes. It should also be noted that this study reported results at each follow-up based on the patients who were still in the trial. Attrition levels for the first 7.5 years were not particularly high and there was little evidence that patients remaining differed from those who did not.

However, it is possible that selective attrition may have left healthier and/or more motivated patients in the intervention group.

Two CCTs also tested an intensified treatment approach. Although one of these studies[24] did not statistically test for differences between intervention and control groups and is therefore of limited value, the results from the SDIS and the other CCT[23] suggest that such education/intensified treatment programmes can have significant and long-lasting effects. In the Mühlhauser study, one group was educated using the Geneva–Düsseldorf model with a 5-day inpatient training and intensified treatment. Because they were educated using a well-documented programme and used usual glucose monitoring materials, this is the most relevant group in comparison with patients who were receiving usual care (no self-adjustment of insulin or self-monitoring). Results 1 year after the training showed that the intervention group had GHb 2.5% lower than the control group, a clinically significant difference. They also had significantly fewer episodes of DKA, fewer hospitalisations and shorter hospital stays. They did, however, have significantly more episodes of severe hypoglycaemia and their BMI was slightly but significantly higher than the control group.

Only one of the four included studies in Type 1 diabetes incorporated a design that allowed an explicit test of the effects of a purely educational intervention. This study[22] did not report some of the statistical comparisons of an education only group against other interventions within the trial. However, the results presented did not indicate that the education only intervention was effective. The education in this case consisted of 6 hours of contact over 1 month and covered a range of diabetes-related topics.

Interventions aimed at self-regulation of insulin in Type 1 diabetes do appear to have significant and long-lasting benefits. These benefits cannot be attributed solely to the education that is offered to the patients, but are more likely due to the associated intensification of insulin treatment. The education involved in treatment intensification programmes is fundamental to their success.

It is of interest that the theoretical motivation behind the intervention with both education and SMBG training in the Terent study was apparently the same as that of the other treatment intensification studies (i.e. to educate about metabolic processes and the relation between eating, exercise and insulin doses). However, the contact time in this study was considerably less overall. This suggests that there may be some minimum level of intensity or overall duration of education that is important to allow patients the ability (perhaps made up of knowledge, experience, confidence, etc.) to achieve self-regulation of insulin that will be beneficial to metabolic control.

Although one programme of intensified treatment (SDIS) has shown long-lasting effects, it would also be of interest to test whether similar effects can be demonstrated in programmes that have initially more intensive training, but without the continuing individualised educational contacts of the SDIS. Unfortunately, no studies using this training method and maintaining a control group for a long follow-up (>2 years) were located. The Starostina study suggests that improved GHb, DKA, hospitalisation rates and knowledge were maintained for 2 years following education and inception of self-regulation of insulin; however, between-group statistical comparisons were not conducted.

Conclusion

Intensified treatment combined with education improves diabetic control and outcomes.

Chapter 5

Effectiveness of interventions for Type 2 diabetes

Background

Generally, the treatment goals for Type 2 diabetes are the same as those for Type 1 diabetes as outlined in Chapter 4. Studies of educational effects in Type 2 diabetes have therefore tended to focus 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. A few studies mentioned that glycaemic control was not a primary goal of the intervention.

In addition to the outcomes discussed previously as being relevant to all studies in diabetes self-management, a few outcomes are specific to Type 2 diabetes. The most important of these is treatment with OHAs. Unlike patients with Type 1 diabetes, patients with Type 2 diabetes are not insulin dependent, although many may eventually be treated with insulin. In most patients with Type 2 diabetes a treatment goal is to minimise or avoid the use of OHAs for as long as possible. It has been suggested that this is important because the insulin-producing beta cells may desensitise over time, lessening the effects of the agents. In addition, the stimulation of these overburdened cells may contribute to their exhaustion. Drug treatment is also more costly and has more side-effects than management with lifestyle changes (e.g. diet and exercise) alone.

Lifestyle changes are therefore a more fundamental element of self-management in Type 2 than in Type 1 diabetes. More emphasis is placed on diet, weight loss and exercise than in Type 1 diabetes.

Sixteen trials 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 and those in which the intervention was focused on one or two aspects of self-management (e.g. diet and/or exercise). The clinical effectiveness of these 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, the setting and so on. There is little consistency among studies that allows for summarising results.

Trials of self-management interventions

Quantity and quality of evidence

Eight studies comparing self-management education for patients with Type 2 diabetes met the inclusion criteria for the review and can be seen in *Table 12* and Appendix 8. Six of these included studies that were RCTs[28–32] (Cooper and colleagues; see footnote to *Table 12*) and two CCTs.[33,34] In the RCTs, study size varied from 51[32] to 256,[28] in the two CCTs study sample sizes were around 125. These two CCTs were evaluating the same underlying programme. Only one included study compared education in more than two groups of patients.[29] The remainder all compared an intervention group with a usual care control group. Three trials were carried out in primary care[28,33,34] two in secondary care,[31,32] one in a university clinic[30] and one across both primary and secondary care (Cooper and colleagues; see footnote to *Table 12*). One trial did not report the setting for the study.[29]

In two studies the duration of diabetes was within 1 year of diagnosis.[29,31] Duration of diabetes in the remaining trials ranged from 5 (Cooper and colleagues; see footnote to *Table 12*) to 10 years.[30] Mean age of participants ranged from 55 to 65 years across all studies. Except for the Trento[30] trial (24 months), length of follow-up from inception was 12 months.

The quality of reporting and methodology of the included studies was generally poor by today's standards (*Tables 13* and *14*). The method of randomisation was unknown in all but one RCT[30]

TABLE 12 *Included studies of self-management education interventions for Type 2 diabetes*

Reference	Intervention	Participants	Duration of intervention	Timing of evaluation
Brown *et al.*, 2002[28] RCT	Two groups: 1. Self-management education. Team provided group education for 52 contact hours 2. Usual care by physicians	256 patients	9 months and 3 months of support group sessions = 12 months	12 months
Campbell *et al.*, 1996[29] RCT	Four groups: 1. Minimal instruction. Team delivered with 2 contact hours 2. Individual education. Team delivered with 8 contact hours 3. Group education. Team delivered with ~4 days total contact time 4. Behavioural programme. One nurse provided at least 6 contact hours	238 patients	Differed between and within groups. Up to 12 months	12 months
Trento *et al.*, 2001[30] RCT	Two groups: 1. Self-management education in groups by a team. Up to 32 contact hours over 2 years 2. Usual care. Seen by physicians every 3 months	112 patients	Varied among patients; up to 2 years	24 months
Cooper *et al.*, unpublished[a] RCT	Two groups: 1. Self-management group education. DSNs delivered with 16 h contact 2. Usual care. No details	89 patients	8 weeks	12 months
Heller *et al.*, 1988[31] RCT	Two groups: 1. Self-management group education (weight loss focus). Delivered by dietitian and DSN with 7.5 contact hours 2. Usual care with physician and also saw dietitian every 3 months	87 patients	6 months	12 months
Raz *et al.*, 1988[32] RCT	Two groups: 1. Self-management group education. Team delivered. Minimum of 12 contact hours 2. Usual care. Follow-up every 2 months	51 patients	12 months	12 months
Domenech *et al.*, 1995[33] CCT (groups from similar medical practices)	Two groups: 1. Self-management education. Group education by physicians. ~7 h contact time 2. Usual care. No details	124 patients	1 month	12 months
Kronsbein *et al.*, 1988[34] CCT (by medical practices with control practices on wait list)	Two groups: 1. Self-management education. Group education by physicians assistants. ~7 contact hours 2. Usual care with GP. No details	127 patients	1 month	12 months

[a] Cooper H, Booth K, Gill G. A randomised controlled study of education for people with Type 2 diabetes: unpublished work, 2002.

TABLE 13 *Quality assessment of RCTs of education for Type 2 diabetes*

Study	Randomisation	Concealment of allocation	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values
Brown *et al.*, 2002[28]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Adequate	Partial
Campbell *et al.*, 1996[29]	Unknown	Unknown	Reported	Yes	Unknown	Partial	Unknown	Reported
Trento *et al.*, 2001[30]	Adequate	Unknown	Reported	Yes	Inadequate	Adequate	Inadequate	Adequate
Cooper *et al.*, unpublished[a]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Inadequate	Partial
Heller *et al.*, 1988[31]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Unknown	Reported
Raz *et al.*, 1988[32]	Unknown	Unknown	Reported	Yes	Adequate	Inadequate	Unknown	Reported

[a] See footnote to Table 12.

TABLE 14 *Quality assessment of CCTs of education for Type 2 diabetes*

Study	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values	Representativeness
Domenech *et al.*, 1995[33]	Reported	Yes	Unknown	Partial	Unknown	Adequate	Yes
Kronsbein *et al.*, 1988[34]	Reported	Yes	Unknown	Adequate	Unknown	Partial	No

and concealment of allocation was not reported in any. The similarity of groups at baseline, and the eligibility criteria were reported in all included trials. Only one study reported an analysis by ITT.[28]

Description of interventions

Although each of the trials apparently developed their interventions independently and without reference to any single theoretical foundation, the interventions were similar in educating patients about a wide range of components of self-management in diabetes. Unfortunately, the descriptions of interventions are often fairly limited and vague. This is despite an attempt to include only trials that provided some detail as to the nature of the intervention. In some cases details of interventions are assumed on the basis of outcomes that are reported or vague descriptions.

Topics that were covered in the intervention arm(s) of all of these studies included: nutrition, diet or importance of weight and self-monitoring (blood and/or urine). The majority of studies also discussed exercise or physical activity[28,29,32–34] (Cooper and colleagues; see footnote to *Table 12*) and complications and/or management of complications.[28,30,31,34] Five studies covered foot care specifically[28,29,33,34] (Cooper and colleagues; see footnote to *Table 12*), three studies included coverage of basic causes and treatment[29,32,34] and four how to handle sick days[28,33,34] (Cooper and colleagues; see footnote to *Table 12*). Two studies[33,34] trained patients to reduce or stop oral agents in the case of hypoglycaemia (Mühlhauser I: personal communication, 2002). Several other topics were incorporated into only one study each.

In most studies several people were involved in providing the training.[28,31–32] These teams were generally made up of physicians, nurses and dietitians. In two studies the interventions were administered by nurses alone[29] (Cooper and colleagues; see footnote to *Table 12*). A physician was the provider for one study[33] and physician's

assistants (no details) provided the intervention in another.[34]

There was considerable variation in the number of hours of contact for each intervention. The interventions also varied in whether sessions were provided over a short interval or were spaced out over time. The study with the least contact time involved four 1-hour sessions that apparently occurred at 3-month intervals.[30] The most brief interventions lasted for 4 weeks.[33,34] Other studies had interventions that involved between 8 and 52 hours of contact time over periods of 3 weeks up to 2 years. Some interventions began with 2–4 more intensive sessions of 90–120 minutes followed up with additional sessions for instance at 3 and 6 months.[29,31,32] One study included four interventions that varied in duration and other characteristics with the shortest intervention being 2 hours and the longest approximately 30 hours of contact.[29]

In all but one study interventions were provided to groups of participants. In the Campbell study,[29] three of the interventions involved individual instruction whereas one intervention was a group intervention (intervention 3).

Most of the studies did not mention that they were based on any particular theory of health psychology or behaviour change. One study was based on patient empowerment (Cooper and colleagues; see footnote to *Table 12*). One used cognitive-behavioural strategies in a behaviour change intervention,[29] and one developed a culturally specific intervention aimed at Mexican Americans based on four meta-analytic reviews of previous diabetes education interventions.[28]

All of these studies attempted to address multiple components of diabetes self-management, but unlike similar interventions applied in patients with Type 1 diabetes 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.

Participants in control groups underwent usual care, most often provided by their physicians or local clinics and received clinic appointments as necessary. In two studies[28] (Cooper and colleagues; see footnote to *Table 12*), the control groups were on the waiting list for the intervention.

Additional characteristics of the studies will be discussed below, as are the results. Attempts will be made to identify characteristics of the studies that might account for differences in obtaining significant effects of interventions, although such suggestions are largely speculative.

Assessment of effectiveness

A wide variety of outcomes were measured across these studies. Only those that were reported in multiple trials or that were judged to be particularly meaningful will be summarised here. For each study all reported outcomes can be found in the data extraction forms in Appendix 8.

Outcomes reflecting diabetic control

Table 15 shows the results for GHb for the included studies of self-management education in Type 2 diabetes.

Only three studies reported significant differences between intervention and control groups in GHb.[28,30,32] All three of these were RCTs. At the 12-month evaluation the intervention group in the Brown study[28] had HbA_{1c} approximately 0.75% lower than the control group. In this study the baseline HbA_{1c} of participants in both groups was high. The intervention group in the Trento study[30] had HbA_{1c} 0.8% lower than the control group at 24 months. Interestingly, the intervention in the Trento 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 poorer BG at the end of the trial. The intervention group in the Raz study[32] had HbA_{1c} 1.35% lower than the control group at 12 months. The other 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 intervention and control groups in some of the studies.

It should be noted that although the Campbell study 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 they cannot be compared with a control group who might also

TABLE 15 *GHb (%) findings from studies of self-management education in adults with Type 2 diabetes*[a]

Study	*n*	Time point	Intervention (mean ± SD unless stated otherwise)	Control	Difference between groups
Brown *et al.*, 2002[28]	Initial total: 256 (128/128)	Baseline	11.81 (3.0)	11.8 (.02)	
RCT	In analysis: 224 (112/112)	12 months	10.89 (2.56) adjusted 10.87	11.64 (.85) adjusted 11.66	$p < 0.05$
Campbell *et al.*, 1996[29]	Initial total: 238 (59/57/66/56)	Reported values are changes from baseline	Minimal education: No follow-up; Individual education: –3.3 (SEM 0.9); Group education: –3.0 (SEM 1.1); Behavioural: –4.8 (SEM 0.7)		
RCT	In analyses: 83 (0/25/19/39)				NS
Trento *et al.*, 2001[30]	Initial total: 112 (56/56)	Baseline	7.4 (1.4)	7.4 (1.4)	
RCT	In analysis: 90 (43/47)	24 months	7.5 (1.4)	8.3 (1.8)	$p < 0.01$
Cooper *et al.*, unpublished[b]	Initial total: 89 In analysis 78 (47/31)	Baseline	7.9 (range 4.5–11)	7.0 (range 4.6–10.6)	
RCT		12 months	7.9 (2.1)	7.2 (1.6)	NS
Heller *et al.*, 1988[31]	Initial total: 87 (40/47)	Baseline	12.3 (95% CI: 11.4 to 13.2)	12.7 (11.9–13.5)	
RCT	In analysis: 75 (36/39)	12 months	9.0 (95% CI: 8.2 to 9.8)	9.9 (8.9–10.9)	NS
Raz *et al.*, 1988[32]	Initial total: 51 (25/26)	Baseline	10.0 (2.7)	9.6 (2.6)	
RCT	In analysis: 49 (23/26)	12 months	8.25 (estimated from graph)	9.6 (from graph)	Time × group interaction: $p < 0.05$
Kronsbein *et al.*, 1988[34]	Initial total: 127 (65/62)	Baseline	7.1(1.6)	6.5 (1.6)	
CCT	In analysis: 99 (50/49)	12 months	7.1 (1.6)	6.7 (1.5)	NS
Domenech *et al.*, 1995[33]	Initial total: 124 (53/71)	Values are changes from baseline	–0.2% (0.4)	+0.8% (0.4)	NS
CCT	In analysis: 79 (40/39)				

[a] Values may represent HbA_1 or HbA_{1c} (see individual data extraction in Appendix 8 for details).
[b] See footnote to Table 12.

have shown improvement and because there is an extremely high attrition rate in this study. It may be that improvements may be attributable to the most motivated patients remaining in the study.

All of the studies that demonstrated significant results were interventions delivered by a team of different professionals, 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.

With one exception (Campbell and colleagues[29]), all of the studies that did not report significant differences had longer intervals from the end of the intervention itself to the follow-up (ranging from 6 months to 48 weeks) than did those that

TABLE 16 *BP findings in studies of self-management education in adults with Type 2 diabetes*

Study	*n*	Time point	Intervention (mean ± SEM unless stated otherwise)				Control	Difference between groups
Campbell *et al.*, 1996[29]	Initial total: 238 (59/57/66/56) In analysis: 64	Values are changes in systolic BP	Minimal education	Individual education	Group education	Behavioural		
RCT	(0/16/11/37)	from baseline	No follow-up	–6.8 (5.8)	–12.4 (6.8)	–16.9 (3.8)		NS
Campbell *et al.*, 1996[29]	Initial total: 238 (59/57/66/56) In analysis: 64	Values are changes in diastolic BP	Minimal education	Individual education	Group education	Behavioural		
RCT	(0/16/11/37)	from baseline	No follow-up	–5.3 (3.0)	–5.0 (4.0)	–7.9 (2.6)		$p < 0.05$ for individual education or group education vs behavioural
Trento *et al.*, 2001[30]	Initial total: 112 (56/56)	No. hypertensive						
	In analysis:	Baseline			34		25	
RCT	90 (43/47)							
		24 months			26		22	NS

reported significant differences between intervention and control groups. Of those reporting significant differences, the Brown study[28] involved the most contact time overall and involved contact at least monthly, the Raz study[32] had three education sessions every 4 months and the Trento study[30] involved four education sessions apparently every 3 months. In other words, among these three studies the longest follow-up without any educational contact was 3 months. These results suggest the possibility that potential effects of educational programmes are either not long-lasting or that the programmes must be delivered such that they are distributed over long intervals. These points are, of course, speculation unless and until they can be tested in experiments in which these interpretations are explicitly tested.

It should be noted that the Brown study,[28] which reported significant effects on HbA_{1c}, did involve the most contact time and it was culturally specific for its target audience of Mexican Americans.

BP

BP was reported in two studies.[29,30] The results are shown in *Table 16*.

The intervention in the Campbell study[29] that involved a behavioural intervention resulted in greater decreases in diastolic BP than in standard group or individual self-management interventions. Whether this is a meaningful difference or whether this effect would be maintained in the long term is unclear. In the Trento study, more patients in the intervention group were no longer considered hypertensive at the end of the study than in the control group. As the difference was not statistically significant, little should be made of this finding. However, there may be a lack of power to detect a difference.

BMI or weight

Outcomes relating to weight or BMI were reported in all included trials and can be seen in *Table 17*.

Four studies[31–34] reported significant differences in BMI or weight (or changes in BMI or weight) between intervention and control groups and one study[30] reported a marginal difference in BMI. In all four studies weight loss was greater in the intervention group than the control group. However, in the Trento study the intervention group had a higher BMI than the control group at both baseline and the 24-month evaluation. Most of the weight losses were not of great magnitude with the exception of those in the Heller study. This study, although educating on multiple aspects of self-management, was primarily directed at weight loss. This programme, starting with individualised weight targets, did produce significant weight loss in the intervention group (5.5 kg); however the control group in the study also lost an average of 3 kg.

Cholesterol and triglycerides

Four studies reported other physiological outcomes,[28–30,32] shown in *Table 18*.

TABLE 17 *BMI or weight findings from studies of self-management education in adults with Type 2 diabetes*

Study	Outcome	*n*	Time point	Intervention (mean ± SD unless stated)				Control	Difference between groups
Brown *et al.*, 2002[28]	BMI	Initial total: 256 (128/128)	Baseline	32.33 (5.97)				32.12 (6.35)	
RCT		In analysis: 227 (113/114)	12 months	32.17 (6.45)				32.28 (6.52)	NS
Campbell *et al.*, 1996[29]	BMI	Initial total: 238 (59/57/66/56)	Values are changes in	Minimal education	Individual education	Group education	Behavioural		
RCT		In analysis: 96 (0/30/25/41)	BMI from baseline	No follow-up	–2.0 (SEM 0.4)	–1.4 (SEM 0.5)	–2.6 (SEM 0.5)		NS
Trento *et al.*, 2001[30]	BMI	Initial total: 112 (56/56)	Baseline	29.7 (4.5)				27.8 (4.1)	
RCT		In analysis: 90 (43/47)	24 months	29.0 (4.4)				27.6 (4.2)	$p = 0.06$
Cooper *et al.*, unpublished[a]	BMI	Initial total: 89	Baseline	32.5 (6.7)				32.1 (6.1)	
RCT		In analysis 78 (47/31)	12 months	31.3 (5.7)				30.5 (3.9)	NS
Heller *et al.*, 1988[31]	Weight (kg)	Initial total: 87 (40/47)	Values are change in weight from	(Mean and 95% CI) –5.5 (4 to 6.5)				–3 (2–4)	$p < 0.05$
RCT		In analysis: 75 (36/39)	baseline						
Raz *et al.*, 1988[32]	Weight (kg,12 months, data from figure)	Initial total: 51 (25/26)	Baseline	75.4 (11.7)				73.4 (11.5)	Time/ group interaction: $p < 0.05$
RCT		In analysis: 49 (23/26)	12 months	73				73	
Kronsbein *et al.*, 1988[34]	Weight (kg)	Initial total: 127 (65/62)	Baseline	76.5 (12.6)				75.1 (12.9)	Diff. in change, $p < 0.01$
CCT		In analysis: 99 (50/49)	12 months	73.8 (12.6)				74.8 (13.2)	
Domenech *et al.*, 1995[33]	Weight (kg)	Initial total: 124 (53/71)	Values are change in weight from	–2.4 (0.5)				–0.4 (0.5)	$p < 0.01$
CCT		In analysis: 79 (40/39)	baseline						

[a] See footnote to Table 12.

Only one trial reported any significant difference in cholesterol or triglycerides between intervention and control groups. Trento and colleagues[30] reported in the text that high-density lipoprotein (HDL) cholesterol was lower in intervention patients at 24 months, but this is inconsistent with values reported in the results table in which an increase in HDL cholesterol is reported for intervention patients between baseline and follow-up whereas it remained the same in control participants. The same study reported that triglycerides were marginally lower in the intervention patients than in control patients. Values reported in the results table suggest that triglycerides were reduced in the intervention group whereas they remained the same in the control group. However, triglycerides were higher at baseline and at follow-up for the intervention group than for the control group.

TABLE 18 *Cholesterol and triglyceride findings from studies of self-management education in adults with Type 2 diabetes*[a]

Study	Outcome	*n*	Time point	Intervention (mean ± SD unless stated)	Control	Difference between groups
Brown *et al.*, 2002[28] RCT	Cholesterol (mmol/l)	Initial total: 256(128/128) In analysis: 225 (112/113)	Baseline	21.7 (2.5)	11.3 (2.7)	
			12 months	10.5 (2.0)	10.4 (2.4)	NS
Campbell *et al.*, 1996[29] RCT	Cholesterol (mmol/l)	Initial total: 238 (59/57/66/56) In analysis: 76 (0/23/19/34)	Values are changes from baseline	Minimal education No follow-up: 0.12 (SEM 0.20); Individual education: 0.16 (SEM 0.16); Group education: –0.33 (SEM 0.15); Behavioural		NS
Campbell *et al.*, 1996[29] RCT	HDL cholesterol (mmol/l)	Initial total: 238 (59/57/66/56) In analysis: 64 (0/21/16/27)	Values are changes from baseline	Minimal education No follow-up: 0.02 (SEM 0.04); Individual education: 0.18 (SEM 0.10); Group education: 0.06 (SEM 0.08); Behavioural		NS
Campbell *et al.*, 1996[29]	Cholesterol risk ratio (total/HDL)	Initial total: 238 (59/57/66/56) In analysis: 61 (0/21/15/25)	Values are changes from baseline	Minimal education No follow-up: –0.25 (SEM 0.03); Individual education: –0.35 (SEM 0.46); Group education: –0.59 (SEM 0.20); Behavioural		NS
Trento *et al.*, 2001[30]	Total cholesterol (mmol/l)	Initial total: 112 (56/56)	Baseline	5.8 (1.1)	5.5 (0.9)	
		In analysis: 90 (43/47)	24 months	5.7 (1.2)	5.6 (1.2)	NS
Trento *et al.*, 2001[30] RCT	HDL cholesterol (mmol/l)	Initial total: 112 (56/56)	Baseline	1.2 (0.3)	1.3 (0.3)	
		In analysis: 90 (43/47)	24 months	1.4 (0.4)	1.3 (0.3)	$p < 0.05$
Raz *et al.*, 1988[32] RCT	Mean blood cholesterol (mmol/l)	Initial total: 51 (25/26)	Baseline	12.5 (2.4)	12.2 (3.1)	
		In analysis: 49 (23/26)	12 months	11.8 (2.1)	12.5 (3.4)	NS
Raz *et al.*, 1988[32] RCT	HDL cholesterol (mmol/l)	Initial total: 51 (25/26)	Baseline	2.6 (0.2)	2.5 (0.2)	
		In analysis: 49 (23/26)	12 months	2.7 (0.2)	2.5 (0.2)	NS
Brown *et al.*, 2002[28] RCT	Triglyceride (mmol/l)	Initial total: 256(128/128)	Baseline	11.9 (7.2)	10.8 (6.6)	
		In analysis: 226 (113/113)	12 months	11.9 (10.8)	11.0 (8.2)	NS
Trento *et al.*, 2001[30] RCT	Triglyceride (mmol/l)	Initial total: 112 (56/56)	Baseline	2.6 (0.7–11.5)	1.7 (0.5–5.2)	
		In analysis: 90 (43/47)	24 months	2.1 (0.7–6.9)	1.7 (0.6–3.9)	$p = 0.053$

continued

TABLE 18 *Cholesterol and triglyceride findings from studies of self-management education in adults with Type 2 diabetes (cont'd)*

Study	Outcome	*n*	Time point	Intervention (mean ± SD unless stated)	Control	Difference between groups
Raz *et al.*, 1988[32] RCT	Blood triglycerides (mmol/l)	Initial total: 51 (25/26) In analysis: 49 (23/26)	Baseline	12.8 (1.8)	11.7 (1.9)	
			12 months	11.8 (1.3)	11.3 (1.7)	NS

[a] Cholesterol levels are presented here in mmol/l with the conversion rate of 1 mg/dl = 0.0555 mmol/l having been used.

Oral hypoglycaemic treatment

Stopping oral agent therapy was an explicit objective of the programme in two studies.[33,34] Both reported significant differences in the use of medications between intervention and control groups. In the Kronsbein study[34] no patients in the intervention group were on insulin at follow-up whereas 10 of 49 patients in the control group were. In the same study 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 study[33] intervention patients had reduced their average daily intake of OHAs (–1.4 ± 0.2 tablets) while the control group had increased intake (+0.9 ± 0.2 tablets).

Interestingly, these studies were both CCTs rather than RCTs. In the Kronsbein study 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 study the intervention and control patients were treated by the same physicians, however, there was no blinding as to which patients were in which group. Surprisingly, these two interventions were also the most brief, consisting of only 6–8 hours of education over 4 weeks.

Outcomes reflecting diabetic end-points

Very few of these studies included complications as outcomes, usually because the follow-up in these studies was too short. However, those that were reported are shown in *Table 19*.

There were no differences between intervention and control groups for any of these outcomes.

Outcomes reflecting QoL 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 QoL and knowledge effects using validated instruments are shown in *Table 20* and details of these measures are given in Appendix 6.

Only one study[30] reported on QoL using a validated scale. 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 of follow-up from inception; however, educational sessions were conducted every 3 months throughout the 2-year period. This intervention did apparently improve patients' QoL whereas QoL appeared to deteriorate in the control group.

Two of three studies[30,34] reporting results for knowledge measures demonstrated that intervention patients had higher knowledge of diabetes than the control patients. This is desirable as 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 (e.g. Glasgow and Osteen[27]).

Only one trial reported any additional validated QoL measures (Cooper and colleagues; see footnote to *Table 12*). That study reported significantly better attitudes to diabetes and its treatment in the intervention group at 12 months [baseline 72.8 (SD 13.2), 12 months 75.1 (SD 11.0)] than the control group [baseline 76.7 (SD 14.2), 12 months 70.5 (SD 11.0)], $p < 0.01$. This test measures the integration of diabetes and its treatment into the lifestyle and personality of the patient. Higher scores indicate better psychological adjustment to diabetes.

TABLE 19 *Diabetic end-points from studies of self-management education in adults with Type 2 diabetes*

Study	Outcome	*n*	Time point	Intervention	Control	Difference between groups
Trento *et al.*, 2001[30] RCT	Diabetic retinopathy (none/mild/more severe)	Initial total: 112 (56/56) In analysis: 90 (43/47)	Baseline 24 months	42/8/6 35/5/3	38/13/5 33/7/7	 NS
Trento, *et al.*, 2001[30] RCT	Foot ulcers (never/past/active)	Initial total: 112 (56/56) In analysis: 90 (43/47)	Baseline 24 months	54/0/2 42/1/0	53/2/1 45/1/1	 NS
Campbell *et al.*, 1996[29] RCT	Proportion consulting ophthal-mology (%)	Initial total: 238 (59/57/66/56) In analysis: 122 (0/38/37/47)	Baseline 12 months	Minimal education / Individual education / Group education / Behavioural NR / NR / NR / NR No follow-up / 97 / 95 / 89		 NS
Campbell *et al.*, 1996[29] RCT	Proportion consulting podiatry (%)	Initial total: 238 (59/57/66/56) In analysis: 103 (0/31/30/42)	Baseline 12 months	Minimal education / Individual education / Group education / Behavioural NR / NR / NR / NR No follow-up / 55 / 73 / 74		 NS

TABLE 20 *QoL and knowledge from studies of self-management education in adults with Type 2 diabetes*

Study	Outcome	*n*	Time point	Intervention (mean ± SD unless stated otherwise)	Control	Difference between groups
Trento *et al.*, 2001[30] RCT	DQOL	Initial total: 112 (56/56) In analysis: 90 (43/47)	Baseline 24 months	67.6 (19) 55.6 (15.9)	66.7 (25) 80.8 (31.5)	 $p < 0.01$
Campbell *et al.*, 1996[29] RCT	Knowledge	Initial total: 238 (59/57/66/56) In analyses: 90 (0/29/26/35)	Values are changes from baseline	Minimal education / Individual education / Group education / Behavioural No follow-up / 4.4 (SEM 0.6) / 4.2 (SEM 0.5) / 5.6 (SEM 0.6)		 NS
Trento *et al.*, 2001[30] RCT	Knowledge	Initial total: 112 (56/56) In analysis: 90 (43/47)	Baseline 24 months	14.9 (7.9) 24 (6.6)	20.2 (7.4) 17.4 (8.6)	 $p < 0.01$
Kronsbein *et al.*, 1988[34] CCT	Knowledge	Initial total: 127 (65/62) In analysis: 99 (50/49)	Baseline 12 months	9 (3) 13 (4)	9 (3) 10 (4)	 $p < 0.01$

DQOL, diabetes quality of life measure.

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 24 months and another made a comparison of four different educational interventions over 12 months. In general, findings demonstrated limited impact on outcomes.

Some effect of education on diabetic control, as measured by HbA_{1c}, was demonstrated; however, these appear to be mostly attributable to longer term interventions with a shorter duration from the intervention's conclusion to the evaluation. There was little effect on weight loss. Two studies reported reduced usage of OHAs in the intervention groups.

Very few studies reported outcomes relating to diabetic end-points. No significant effects were demonstrated.

Patients' QoL was assessed with a validated measure in only one trial. QoL was better in the intervention group than the control group. Knowledge was found to be higher among participants in the intervention groups in two 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 have attempted to address specific, limited topics in diabetes self-management.

Quantity and quality of evidence

Eight studies (seven RCTs, one CCT) comparing more focused self-management education for patients with Type 2 diabetes met the inclusion criteria for the review and can be seen in *Table 21* and Appendix 8. These interventions focused on diet and exercise (four studies[35–37,42]), diet,[38] exercise,[40] weight versus self-regulation[41] or weight versus SMBG.[39] Study sample sizes were generally small, varying from 20[41] to 104.[42] Three of the included studies compared education in more than two groups of patients.[35,38,42] All trials that reported the study setting carried out the trial in primary care. Two trials did not report the setting.[35,41] Duration of diabetes was not widely reported. In the four trials that report duration this ranged from newly diagnosed[36] to 13 years.[37] The majority of trials followed up their participants for 12 months from inception, the follow-up was 18 and 24 months in the Kaplan and Uusitupa trials, respectively.

The quality of reporting and methodology of the included studies was poor by today's standards (*Tables 22* and *23*). No details of an adequate method of randomisation or concealment of allocation was 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 intention to treat.

Description of interventions

These interventions, owing 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 are vague or incomplete. Some assumptions as to the interventions have been made based on outcomes or vague descriptions.

Interventions for diet and exercise

Four studies focused on diet and exercise.[35–37,42] Detailed dietary education was provided in each of these studies and two of the four[36,37] used individualised dietary programmes. Another[35] used the ADA exchange diet. Little detail of the nature of the dietary education was reported in the fourth study.[42]

Exercise programmes were individualised in two of the studies[35,37] and in one other[36] 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.[42] Three of these interventions used behaviour modification principles to greater or lesser extents. One study[35] required a monetary deposit that was returned with the meeting of goals and meeting attendance. One used contracts[37] and the other[36] used food records.

These studies all involved at least some group work.

TABLE 21 *Included studies of focused self-management education for Type 2 diabetes*

Reference	Intervention	Participants	Duration of intervention	Timing of evaluation
Kaplan *et al.*, 1987[35] RCT	Four groups: 1. Group diet education. Dietitian delivered. 20 contact hours 2. Group exercise education. Contact hours not given 3. Group diet and exercise education over 5 weeks, no details of contact time 4. Control education in group with team – each gave a lecture. ~14 contact hours	87 patients	10 weeks	18 months
Uusitupa *et al.*, 1992–6[36] RCT	Two groups: 1. Diet and exercise education. Provided by a team. Contact = 6 clinic visits (duration not given) 2. Usual care control. Local health centre visits every 2–3 months + outpatient clinics (both groups given basic diabetes education)	86 patients	12 months	24 months
Ridgeway *et al.*, 1999[37] RCT	Two groups: 1. Group diet and exercise education. Nurse and dietitian delivered. 9 contact hours 2. Usual care control. No details	56 patients	6 months	12 months
Wing *et al.*, 1985[38] RCT	Three groups: 1. Diet – behaviour modification 2. Nutrition education 3. Usual care (with nutrition education) Groups 1 and 2 = group education provided by psychologist and nutritionist. Contact = 16 weekly sessions Group 3 = content identical with (2) but only 4 monthly meetings	53 patients	16 weeks	16 months
Wing *et al.*, 1986[39] RCT	Two groups: 1. Diet – weight control. Contact time not given 2. Diet – SMBG. Contact time ~20 meetings	50 patients	12 months	62 weeks
Samaras *et al.*, 1997[40] RCT	Two groups: 1. Exercise education. Group sessions provided by a team. Contact time ~6 h 2. Usual care. Routine clinic visits + 3 assessment visits (no details of duration)	26 patients	6 months	12 months
Wing, *et al.*, 1988[41] RCT	Two groups: 1. SMBG with education on meaning of SMBG (self-regulation), 13 sessions 2. SMBG (self-monitoring). Contact time not given	20 patients	10 months	68 weeks
Gilliland *et al.*, 2002[42] CCT	Three groups: 1. Friends and family (FF). Group culturally appropriate diet and exercise education with support 5 sessions, one every 6 weeks, for ~2 h 2. One-on-one (OO). Individual culturally appropriate diet and exercise education. 5 sessions, once every 6 weeks for ~45 minutes. 3. Usual care control (some education but not culturally appropriate and no details given)	104 Mexican American patients	10 months	12 months

TABLE 22 *Quality assessment of RCTs of focused education for Type 2 diabetes*

Study	Randomisation	Concealment of allocation	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values
Kaplan *et al.*, 1987[35]	Unknown	Unknown	Reported	Yes	Unknown	Inadequate	Unknown	Reported
Uusitipa *et al.*, 1993[36]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Inadequate	Unknown
Ridgeway *et al.*, 1999[37]	Unknown	Unknown	Reported	Yes	Unknown	Inadequate	Inadequate	Adequate
Wing *et al.*, 1985[38]	Unknown	Unknown	Reported	Yes	Unknown	Partial	Unknown	Partial
Wing *et al.*, 1986[39]	Unknown	Unknown	Reported	Yes	Adequate	Partial	Unknown	Reported
Samaras *et al.*, 1997[40]	Unknown	Unknown	Reported	Yes	Unknown	Partial	N/A	N/A
Wing *et al.*, 1988[41]	Unknown	Unknown	Reported	Yes	N/A	Partial	Inadequate	Partial

TABLE 23 *Quality assessment of CCT of focused education for Type 2 diabetes*

Study	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values	Representativeness
Gilliland *et al.*, 2002[42]	Reported	Yes	Unknown	Adequate	Inadequate	Partial	No

Providers of the interventions varied but generally involved teams of specialists such as dietitians, nutritionists, DSNs and physicians. In the Gilliland study a trained community mentor provided the intervention.

The duration and intensity of the interventions varied. Two interventions involved approximately 9 hours of contact.[36,37] One of these involved six monthly sessions and the other six sessions bimonthly, and another[35] involved 20 hours of contact in ten 2-hour meetings over 10 weeks. The group intervention in the Gilliland study[42] involved approximately 12 contact hours over 10 months and the individual intervention approximately 4 hours over the same period.

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

Other focused interventions

Four other studies involved focused interventions that were each unique.

One study (Samaras and colleagues, 1997[40]) 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.[43] The intervention involved group sessions focusing on barriers to exercise,

diabetes and exercise, self-esteem, goal-setting, etc. Education sessions were followed by a group aerobic exercise session. The intervention formally involved 6 months of sessions, but exercise sessions were available after 6 months.

One study (Wing and colleagues, 1985[38]) compared a diet intervention with a weight loss-focused intervention. This study did not report any between-group differences and therefore will not be discussed further.

A second study (Wing and colleagues, 1986[39]) 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. Patient deposits were returned on the basis of meeting goals and attendance. There were 12 weeks of weekly meetings followed by monthly meetings for the next 6 months and follow-up sessions at 9 and 12 months.

Another study (Wing and colleagues, 1988[41]) was similar to the previous one using a behavioural weight control programme. 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 24 shows the results for GHb for the included studies that considered focused interventions.

The Kaplan intervention involving combined diet and exercise[35] produced significantly lower HbA_{1c} than in a control group who received only didactic education. The diet plus exercise intervention produced a sizeable reduction in HbA_{1c} whereas the drop was small in the diet group and HbA_{1c} increased from baseline in the exercise group and education group. 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 study,[36] mean levels of HbA_{1c} did not differ between intervention and control groups (although there was a marginal difference at 12 months), but the proportion of patients with $HbA_{1c} \leq 7.0\%$ 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 CCT,[42] despite all groups seeing an increase in HbA1c the two intervention groups combined showed a significantly smaller rise than the control group.

The Samaras exercise study[40] reported no overall significant differences in HbA_{1c} between intervention and control patients. However, HbA_{1c} levels among patients who were treated with metformin or diet alone rose less in intervention patients (change +0.4) than in control patients (+1.5%), $p < 0.05$. The fact that HbA_{1c} rose in both groups is not encouraging.

The remaining four studies did not report any differences in measures of GHb between intervention and control groups (Ridgeway study[37]) or between different interventions (Wing studies[38,39,41]).

BP

Only two studies[36,42] reported BP results. There were no significant differences between intervention and control groups in the Uusitupa study, whereas there was a significant difference in diastolic BP between the two intervention groups combined [FF –6.5 (2.0), OO –0.4(1.7)] and the control group [–0.3 (2.1)] in the Gilliland CCT.

BMI/weight

Five studies reported either BMI or weight.[36,37,40–42] In none of these studies was there a significant difference between intervention and control groups. In one study[42] there was a significant difference in weight between the two intervention groups combined [FF –2.0 (1.5), OO –1.8(1.5)] compared with the control group [+1.7 (1.8)].

Cholesterol and triglycerides

Four studies reported cholesterol and triglyceride levels.[36,37,40,42] There were no reported differences in cholesterol, HDL cholesterol, low-density lipoprotein (LDL) cholesterol or triglycerides in these studies.

Treatment intensity

Uusitupa and colleagues[36] reported the percentage of patients taking glucose-lowering drugs. At 24 months 12.5% of intervention patients were taking drugs whereas 34.8% of control patients were, $p < 0.01$. Wing and colleagues[39] reported no

TABLE 24 *GHb (%) findings from studies of focused education in adults with Type 2 diabetes*

Study	Outcome	*n*	Time point	Intervention (mean ± SD unless stated otherwise)				Control	Difference between groups
Kaplan *et al.*, 1987[35] RCT	HbA_1 %	Initial total: 87 In analysis: 76	Baseline	Diet	Exercise	Diet + exercise	Education		Overall difference between groups, $p < 0.10$; diet + exercise differs from education, $p < 0.05$
				8.97 (2.82)	8.16 (3.44)	9.18 (2.46)	8.21 (1.54)		
			18 months	8.51	9.46	7.70	8.57		
Uusitupa *et al.*, 1992, 92, 93, 93, 94, 96[36] RCT	HbA_{1c} %	Initial total: 86 (40/46) In analysis (24 months): 82 (38/44)	Baseline	7.1 (1.8)				7.8 (2.0)	
			12 months	6.6 (1.6)				7.5 (1.7)	$p = 0.06$
			24 months	7.2 (1.9)				8.0 (1.6)	NS
Uusitupa *et al.*, 1992, 92, 93, 93, 94, 96[36] RCT	HbA_{1c} % (adjusted)	Initial total: 86 (40/46) In analysis (24 months): 82 (38/44)	Baseline	7.4				7.8	
			12 months	6.7				7.3	NS
			24 months	7.4				7.9	NS
Uusitupa *et al.*, 1992, 92, 93, 93, 94, 96[36] RCT	HbA_{1c} % patients with ≤ 7.0%	Initial total: 86 (40/46) In analysis (24 months): 82 (38/44)	Baseline	NR				NR	
			12 months	74.4%				47.8%	$p < 0.01$
			24 months	55.3%				31.8%	$p < 0.05$
Ridgeway *et al.*, 1999[37] RCT	GHb	Initial total: 56 (28/28) In analysis: 38 (18/20)	Baseline	12.3 (2.2)				12.3 (SD3.0)	
			12 months	11.52				11.64	NS
Gilliland *et al.*, 2002[42] CCT	HbA_{1c} % (adjusted)	Initial total: 159 In analysis: 104 (32/39/33)	Reported values are changes from baseline	FF		OO		+1.2 (0.4)	Between 3 groups, $p < 0.05$ Between FF/OO combined and control, $p < 0.05$
				+0.5 (0.3)		+0.2 (0.3)			
Other focused interventions									
Wing *et al.*, 1986[39] RCT Weight vs SMBG	HbA_1	Initial total: 50 (25/25) In analysis: 45 (22/23)	Baseline	Weight control		Glucose monitoring			
				10.86 (2.0)		10.19 (2.51)			
			12 months						
				10.44 (2.16)		10.19 (2.29)			

continued

TABLE 24 *GHb (%) findings from studies of focused education in adults with Type 2 diabetes (cont'd)*

Study	Outcome	*n*	Time point	Intervention (mean ± SD unless stated otherwise)		Control	Difference between groups
Samaras *et al.*, 1997[40] RCT Exercise	HbA_{1c} (reported values are changes from baseline)	Initial total: 26 (13/13) In analysis: 26 (13/13)	12 months	+ 0.86 (SEM 0.29)		+ 0.86 (SEM 0.27)	NS
Wing *et al.*, 1988[41] RCT self-regulation vs self-monitoring	HbA_1	Initial total: 20 (10/10) In analysis: 17 (9/8)	Baseline 12 months	Self-regulation 10.57 (SEM 0.44) 10.8 (SEM 0.8)	Self-monitoring 10.54 (SEM 0.55) 9.71 (SEM 0.78)		NS

significant differences in medication decreases between patients trained in weight control and those trained in glucose self-monitoring.

Outcomes reflecting QoL and cognitive measures

One study[35] considered QoL effects using a validated measure (see Appendix 6). In this study QoL was significantly better in diet (+0.03) and diet plus exercise groups (+0.06) than in a didactic education control group (–0.0.04). The differences are small, but placed on an overall scale of 0–1.0, they may be meaningful to patients.

Summary of results from interventions in Type 2 diabetes

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 blood glucose control (e.g. diet and/or exercise). There have also been limited attempts to tailor interventions to particular cultural sub-groups of the population (e.g. Mexican Americans).

Generally, these programmes have had a limited impact on outcomes that indicate control of diabetes (e.g. HbA_{1c}), QoL, or long-term end-points (e.g. complications).

Arguably the most important indicator of diabetic control is GHb. Multifaceted interventions that affected GHb seemed either to be delivered over long intervals or to require frequent contact between patients and trainers. None of the multifaceted interventions produced long-lasting effects on GHb with limited, short-term interventions. However, there were two focused interventions that did result in long-lasting effects on GHb and one CCT reported smaller increases in HbA_{1c} in intervention groups than in a control group. Speculatively, it may be that focused interventions can result in longer lasting effects because patients can remain focused on a single goal. Culturally appropriate interventions may also have a limited positive impact.

Reductions in the need for OHAs may also be an important measure of the success of an intervention. This may be particularly true if GHb levels are already relatively low in patients. Two multifaceted interventions demonstrated reduced use of oral agents[33,34] as did one focused intervention.[36]

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 oral agents 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 end-points such as diabetic complications. None of the studies testing participants with Type 2 diabetes reported significant effects on end-points such as short-term complications or hospital admissions.

One study of a multifaceted intervention reported a significant improvement in QoL.[30] Again, this was an intervention that involved multiple sessions spaced over the entire evaluation period and may reflect the effects of continual contact. Another study reported significant improvements in attitudes toward diabetes in intervention patients. Any improvements in patients' QoL or perceived control of disease are certainly desirable. However, interventions for diabetes self-management are generally aimed also at improving diabetic control. If an intervention only produces QoL effects then it may well be that other interventions focused on QoL may produce far greater benefits in this realm (e.g. psychological interventions).

Two 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 again desirable, but its relation to metabolic control is questionable.[27]

Most of the interventions aimed at Type 2 diabetes were group interventions. The included designs 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 in groups 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 toward behaviour modification. In addition, group interventions are generally less costly and allow staff to use the time they devote to patient education more efficiently.

Conclusion

Overall, the results of educational interventions aimed at patients with Type 2 diabetes are difficult to interpret. There were positive effects of interventions in each of the Types of outcomes considered. However, many studies reported few or no significant effects of educational interventions. It is impossible on the basis of the limited significant intervention effects to determine which specific characteristics of diabetes education for patients with Type 2 diabetes will reliably produce significant impacts on any of the reported outcomes. Because of the variations in interventions and their impacts and also the methodological limitations of these studies, no firm conclusions are possible about possible educational interventions that would have significant, long-lasting effects.

Chapter 6

Effectiveness of interventions including patients with either Type 1 or Type 2 diabetes

Trials of self-management interventions

A few studies have included patients with either Type 1 or Type 2 diabetes. Although, practically, many diabetes education programmes may include patients with both types of diabetes, these studies are limited in their usefulness because they do not report results separately for patients with Type 1 versus Type 2 diabetes. Because of the different aetiology, differing risk of certain complications (e.g. ketoacidosis) and different treatment options it would seem better to educate and evaluate these groups separately.

Quantity and quality of evidence

Three RCTs,[44–46] apparently included patients with either Type 1 or Type 2 diabetes. Two of these studies were undertaken within secondary care and in one the setting was unclear.[46] One CCT,[47] undertaken in primary care, does not report the type of diabetes (see *Table 25* and Appendix 9). Study sizes in the three RCTs were 206, 302 and 106, respectively.[44–46] Two trials compared an intervention group with a usual care control[44,45] and one trial[46] compared two different educational interventions. In this final trial, the two educational interventions were also compared with a non-randomised convenience control group and

TABLE 25 *Included studies of self-management education for patients with either Type 1 or Type 2 diabetes*

Reference	Intervention	Participants	Duration of intervention	Timing of evaluation
Bloomgarden *et al.*, 1987[44] RCT	Two groups: 1. Self-management education. Group education provided by nurse and dietitian. No details of numbers of sessions 2. Usual care. Usual contact, no details provided	302 insulin-treated Type 1 or Type 2 patients	1.6 ± 0.3 y in education group and 1.5 ± 0.3 y in control group.	1.6 ± 0.3 y and 1.5 ± 0.3 y
Glasgow *et al.*, 1997[45] RCT	Two groups: 1. Brief dietary education. Provided by researcher to individual patients. 20 minutes initial contact with computer assessment then telephone contact at weeks 1, 3, 12 + 24 2. Usual care. Clinic visits every 4 months, plus telephone call at 3 and 24 weeks	206 Type 1 or 2 diabetes patients	9 months	12 months
Raji *et al.*, 2002[46] Groups 1 & 2 RCT, group 3 matched but non-randomised	Three groups: 1. Intensive education. Team provided group education over 3.5 days 2. Passive education. Educational materials mailed to patient's home 3. Usual care. No details	106 patients in RCT (type not defined) + 56 matched usual care control (those declining participation)	Intervention 1, 3.5 days; intervention 2, once every 3 months for 12 months	12 months
Gilden *et al.*, 1992[47] CCT (usual care group non-randomised matched)	Three groups: 1. Self-management education 2. Self-management education plus support 3. Usual care Groups 1 and 2: team provided group education once a week for 6 weeks. Group 2 had support group sessions monthly for 18 months Group 3: no details	32 patients (type not defined)	6 weeks for education only group. Support = 18 months	24 months

TABLE 26 *Quality assessment of RCTs of education for either Type 1 or Type 2 diabetes*

Study	Randomisation	Concealment of allocation	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values
Bloomgarden *et al.*, 1987[44]	Unknown	Unknown	Reported	Yes	Unknown	Adequate	Unknown	Partial
Glasgow *et al.*, 1997[45]	Adequate	Unknown	Reported	Yes	Unknown	Partial	Unknown	Unknown
Raji *et al.*, 2002[46]	Unknown	Unknown	Unknown	Yes	Unknown	Inadequate	Adequate	Reported

TABLE 27 *Quality assessment of CCT of education for either Type 1 or Type 2 diabetes*

Study	Baseline characteristics	Eligibility criteria	Blinding of assessors	Primary outcome results	ITT analysis	Missing values	Representativeness
Gilden *et al.*, 1992[47]	Unknown	No	Unknown	Adequate	Unknown	Unknown	No

any reported results from comparisons with this group are effectively from a CCT. In the CCT 32 patients were divided between three study groups. In three studies[44,45,47] the duration of diabetes was between 10 and 13 years and in one[46] duration of diabetes was not reported. In two RCTs the proportion of patients with Type 2 diabetes was 76%.[44,45] This proportion was not reported for the other RCT. Mean ages within the trials ranged from 56 to 68 years. Trial duration differed amongst the four studies; this was 12 months in the Glasgow[44] and Raji[46] studies, approximately 19 months in the Bloomgarden trial,[44] and 24 months in the Gilden CCT.[47]

The quality of reporting and methodology of the included studies was generally poor (*Tables 26* and *27*). The method of randomisation was reported in only one RCT[45] and concealment of allocation was not reported in any trial. The similarity of groups at baseline (only HbA_{1c} in the Raji study), and the eligibility criteria were reported in RCTs, but were not reported in the CCT. One of the studies reported an analysis by ITT.[46]

Description of intervention

Three of the studies were full self-management programmes[44,46,47] whereas one focused on diet.[45] Details of the educational interventions have varied between reports.

The topics covered in the studies of full self-management programmes included general knowledge about diabetes, nutrition and self-care techniques. The Bloomgarden study[44] included only insulin-treated patients and therefore also covered insulin administration. It also included individualised diet instruction and discussion of macrovascular disease. The Gilden study[47] offered the same education to two groups, but in one group included social support. Therefore, topics for this group included social work support services and stress management. A third group in this study received no intervention. The Raji study[46] used education based on the ADA recommendations and included, in addition to the above, discussion of coronary artery disease.

The providers for the Bloomgarden study were a nurse educator and a nutritionist whereas teams provided education in the Gilden and Raji (intervention 1) studies. The social support aspect of the Gilden study was self-directed by patients.

The Bloomgarden study involved nine group sessions and lasted for approximately 1.5 years. The Gilden study involved six weekly sessions for the education group and 6 weeks of education plus 18 monthly sessions for the education plus support group. The Raji study involved 3.5 days of group education for the intensive education group and mailed information every 3 months (four mailings) for the passive education group.

TABLE 28 *Knowledge from studies of adults with either Type 1 or Type 2 diabetes*

Reference	*n*	Time point	Intervention (mean ± SEM unless stated otherwise)		Control	Differences between groups
Bloomgarden *et al.*, 1987[44]	Initial total: 302 (145/157)	Baseline	5.3 (SD1.6)		5.3 (SD1.7)	
RCT	In analysis: 266 (127/139)	~19 months	5.8 (SD 1.6)		5.3 (SD 1.7)	$p < 0.01$
Gilden *et al.*,1992[47]	Initial total: 32 (11/13/8)		Education and support	Education alone		
CCT	In analysis: 32 (11/13/8)	Baseline	36 (4)	NR	NR	
		24 months	38 (1)	36 (1)	34 (1)	Education/support: education, $p < 0.05$ Education/support: control, $p < 0.05$

One study[45] used a diet intervention that involved patient-centred goal setting. This intervention involved 20 minutes of initial contact with telephone follow-ups at 3 weeks and 3 and 6 months. This intervention was led by a researcher.

Assessment of effectiveness

Outcomes reflecting diabetic control and diabetic end-points

There were no significant differences between the intervention and control groups on any control or end-point measures in the Bloomgarden study. Likewise, the two intervention groups [intensive (8.0%) and passive education (8.0%)] did not differ in HbA_{1c} in the Raji study. A group of patients who had declined participation in the Raji trial were matched to the passive education group. The two education interventions combined resulted in a significantly greater decrease from baseline HbA_{1c} than in this non-randomised control group (HbA_{1c} at 12 months: 8.0 ± 1.4% versus 8.6 ± 1.8%), $p < 0.05$.

In the Gilden CCT both of the education groups (education and support, 6.6%; education alone, 6.5%) had lower HbA_{1c} than the control group (8.4%), $p < 0.05$, after 2 years. The two educated groups did not differ from one another.

Neither HbA_{1c} nor BMI were significantly different for intervention and control patients in the Glasgow study that focused on diet.[45] This study reported that serum cholesterol was significantly lower in intervention patients (208) than in control participants (226), $p < 0.05$. Results from a food habits questionnaire were also significantly better in the intervention (2.06) than control patients (2.26), $p < 0.05$. The questionnaire measured four dimensions of fat-related dietary habits.

Outcomes reflecting QoL and cognitive measures

QoL was assessed using a validated measure only in the CCT (see Appendix 6 for details). This study[47] tested QoL using a scale that had two subscales. The QLa subscale measured more demanding and intensive lifestyle changes due to diet, exercise and other general factors. QLb reflected less demanding behaviour including medication compliance and self-testing. Higher scores reflect better knowledge and perception of QoL. Both aspects of QoL as well as total QoL score were better in the group receiving both education and support than in the control group [total QoL scores (mean ± SEM): education + support = 78 ± 5; education = 71 ± 6; control = 64 ± 3]. The education and support group also had higher total QoL scores than the education alone group. Unfortunately, it is not clear whether the group receiving education alone was statistically compared with the control group.

Knowledge

Knowledge about diabetes was assessed using a validated instrument in two studies.[44,47] These knowledge findings can be seen in *Table 28* and description of the knowledge measure in Appendix 6.

Two studies reported that interventions improved knowledge scores. In the Gilden study[47] the education plus support group scored better than both the education group and the control group. It should be noted that part of the support sessions involved continuing education. In the Bloomgarden study[44] intervention patients had higher knowledge scores than the control patients.

These effects, although statistically significant, do not appear to be large. As noted previously, there is little indication that improved knowledge alone is related to better overall self-management.

Summary of results from studies including patients with either Type 1 or Type 2 diabetes

On measures of diabetic control, the results of two included studies[46,47] suggest that it is possible to lower HbA_{1c} levels following an educational intervention. Both of these results involved comparisons between non-randomised intervention and control groups and one CCT was very small. Perhaps surprisingly, one RCT[46] reported that intensive group education and passive education (mailings) were equally effective in reducing HbA_{1c} when compared with a non-randomised control group. It should be emphasised that despite the two intervention groups being randomised, the control group was not. Noteworthy too is the lack of information about whether treating physicians were blinded as to patients' participation in the study. It is possible that participating patients were treated more intensively than those who were not participating. This study also did not report any information on the duration of diabetes and it is therefore possible that large numbers of newly diagnosed patients might have lowered their HbA_{1c} simply in response to the diagnosis (this is consistent with a substantial decrease in HbA_{1c} in the control group as well as the intervention groups). Finally, this study with 99% males did not include a representative patient sample.

In one CCT the effects on HbA_{1c} were long lasting as the intervention lasted for only 6 weeks and the follow-up was at 2 years. This study was a CCT rather than an RCT. It also included only male participants and had very few participants. The degree to which these results may generalise should be scrutinised. It is also unfortunate that the statistical tests in this study are not sufficiently well described to determine whether the education alone group was specifically compared with the control group for all measures. The inclusion of these comparisons could have answered important questions about the potential impact of education alone.

The two remaining included RCTs did not demonstrate significant differences in HbA_{1c} between the intervention and control groups. The Bloomgarden trial involved ongoing education throughout the study period and the time from the end of the intervention to the follow-up was only 3 months in the Glasgow trial.

There may also be an impact on QoL by educational interventions for diabetes; unfortunately, however, only one of these included studies assessed QoL with a validated measure. In this study patients who received both education and support reported a higher QoL than patients who received education alone or than control patients. This is not surprising as the support component of this intervention was specifically aimed at QoL.

Two studies reported significant effects on knowledge. This would be expected from educational interventions. Although the effects were statistically significant they were not large.

Conclusion

Overall, the evidence for effects of education within mixed groups of patients is fairly limited. As in the interventions for Type 2 diabetes, it would be difficult to draw any firm conclusions about what interventions or characteristics of interventions have a substantial impact in groups of patients with either Type 1 or Type 2 diabetes.

Chapter 7

Evidence from systematic reviews

A number of systematic reviews of educational interventions in diabetes were identified (see Appendix 10 for a list). In addition, a large number of literature reviews that did not use systematic methods were located but will not be discussed further (see Appendix 10).

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. Owing 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.

Brief summaries are provided below.

Reviews of interventions in Type 1 diabetes

No systematic reviews were located that considered interventions only in patients with Type 1 diabetes.

Reviews of interventions in Type 2 diabetes

Five systematic reviews of interventions in Type 2 diabetes were located.[48–52]

In the review by Norris and colleagues,[48] 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[49] was based on the search strategy of the previous review and discussed a subset of the same trials included in the above review. Thirty-one studies were assessed to evaluate the effects of self-management education on glycaemic control. As in the previous review, studies with shorter follow-up periods than in the current review were included. 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-ups of ≥4 months, suggesting that it is difficult to maintain improvements in glycaemic control without maintenance of educational/supportive contact.

Norris and colleagues[50] 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 BP and was also inadequate to assess the effects of interventions in the workplace or at home.

A review was also conducted by the Alberta Heritage Foundation for Medical Research.[51] 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).

A review by Huang and colleagues[52] focused on cardiovascular outcomes. This review included

trials that varied treatment intensity and the use of cholesterol-lowering and BP-lowering interventions. As they were not specifically trials of patient education, this review will not be discussed further.

Reviews of interventions in diabetes generally

Ten reviews included studies that recruited patients with either Type 1 or Type 2 diabetes. Although these reviews may be useful in relation to practical programmes that may include patients with either type of diabetes, it does seem more useful to consider each type of diabetes separately for reasons discussed previously.

A series of reviews by Brown[53–55] and another by Padgett and colleagues[56] seem to be most frequently cited and influential. The original Brown meta-analysis included 47 studies that were widely variable across a range of characteristics (e.g. design, intervention). Despite this, results were pooled to determine overall effects of educational intervention with the result that education was deemed to yield positive results. However, the usefulness of combining such disparate studies across multiple outcomes is very questionable. There was no indication as to whether positive results were long-lasting.

In a follow-up to the original meta-analysis, Brown[54] included further studies and more outcomes of a psychological nature, including 82 studies. The methods and results differed little from the original review. It was concluded that education led to positive results for knowledge, self-care behaviours, insulin injection and weight loss, metabolic control and psychological outcomes. Again, there was no indication as to whether these results were from trials with reasonably long follow-up periods, and there was also no differentiation as to results for patients with Type 1 versus Type 2 diabetes. Data from the second Brown meta-analysis were re-analysed[55] to consider more closely the effects of study and patient characteristics on patient outcomes. This review included 73 studies and concluded that education was more effective in younger patients, particularly for knowledge outcomes. HbA_{1c} levels improved in the short term (up to 6 months), but improvements were lost after 6 months. In this analysis length of the intervention did not appear to influence outcomes. Generally, smaller effects were found in studies with more rigorous methods.

A further meta-analysis by Brown and Hedges[57] was focused on testing a particular theoretical model for predicting metabolic outcomes. Owing to the very specific nature of this analysis it will not be discussed further.

A systematic review by Padgett and colleagues[56] included 93 studies. This review focused on evaluating the nature of the intervention. The review concluded that there was an overall moderate positive effect of educational intervention. Effects were greatest for physical effects (although this outcome was not defined and could include a wide variety of measures) and for knowledge. Diet and social learning interventions were most effective. Generally, patient characteristics and type of intervention were not correlated with effect sizes. Again, these results are combined across widely divergent studies including studies of children and adolescents in addition to adults. There is little indication as to whether effects were long-lasting, but separate analyses on a small number of studies indicated that effects diminished over time. For instance, an effect size in four studies of +0.36 for HbA_{1c} at 6 months was reduced to +0.03 at 12 months (this supports the inclusion of trials with a minimum follow-up of 12 months in the current review).

Six additional systematic reviews were located.[58–63] One of these[63] was a review of computerised education and included only five trials in diabetes. Another focused on computer-based systems primarily oriented toward patient management.[60] These will not be discussed further here. Albano and Jacquemet[58] included 37 papers and focused primarily on how interventions are reported. They concluded that educational interventions are not well described and that interventions focus on a very narrow range of possible outcomes. A review by Fain and colleagues[61] included 78 studies, but failed to offer summary statements about outcomes, instead again lamenting the narrow range of outcomes evaluated and poor descriptions of interventions. Whittemore[62] included 71 studies in her review. This review again concluded that there were positive outcomes associated with programmes that focused on self-management, emphasised behavioural strategies and provided culturally relevant information. Once again, however, a very diverse set of studies are combined and we are left with little idea as to specific intervention strategies that are effective and whether effects are long-lasting. Griffin and colleagues[59] in a report to the British Diabetic Association (BDA) [D(UK)] reviewed 57 trials and

seven meta-analyses of a variety of interventions, including some of practitioner education. They also concluded that educational programmes are beneficial for patients across a range of outcomes. However, they also stress that limitations of the research methods reduce the strength of the evidence provided.

A number of worrying methodological shortcomings of studies in diabetes education were noted in the systematic reviews (e.g. inadequate description, lack of theoretical model, attrition). Most of these correspond with the shortcomings of the studies discussed in this report in the section 'Other issues and methodological concerns' (p. 68).

Chapter 8

Adverse effects

Reviews of clinical interventions such as surgical or pharmacological interventions would include an explicit discussion of the adverse effects associated with the intervention. In the case of an intervention such as patient education the definition of adverse effects is not so clear.

It has been mentioned in the context of trials of intensified treatment in Type 1 diabetes that these interventions may increase the risk of hypoglycaemic episodes. This elevated risk was also reported in early trials of intensified treatment such as the DCCT. However, it has been disputed that intensified treatment necessarily leads to an increased risk of hypoglycaemia (e.g. Berger and Mülhauser[64]).

Just as the potential benefits of intensified treatment programmes cannot be simplistically attributed to the education that provides the foundation for the programmes, the education is not necessarily linked to adverse effects. Education itself is not likely to be responsible for any potential increase in hypoglycaemia. It is more likely that the increased use of insulin is responsible for increases in hypoglycaemic episodes.

The included studies did not report any other adverse effects associated with patient education. It should be pointed out, however, that many studies did have high rates of attrition. One can only speculate as to whether there are adverse events such as anxiety or stress that contribute to patient drop-out.

Chapter 9

Research in progress

A number of research projects of a variety of educational interventions for patients with diabetes are under way.

DAFNE trials

The DAFNE evaluation (see details in Appendix 4) has been expanded and extended for another 12 months to include seven more centres and up to 1000 participants. The aim is also to learn more about how DAFNE courses can be implemented across the NHS. Work is also under way to develop a new DAFNE programme for children with Type 1 diabetes and in the future it is hoped to develop a programme for people with Type 2 diabetes.

Other controlled trials

Two other controlled trials have been identified from searches of the National Research Register.

A randomised comparative trial of group education and distance learning in the self-management of Type 2 diabetes is currently underway in Bolton, Lancashire. The study aims to evaluate which patients benefit from distance learning and which benefit from group education. Outcomes include lifestyle measures, confidence, emotional adjustment, weight concerns, barriers to diet and medical outcomes. The trial is expected to end in September 2004 but there are no details as to the length of follow-up.

A controlled comparison of the effectiveness of two education programmes for patients with Type 2 diabetes is currently underway. The study aims to evaluate whether a short, 2.5-hour session with or without exercise or a 6-week programme with or without exercise is more beneficial. Outcomes include GHb, BP, weight and QoL. The trial was expected to end in 2002 but there are no details as to the length of follow-up.

Ongoing systematic reviews

Two systematic reviews of relevance are under way for the Cochrane collaboration; both reviews are expected to be published in 2003. One of these is a review of psychological interventions for improving glycaemic control in patients with diabetes and the other is a review of group-based self-management strategies in people with Type 2 diabetes.

Chapter 10

Economic analysis

Overview of economic assessment

The aim of this chapter is to assess the cost-effectiveness of patient education models for diabetes. Our economic analysis includes a systematic review of the cost-effectiveness literature relating to patient education models for diabetes, a review of the economic analysis submitted to NICE by the DAFNE Study Group and the submission to NICE from the Association of Clinical Diabetologists (detailing experience at Poole Hospital NHS Trust). In addition, literature relating to the assessment of the cost-effectiveness of treatments for diabetes and the literature concerning modelling for diabetes have been considered for comparative purposes.

Methods

A systematic literature search was undertaken for economic evaluations of patient education models for diabetes. Methodological details of this search are presented in Appendix 2.

A more general search of the literature was undertaken to identify model-based economic assessments of treatment of diabetes.

Results of the systematic search for economic evaluations of patient education models for diabetes

The literature search identified only two studies, both from the USA, that consider the economic evaluation of education models for diabetes.[45,65] Kaplan and colleagues[65] present a cost–utility analysis (CUA) alongside the findings from an RCT in Type 2 diabetes. Glasgow and colleagues[45] present cost-effectiveness findings based on intermediate outcomes, alongside a RCT in patients with Type 1 and Type 2 diabetes. We believe the two cost-effectiveness studies identified do not offer a basis on which we can assess the cost-effectiveness of patient education models for diabetes in the context of this review, but for completeness they are discussed below. A number of other studies were identified that presented findings on costs related to patient education models, and we also discuss these below.[24,66–68]

Economic evaluations

Kaplan and colleagues[65] evaluated the cost–utility of behavioural interventions in an experimental study of 76 adult patients with Type 2 diabetes. The study is based on findings from a RCT that has been discussed in Chapter 5 of this report.[35] The study reports on four groups, using two groups for comparison in the CUA. The CUA is based on comparison of an education control group and a group undergoing a diet plus exercise programme, where significant improvements in health status (from diet plus exercise) were reported over an 18-month period.

The education group, used as the control, was exposed to healthcare specialists (e.g. endocrinologist, dietitian, ophthalmologist), who each offered a 2-hour presentation over a 10-week period. The exercise and diet group received detailed instruction on these two aspects over the same time period (2-hour sessions over a 10-week period). Kaplan and colleagues[65] estimate costs of the diet and exercise intervention (1986 prices) at approximately US$1000. Costs comprised history and physical examination, laboratory charges, charges for behaviour modification sessions and charges for medical consultations. No side-effects were reported in the study, therefore costs for these items were not included. Benefits were estimated based on the reported scores on the Quality of Well-Being scale (QWB), and scores were used to reflect well-years; QWB scores range on a continuum of health from 0 (death) to 1 (asymptomatic function). Over an 18-month period, using estimates from the QWB, the diet and exercise intervention was reported to offer 0.06 additional units of well-being (compared with baseline), and the education control was reported to result in a reduction of –0.04 units of well-being (compared with baseline); a difference of 0.092 units of well-being is reported between the comparator groups at the 18-month assessment. A cost–utility estimate of US$10,870 per well-year (1986 prices) was presented by the authors, where a 1-year benefit rate is calculated based on the difference between treatment and control groups at each assessment point (3, 6, 12 and 18 months) weighted by duration of stay (this

calculated 1-year rate is reported to be 0.092 units of well-being). The actual difference in QWB scores at 12 months is reported to be 0.043 units. Sensitivity on the effectiveness parameter resulted in a range of cost–utility estimates of US$21,740–5435 per well-year.

The study by Kaplan and colleagues has limitations. It is based on one experimental study with very small numbers of self-selected patients randomly assigned across four different groups (numbers in groups are not reported); the study is discussed under clinical effectiveness in Chapter 5. The way in which benefits have been assessed as part of the CUA, using indirect modelled tariff values for the QWB scores (detailed health state data/scores are not provided), is open to criticism, as is the weighted 1-year benefit used in the CUA. Scores are not those of the patients themselves, but reflect scores modelled from responses from samples of the general public. The model for the QWB assigns a well-being score based on a classification of study participants according to the QWB descriptive scales (i.e. mobility, physical activity, social activity) and a reporting of symptoms. The QWB uses decrements in well-being based (from a position of 1.0 reflecting asymptomatic/optimum function) on weights derived from the general population for health states described using the three QWB descriptive scales, and additional decrements based on reported symptoms. For example, where patients report under symptoms 'general tiredness, weakness, or weight loss' (this is QWB symptom number 10), the QWB tariff reduces well-being by –0.259 (on a scale of 0–1). Given the small numbers of patients in intervention groups (i.e. 76 patients randomised across four groups), it is possible that average benefits could be influenced by variations in the two comparator groups, or adverse events (e.g. onset of complications) in either group (neither baseline characteristics nor adverse events are reported in the study). Further detail on the study is presented in Appendices 11 and 12. In the context of this review, it is noted that the control group is an education group, albeit information only and not behavioural strategies, with the intervention being directed at focused education on diet and exercise and participation in group exercise sessions.

Glasgow and colleagues[45] report the findings from a RCT examining an intervention focused on behavioural issues related to dietary self-management, compared with usual care, in adults with diabetes (both types). The study findings have been discussed in Chapter 6 of this report and further detail is presented in Appendix 9. Glasgow and colleagues present estimates of cost-effectiveness based on intermediate health outcomes (i.e. percentage reduction in dietary fat, percentage reduction in saturated fat and reduction in serum cholesterol). Benefits are based on findings from the trial, using a dietary self-management questionnaire to identify differences in dietary intake and physiological measures of serum cholesterol. Costs were calculated for the computer-based intervention package. Cost items included computer hardware and software, delivery materials (e.g. handouts, pamphlets), supplies, labour costs for health educators, nurses, physicians and support staff, postage and telephone charges. Capital costs were depreciated over year 1 in the base case analysis, and base case analysis did not include facility space and labour costs for training (of educators); these were considered in sensitivity analyses.

Glasgow and colleagues estimate costs for the delivery of the dietary self-management intervention to be US$137 per participant. Costs were combined with outcomes data on fat consumption, saturated fat consumption and serum cholesterol (there were no significant effects on HbA_{1c}). The marginal cost per unit improvement in these outcomes were: US$62 per reduction of each per cent in dietary fat; US$105 per percentage reduction in saturated fat; and, US$8 per mg/dl reduction in serum cholesterol. Cost-effectiveness estimates were also presented for three different-sized potential patient groups, to reflect economies of scale (these were similar to the study estimates above). Further detail on this study is presented in Appendices 11 and 12.

Costing studies

The literature search identified five studies, all based outside the UK, that presented some data on costs associated with various patient education models for diabetes. These studies are discussed in outline for information only (note: all except the study by Starostina and colleagues did not meet inclusion criteria specified in the review of clinical effectiveness).

Starostina and colleagues[24] present findings from a Russian prospective controlled study to assess BG self-monitoring in Type 1 diabetes. The study has been discussed in Chapter 4 of this report. The intervention comprised methods prescribed by Mühlhauser and colleagues[23] (discussed in Chapter 4) and comprised a 5-day inpatient treatment and training programme. The authors present cost estimates for the intervention in

roubles (Rb), with costs for materials and drugs also presented in German marks (DM). The direct costs for the hospitalisation associated with the intervention are reported at 4200 Rb (assume 1994 prices; not stated in paper), with the authors presenting cost offsets (reduced hospitalisations, and reductions in lost productivity), to establish a net cost saving associated with the intervention. Methodological uncertainties over the study reporting also give rise to concerns (see Appendix 7).

De Weerdt and colleagues[68] provide findings from a Dutch study involving 6-month follow-up in insulin-treated patients with diabetes. QoL was assessed using a Dutch version of the Bradburn Affect-Balance Scale and a subjective rating system (where overall QoL was rated on a scale from 0 to 10, low to high). The study did not identify any statistically significant differences in outcomes (e.g. QoL, HbA_{1c}, adverse events) and therefore no cost-effectiveness analysis was undertaken. The authors do provide some insight to the costs associated with the intervention. The intervention was outpatient based and consisted of four weekly group sessions of 3 hours duration, for groups of about 10 patients. The programme was structured and consisted of video, written and practice materials, with relevant aspects of self-care discussed throughout. The education sessions were led by a trained nurse, a dietitian or a patient with diabetes, with a physician present at the beginning of each session. The authors present estimates of the cost of the education programme. Each single education programme involved 4 hours of physician time, 14 hours for the session leader (healthcare worker or patient) and 18 hours for each participant. Costs per education programme were estimated at NLG 1325 (US$795), and estimated costs per patient were NLG 165 (US$100), based on an average of eight patients per programme. With costs of other education materials taken into account the cost per patient increased to NLG 240 (US$144). These costs include the cost for participants' time. In the overall assessment of cost the authors found no significant differences in the use of health services, no significant difference in the number of sick days for patients, no differences in insulin dose and that the frequency of BG monitoring increased in the experimental groups. Information is not presented for the costs of the control group.

Pieber and colleagues[67] report findings from a prospectively controlled trial to assess the efficacy of a treatment and teaching programme in patients with Type 2 diabetes in Austria. The intervention group comprised 53 patients undergoing a structured DTTP and the control consisted of 55 patients without the programme. The DTTP consisted of four weekly teaching sessions (90–120 minutes each) for groups of 4–8 patients. The follow-up was 6 months and differences were detected in outcomes related to glycaemic control. The authors do not present disaggregated cost analysis. They report that the DTTP reduced routine health care costs by an average of 594 Austrian schillings (UK £33) per patient per year due to the reduced prescription of OHAs. The cost for glycosuria self-monitoring in the intervention group was 8% and the learning material 6% of the routine diabetes treatment costs. Similarly, Gagliardino and Etchegoyen[66] present findings from an observational study in a sample of Type 2 diabetic patients ($n = 446$) in 10 Latin American countries. The intervention comprised a structured educational model, covering four weekly teaching units (90–120 minutes each) and a reinforcement session at 6 months. The authors present some findings on the costs associated with the intervention, although they do not present estimates of the actual intervention costs. Findings from Gagliardino and Etchegoyen indicate that the intervention resulted in a decrease in drug use, as there was a significant reduction in the percentage of patients taking OHAs, antihypertensive drugs and cholesterol lowering agents (all with $p < 0.05$). However, we must remain aware of methodological concerns with respect to these studies that may introduce bias in various forms.

Gruesser and colleagues[69] report a German study to evaluate the practicability and efficacy of a structured treatment and teaching programme for non-insulin-treated patients with Type 2 diabetes in a primary care setting. This involved a survey of physicians, and their office staff, who had participated in a training course related to the delivery of patient education to patients with diabetes. The course covered materials on patient education methods as prescribed by Mühlhauser and colleagues[23] (i.e. the Geneva–Düsseldorf model). The study also describes a retrospective data analysis for patients from 17 randomly selected physicians' records (physicians who participated in the training course). The authors present limited data on costs of the education programme. The authors report remuneration data covered by health insurance for education programme costs. Education costs are reported at US$49 per patient (assuming 1992 costs), with an additional patient cost for self-monitoring of about US$34 per patient. The study does not offer

further detail on the actual cost components for the education programme. There was a substantial reduction in the prescription of oral antidiabetic agents (e.g. glibenclamide) in patients undergoing education programmes.

The literature is not very clear on the costing of educational interventions and is characterised by heterogeneous methods for costing and presentation.

Assessing the cost-effectiveness of patient education models in diabetes

This review is interested in assessing the additional costs associated with patient education models for diabetes, and the additional benefits attributable to the education models, when compared with usual care, in order to consider the cost-effectiveness of the education models. Such an assessment is complex owing to the nature of diabetes and to the format of patient education models, which are often part of a wider package of care, involving other aspects of treatment for diabetes (e.g. alterations in insulin and oral medications). There has been a great deal reported on the merits of intensive insulin therapy versus conventional insulin therapy, and studies such as the DCCT[10] and UKPDS[9,70] have demonstrated that intensive therapy is a clinically and cost-effective treatment option. We are not examining the benefits of intensive versus conventional therapy in this review; we seek to assess the benefits of patient education models, and care must be taken to ensure that patient education models under review are considered on their merits, regardless of the known benefits of more intensive diabetic therapy. Generally, patients will use the education models to self-manage their existing insulin treatment (i.e. either conventional or intensive therapy), or to manage their treatment of Type 2 diabetes. However, it may also be that owing to patient education (and subsequent treatment intensification) some patients will cross over from conventional therapy to intensive therapy. On these occasions it is not the change in therapeutic treatment option that an economic evaluation should seek to assess, but the role of the patient education model, which, due to difficulties in disentangling the costs and benefits of combined components of treatment (i.e. education and medication), proves a difficult task.

The benefits of treatment in diabetes are primarily assessed using clinical measures of glycaemic control, for example HbA_{1c} (discussed in Chapters 2 and 3), with secondary outcome measures often related to QoL and the incidence of longer term diabetic complications. In the clinical review the main benefits from patient education models are presented as reductions in HbA_{1c}. The evidence for Type 1 diabetes is more compelling than that for Type 2 diabetes or for mixed patient groups (types 1 and 2), where findings are unclear. Given these findings, the economic analysis considered in this report is primarily based on Type 1 diabetes.

The majority of trials of patient education are short term, not extending beyond a 1–2-year follow-up, so data on long-term outcomes are not widely available. In order to assess the long-term impact of health technologies in diabetes treatment, and to consider the cost-effectiveness of technologies, economic models have extrapolated available data. We review below the economic modelling literature as it relates to diabetes.

General literature on modelling of cost-effectiveness in treatment of diabetes

Only a limited number of model-based approaches have assessed economic outcomes and cost-effectiveness for Type 1 or Type 2 diabetes. *Table 29* provides summary detail on the modelling approaches identified. Models are described in outline below in order to consider if they offer an opportunity to assess the cost-effectiveness of patient education, where differences in treatment groups are primarily based on HbA_{1c}. A detailed review of these models can be found in Appendix 13, which presents a summary of a critical appraisal of these studies by Chilcott and colleagues.[71]

DCCT Research Group

The DCCT[10] was a multi-centre RCT comparing the effects of intensive diabetes therapy with those of conventional diabetes therapy on the development and/or long-term progression of diabetes complications of Type 1 diabetes (IDDM). The intensive therapy was designed to achieve BG values as close to the normal range as possible with three or more daily insulin injections or treatment with an insulin pump. Conventional therapy consisted of one or two insulin injections per day (note that conventional insulin therapy was probably less than in the UK, where most patients would receive two injections of mixtures per day). The DCCT has been discussed in detail elsewhere.[10] Most economics assessments in the field of diabetes have been undertaken using largely homogeneous modelling methods, using the data from the DCCT.

TABLE 29 *Approaches to modelling the cost-effectiveness of Type 1 and Type 2 diabetes*

Study	Study design	Approach	Intervention	Diabetes
DCCT[72]	Modelling	Cost-effectiveness	Conventional versus intensive therapy	Type 1
Palmer *et al.*, 2000[73]	Modelling	Cost-effectiveness	Conventional versus intensive therapy (various treatment options)	Type 1
Tomar *et al.*, 1998[74]	Modelling (based on DCCT model above)	Cost-effectiveness	Conventional versus intensive therapy (plus costing study)	Type 1
Eastman *et al.*, 1997[75]	Modelling	Cost-effectiveness	Conventional versus intensive therapy	Type 2

The model used by the DCCT Research Group[72] for Type 1 diabetes compares the lifetime benefits and costs of conventional and intensive therapy as implemented in the DCCT.[10] The model is a Monte Carlo simulation, used to predict the incidence of microvascular and neurological complications in a hypothetical sample of 10,000 persons with Type 1 diabetes. The model randomly selects from the hypothetical population (either a primary prevention cohort or secondary prevention) and assigns characteristics (e.g. age, disease characteristics). It uses 12 health states to capture disease characteristics, grouped according to the three major complications studied in the DCCT (retinopathy, neuropathy, nephropathy), and simulates the course of the patient's disease over his or her expected lifetime. The model uses 1-year cycles and at each cycle an individual is in one of five retinopathy health states, one of four nephropathy health states and one of three neuropathy health states. The probability that a patient will advance to a more severe stage of disease in a given year depends on the patient's current state of health, treatment regime (i.e. intensive versus conventional insulin therapy) and treatment duration. The model cycles through time at a patient level, until the patient exits the model (due to death), and then the next patient is selected from the hypothetical sample. This process is repeated in the DCCT analysis for a sample of 10,000 individuals. At the end of the modelling process (the simulation), the time spent in each of the treatments and health states and the time spent alive are calculated, costs are assigned and mean statistics are calculated by treatment group (conventional versus intensive). The DCCT model does not consider hypoglycaemic events.

The DCCT model uses empirical data on disease progression, over 9 years, from the DCCT, and a series of statistical models (Weibull models) to predict the probability of patients advancing to differing stages of disease progression such as background retinopathy, and/or neuropathy [e.g. Weibull model, $\alpha \times \beta \times t(\alpha - 1)$, where α and β are statistical parameters determined by the study and t is the parameter for duration of treatment; different α and β parameters were determined to reflect conventional and intensive treatment probabilities of progression of disease]. These methods are not transferable to the assessment of patient education models for diabetes, using HbA_{1c}, as they do not use HbA_{1c} directly to model the effect of treatment.

Palmer and colleagues

The diabetes disease model developed by Palmer and colleagues[73] considers the cost-effectiveness of a range of intensive interventions for Type 1 diabetes compared with conventional therapy, to consider optimal lifetime treatment patterns. A variant of this model has been used in an earlier NICE submission on pioglitazone in Type 2 diabetes,[71] but the Type 2 model has not been published to date. The Type 1 model from Palmer and colleagues is a micro-simulation model, simulating the experiences of individual patients (similar to the DCCT model). The model comprises a series of Markov sub-models, representing the development and consequences of renal disease, retinopathy, amputation, myocardial infarction, stroke, major hypoglycaemic events and ketoacidosis. The data are generally drawn from the DCCT and Wisconsin Epidemiological Study of Diabetic Retinopathy (WESDR)[76] studies, largely reflecting transit probabilities to defined health states, and these transit probabilities are not dependent on HbA_{1c} to differentiate between patient groups.

Tomar and colleagues

The model by Tomar and colleagues[74] is not described in this report as it is based on the approach documented by the DCCT Research

Group (as above), and does not offer additional data to inform on the modelling of diabetes for the assessment of patient education models. See the cited reference for further detail.

Eastman and colleagues

Eastman and colleagues[75] present a diabetes model and subsequent cost-effectiveness findings[77] for Type 2 diabetes. The model predicts rates of microvascular complications, cardiovascular disease (CVD) and mortality that are consistent with the known epidemiology of Type 2 disease in the USA.

A large proportion of the authors on these papers were part of the DCCT Research Group, and the structure of the model is very similar to that of the DCCT model discussed above, although there are some differences in scope (i.e. CVD) and in the definitions across disease health states. The model uses a structure similar to the DCCT Type 1 model (i.e. Monte Carlo simulation techniques, 1-year cycles, US population, sub-models for specific complications plus a mortality sub-model), with the addition of a heart-disease sub-model, and the authors apply it to Type 2 disease.

The effect of glycaemic control on microvascular complications is simulated by adjusting the incidence rates for complications under standard care (data on HbA_{1c} for standard care are from WESDR) using HbA_{1c} data for comprehensive care (i.e. a comparison of different modalities of treatment, standard versus comprehensive). In assessing microvascular complications in this way the level of HbA_{1c} is a direct input to the transit probabilities used in the model (i.e. ratio of the average HbA_{1c} in standard care to the average HbA_{1c} in comprehensive care); however, the HbA_{1c} inputs are transformed using a power function (to reflect risk gradients) and then multiplied using hazard rates for standard care. [The effect of glycaemic control is simulated by adjusting incidence rates for complications under standard care, where relative hazard rates = $c^{\beta} \times$ hazard rates under standard care, where c = HbA_{1c} (comprehensive care)/HbA_{1c} (standard care), and β is a parameter value determined from DCCT retinopathy research in IDDM patients.] The model presented uses hazard rates from the WESDR, where rates are the average of those for patients taking insulin and those not taking insulin, with rates categorised by duration of diabetes (e.g. 1–4, 5–9, 10–14 years). Base analysis assumes glycaemic control has no effect on CVD. Data on risk gradients are drawn from the DCCT[78] and the model assumes that the DCCT risk gradients in Type 1 apply to Type 2 disease.

Applying these modelling approaches to the assessment of the cost-effectiveness of patient education models

The evaluation of patient education models requires a mechanism for modifying risk of long-term complications according to HbA_{1c}, within patient groups who are generally maintaining their mode of treatment (i.e. conventional or intensive). The published modelling approaches available for Type 1 diabetes do not offer an opportunity to undertake such modelling. The Type 2 model by Eastman and colleagues[75,77] does use HbA_{1c}, but it requires additional parameter inputs to establish transit probabilities (data on relative risks between patient education and control groups are not available).

Critical appraisal of the cost-effectiveness analysis presented in the submission from the DAFNE Study Group to NICE

The DAFNE programme for Type 1 diabetes (see the section 'How effectively is diabetes education being provided at present?', p. 7) is a form of structured patient education. An evaluation of DAFNE is ongoing, soon to be published, and the DAFNE Study Group has submitted a report to NICE on the clinical and cost-effectiveness of the DAFNE intervention. The clinical effectiveness data from DAFNE have not been included as part of this review as the design of the study does not include a comparison with a concurrent control group for a period of ≥12 months. However, given the absence of literature on the cost-effectiveness of patient education models for diabetes, and the obvious interest in the DAFNE intervention, we review the economic component of the submission from the DAFNE Study Group.

In order to outline the cost-effectiveness analysis and the economic model presented by the DAFNE Study Group, we use a structured proforma for the critical appraisal of economic submissions.[20] We provide an outline review of the different component parts (e.g. structure, data, analysis) of the model presented by the DAFNE Study Group.

Statement of the problem

The DAFNE submission contains a clear statement that the economic analysis is assessing the cost-effectiveness of DAFNE to the NHS over a 10-year period. The economic evaluation states that cost-effectiveness analysis is based on modelling the costs and outcomes of DAFNE relative to baseline

(current standard practice of two or three pre-specified insulin dose injections a day), and the evaluation considers Type 1 diabetes only (as this was the focus of the DAFNE study). The submission does indicate that DAFNE has the potential to be adapted to Type 2 diabetes, but does not offer any detail within the economic evaluation. The form of evaluation is cost–utility analysis, with results in terms of costs and quality-adjusted life-years (QALYs) presented separately. The submission reports that DAFNE is dominant (i.e. offers greater benefits than usual care and a net cost saving over time) in terms of the cost-effectiveness analysis, hence summary cost-per QALY statistics are not appropriate. However, we discuss these findings further below, in the context of the data and the assumptions used to consider the cost-effectiveness of the intervention.

The comparator

The evaluation uses current standard practice of two or three pre-specified insulin dose injections per day as the comparator. There is no discussion over the rationale behind the comparator, but earlier discussions within the NICE appraisal process have indicated that 'usual care' is difficult to define in the context of patient education. The base case cohort used in the DAFNE economic model are stated as having 3.6 insulin injections per day.

Intervention: patient education model

The DAFNE intervention is presented in detail within the submission, and briefly defined as DAFNE with dietary freedom and insulin dose adjustment, in the overview of the economic evaluation (see further detail in the sections 'How effectively is diabetes education being provided at present?', p. 7, 'DAFNE trials', p. 51, and Appendix 4).

Summary of the cost-effectiveness model

The cost-effectiveness model considers the long-term cost and benefit implications of delaying the onset of microvascular complications of diabetes. The DAFNE clinical findings show a reduction in HbA_{1c} compared with control groups at 6 months, and differences between HbA_{1c} are used to assess the cost-effectiveness of the intervention over time, when compared with current standard practice. However, it must be noted that the data on HbA_{1c} used in the base analysis are not that reported in the DAFNE study, but are based on Austrian, German and DAFNE trial data.

The model consists of a series of sub-models that simulate the progression of microvascular complications (nephropathy, neuropathy, retinopathy, erectile dysfunction), plus severe hypoglycaemia and ketoacidosis. Macrovascular complications are not addressed in the submission, which is reasonable given the uncertainty surrounding the relationship between HbA_{1c} and macrovascular disease.

Sub-models for nephropathy, retinopathy and neuropathy are similar to those we see in the models documented above.[72,73,75] The model introduces a sub-model to describe patient experience of erectile dysfunction, for severe hypoglycaemia (although the model assumes no difference between intervention groups with respect to severe hypoglycaemia) and ketoacidosis. Mortality within the model is tied to the nephropathy sub-model.

Cohort information

The economic evaluation is based on a cohort analysis of 100 intervention and 100 control patients. The cohort is defined using the DAFNE trial patient characteristics.

One important aspect of the base characteristics is the mode of insulin treatment, that is, conventional or intensive. The model assumes a base case of over three insulin injections per day, which according to the protocol used in the DCCT (DCCT is the source for much of the data on hazard rates) would constitute intensive therapy; however, the base case probabilities (hazard rates) for development of complications (discussed below) are generally based on conventional insulin therapy (fewer than three insulin injections per day).

Assessment of the impact of the intervention (glycaemic control)

The model uses baseline data from Austrian, German and DAFNE trial data to inform on the reduction in HbA_{1c}. The base analysis assumes a reduction of –0.9% in HbA_{1c}, with benefit assumed to remain over a 4-year period, and thereafter a benefit of –0.26% is assumed. Data from the clinical review detailed in Chapter 4 indicate that patient education may reduce HbA_{1c}, although the findings are variable. The only true test of patient education in Type 1 did not find a statistically significant difference in HbA_{1c}[22] (although this study was a small underpowered RCT), while one slightly larger RCT (SDIS[21]) and a larger CCT study from Mühlhauser and colleagues[23] indicate that patient education may have lasting effects on HbA_{1c}. The DAFNE Study Group report a 0.53% reduction in HbA_{1c} in the DAFNE intervention group over 12 months compared with baseline;

data at 6 months showed a 1% reduction in HbA_{1c} compared with a control group (however, as stated, these results must be viewed with caution owing to the design of the DAFNE trial).

The DAFNE submission does not discuss the use of HbA_{1c} to predict differences in long-term complications. Although data from long-term trials and epidemiological studies have provided evidence that 'good' metabolic control reduces chronic complications (e.g. DCCT Research Group,[10] WESDR[76] and UKPDS[79]), studies do not provide a definitive assessment of the causal relationship between specific levels of glycaemic exposure (HbA_{1c}) and the risk of complications,[78] as confounding is possible from a number of sources.

Clinical outcomes

Long-term complications

Long-term complications (retinopathy, neuropathy and nephropathy) are modelled based on (a) probabilities of disease (hazard rates) from DCCT findings and from unpublished data (Eastman RC and colleagues: personal communication) and (b) a method of modifying the probability of disease according to differences in HbA_{1c} between intervention and control groups. This risk modification methodology is published by Eastman and colleagues[75,77] in relation to the assessment of standard care versus comprehensive care in Type 2 patients. The equation used to provide a relative hazard rate for long-term complications (using differences in HbA_{1c}) employs values reported from the DCCT.[78]

The erectile dysfunction sub-model is based on a study by Klein and colleagues,[80] where probability of disease is determined via statistical modelling, using HbA_{1c} as a risk-modifying variable. Risks for erectile dysfunction are dependent on the neuropathy sub-model.

Adverse events

The model structure includes sub-models for severe hypoglycaemia and ketoacidosis. Severe hypoglycaemia is assumed to be the same for both intervention and control groups within the model, although there is a small effect due to differences in mortality. Given this assumption, it may have been appropriate to exclude the sub-model for severe hypoglycaemia from the model presented (although it does offer an opportunity to consider hypoglycaemia in any sensitivity analyses). The sub-model for ketoacidosis uses effectiveness data from an Austrian study, which assumes a reduction in ketoacidosis events, not DAFNE trial data (where no significant differences are reported). DAFNE trial data, and data from other aspects of the clinical data reviewed as part of this report (detailed in Chapters 4–6), have not identified any conclusive difference between intervention and control groups for ketoacidosis. Ketoacidosis does have a major impact on the DAFNE estimate of net costs associated with patient education models (presenting as a cost offset due to the assumed reduction in events for the education group), and some consideration should be given to the base case assumption in the context of the DAFNE review.

Costs

The DAFNE submission uses only direct NHS costs for medical interventions, categorised as either diabetic treatment or microvascular complications.

The assessment of the cost for DAFNE is comprehensive, resulting in an estimated DAFNE cost per person attending of £545 (this is the cost used in the economic model). This estimate includes costs associated with delivering the DAFNE programme and the training and education required, together with ongoing quality assessment, with these estimated average costs per centre spread across an expected 120 attendees per centre per year.

Costs associated with microvascular complications are presented in outline, with appropriate unit cost data sources. Nephropathy and neuropathy are the two complications with the greatest potential cost impact, and this is borne out by the summary cost data presented in the model. Retinopathy is a significant complication of diabetes but it is not as costly to treat, and it should be borne in mind that all patients should have regular screening and early laser treatment if necessary, which will reduce visual loss considerably. Assumptions surrounding treatment patterns for patients with nephropathy are from expert opinion. Within neuropathy, treatment for foot ulcers is a significant potential cost item. Given the large costs associated with the treatment of nephropathy and neuropathy, relatively small differences in patient experiences (intervention versus control) will produce substantial cost differences.

Costs for ketoacidosis and severe hypoglycaemia are based on data from the NHS reference cost listings.[81] The cost for ketoacidosis appears reasonable given that the condition requires hospitalisation on each occasion. Given the assumption in the model of equal patient experience with respect to severe hypoglycaemia

(reflected in clinical trial data), the costs associated with severe hypoglycaemia should have no impact on base case analysis (other than through the mortality effects across groups). The assumptions surrounding the incidence of ketoacidosis should be viewed with caution as such assumptions are not supported by the clinical trial data in the Southampton review of the clinical effectiveness of the interventions (the section 'Assessment of effectiveness', p. 16, reports that there is limited evidence, two trials report conflicting evidence, with one RCT reporting no significant difference and one CCT reporting a significant reduction in events).

Benefits/utilities

Utility data for the cost-effectiveness model are derived using data from a survey of Type 2 patients and the modelling of results in conjunction with patient characteristics, complications and health state values/utilities from a direct visual analogue scale (VAS) response and an indirect score from the EQ-5D (EuroQol health state classification questionnaire) tariff values. The data applied to yield estimates of QALYs experienced by patients are not yet published and are supported by an abstract from one of the authors of the submission, Bagust and colleagues.[82] Caution must be exercised over the interpretation and use of the data, for several reasons.

First, values from Type 2 patients, who will generally have developed diabetes later in life, may not be generalisable to Type 1 patients, who will often have had the disease for most of their lives. There is a growing literature on the context of health state values/utilities and the importance of adaptation effects (where patients adapt over time to morbid conditions), and also the impact of patient/respondent experience of illness and duration of disease, on health values/utilities.[83–85]

Second, the data used to estimate QALY values within the model are not clearly stated. The data presented as an appendix to the DAFNE model are not the data applied within the model calculations. The model applies utility data that are derived using a multiplicative model and evidence to support the validity of the multiplicative model has not been provided (abstract only, as above).

The literature on health state values associated with diabetes is not large, but a few studies indicate that the differences in scores between those with complications and those without may not be as large as indicated in the study described in the DAFNE submission. Below we discuss some of the available health state valuation studies in order to offer context and background for the present review, aware of the fact that some of these studies are small experimental studies and findings may not be generalisable.

A recent publication from Redekop and colleagues[86] reports data from the Dutch sample studied in the same health utility survey cited by the authors of the DAFNE analysis. The data reported are based on health state values derived using health state descriptions from patients with Type 2 diabetes and the EQ-5D tariff values,[87] and also direct VAS scores from the sample. The authors report a derived EQ-5D utility score (n = 1136) of 0.81 for patients with no complications and 0.72 for patients with microvascular complications. The VAS score was 0.72 for no complications and 0.67 for microvascular complications (n = 1224).

Wu and colleagues[88] present analyses on health state values for diabetes derived via a mapping process, from SF-36 (Short-Form 36 Health Status Questionnaire) responses to the values available from the QWB. The findings are from an experimental study based on analysis from a sample of 89 respondents completing the SF-36. The paper presents estimates of QWB scores associated with a move from 'general population health state values' to a condition in which patients are 'Type 1 diabetics, with no complications', and from the 'no complications' diabetic state to a state involving 'diabetic retinopathy', these estimates may be helpful to add context to the present review. *Table 30* presents outline findings from the study by Wu and colleagues. Caution must be exercised when considering the data presented in their experimental study.

Data from Wu and colleagues[88] indicate that health state values associated with different states show only small differences in valuations, for example for a move from 'no complications' to 'other' (i.e. neuropathy or nephropathy alone) we see a change of 0.03, 0.02 and 0.09 for the age groups in *Table 30*. However, as indicated by the data, there are some inconsistencies with the findings from the study.

With regard to diabetic retinopathy, Brown and colleagues[89] report utility values associated with varying degrees of visual loss from diabetic retinopathy. Utility values were elicited using standard gamble (SG) and time trade-off (TTO)

TABLE 30 *Age- and health-specific QWB scores*[a]

Age (years)	General population[b]	Type 1 diabetes with no complications	Type 1 diabetes with retinopathy only	Other[c]
<45	0.82	0.73 ± 0.07	0.76 ± 0.05	0.70 ± 0.08
45–64	0.75	0.68 ± 0.09	0.72 ± 0.09	0.66 ± 0.07
≥ 65	0.70	0.64 ± 0.08	0.62 ± 0.07	0.55 ± 0.05

[a] QWB scores range on a continuum of health from 0 (death) to 1 [asymptomatic function (perfect health)].
[b] Data on general population are from previous studies; see Wu and colleagues[88] for details.
[c] Individuals with Type 1 diabetes with diabetic neuropathy or nephropathy alone, or with other complications.
From Table 3 in Wu S, Sainfort F, Tomer R. *et al.* Development and application of a model to estimate the impact of Type 1 diabetes on health-related quality of life. *Diabetes Care* 1998;**21**:725–31.

techniques, across five sub-groups with varying degrees of visual loss, ranging from 0.85 to 0.59 for TTO and from 0.70 to 0.90 for SG scores. Overall, in the sample of 95 respondents the TTO values were 0.77 and the SG scores were 0.88 (with visual acuity ranging from 20/20 vision to hand motion visual acuity in the best eye).

Kiberd and Jindal,[90] in a study on screening to prevent renal failure in insulin-dependent patients with diabetes, estimate the health state utility for patients with diabetes to be 0.838; utilities vary between 1.0 (perfect health) and 0 (death). The authors determined these values using a TTO format in a sample of 17 healthcare workers not associated with their study (this sample consisted of nephrologists, clinical house staff, nurses and one social worker). The sample of healthcare workers estimated values for six health states, one of which was "insulin-dependent diabetes alone". The authors do not report any further detail on the health state valuation exercise.

Studies on the QoL related to diabetes indicate that complications have a significant impact on patient's health-related QoL (WESDR,[91] DCCT[92]). However, the literature on health state values for diabetes and diabetic complications is not extensive and it is not possible to say with confidence what the impact may be in terms of the disutility associated with diabetic complications. Therefore, we suggest that caution should be exercised when applying the data from Bagust and colleagues,[82] which involves substantial reductions in QALY values for some of the health states used in the model.

Mortality

Mortality enters the model via the sub-model for nephropathy. Data on mortality are drawn from a 10-year observational follow-up study on a sample of 939 insulin-dependent diabetic patients.[93]

TABLE 31 *DAFNE study group base case cost-effectiveness results*

		Per patient
Incremental cost	Undiscounted	–£3012
	Discounted	–£2679
Incremental EQ-5D QALY	Undiscounted	0.12
	Discounted	0.11
Incremental VAS QALY	Undiscounted	0.10
	Discounted	0.09
Incremental life-years	Undiscounted	0.05
	Discounted	0.05

Reproduced from Table 3.5 in the NICE submission by the DAFNE Study Group.

Incremental cost-effectiveness

The results from the DAFNE model analysis presented (base case) offer incremental costs that reflect a cost saving over time and incremental benefits over time which are positive, therefore the submission reports that the DAFNE intervention is dominant over the current standard practice. *Table 31* presents the base case results in the DAFNE Study Group submission (their Table 3.5).

Sensitivity analysis

One-way sensitivity analysis has been undertaken and reported in the submission. Given the large number of data points and assumptions applied in the model and the manner in which many of the assumptions may interact, it would have been useful to have had details on multivariate sensitivity analyses. Sensitivity analysis does not report impact of variations in the assumptions surrounding QALY values.

Southampton assessment of cost-effectiveness

General

As discussed above, we have not identified suitable modelling methodology to consider the cost-effectiveness of patient education models versus usual care. The submission to NICE from the DAFNE Study Group uses data from a number of sources, together with modelling methods published for Type 2 and data from unpublished sources to estimate the cost-effectiveness of the DAFNE intervention.

In order to make some judgement as to the potential cost-effectiveness of patient education models, we use some data from the DAFNE submission together with other assumptions, described below.

Costs

The intervention costs estimated for the DAFNE intervention provide a good basis on which to consider the costs for patient education models for Type 1 diabetes. As with the DAFNE approach, two other clinical trials[94,95] for Type 1 diabetes are based on the methods developed by Mühlhauser and colleagues in Düsseldorf.[23] The DAFNE submission estimates the cost for the structured education programme to be approximately £545 per patient attending, with the programme delivered on an outpatient basis. Should the DAFNE intervention be applied to Type 2 diabetes, we would expect it to have similar resource and cost implications to those for Type 1.

We present in Appendix 14 estimates of UK staff costs for the educational interventions described in the four trials included in the clinical review covering Type 1 diabetes, together with estimates related to the DAFNE educational intervention. We estimate that the SDIS[21] intervention would involve a minimum staff cost of £506 in year 1, with an ongoing staff input at approximately £145 per year. The minimum staff costs for education described in studies by Terent and colleagues[22] and Starostina and colleagues[24] are estimated at £567 and £578, respectively, and the study described by Mühlhauser and colleagues[23] has an estimate of minimum staff costs of between £130 and £163. All of these studies will have additional costs associated with educational materials, training, capital set-up costs and ongoing quality assessment costs.

The submission to NICE from the Association of Clinical Diabetologists (ACD), detailing experience of education at Poole Hospital, documents a programme of education for newly diagnosed Type 2 diabetes, consisting of three diabetes education sessions (DESs) spread over a period of 8–10 weeks, with an outpatient appointment with a consultant at 4 months following diagnosis. The costs associated with the diabetes education programme in Poole are estimated to be approximately £33,000 per year for the centre; approximately £66 per patient based on an estimated 500 new patients per year. This is a crude estimate of direct input resource, with some allowance for overhead costs. Other ongoing costs will need to be considered (e.g. training, audit, facility space), but it offers an indication of the relatively low intervention costs of the patient education developed in Poole. Using the cost estimates from the ACD submission, and applying the estimate from the DAFNE Study Group of 120 Type 1 patients trained per centre per year, would offer a cost estimate of £275 per patient attending the programme. The submission from the ACD offers an indication of the benefits from the programme; however, the methods are not detailed and the study appears to be a pragmatic observational study, with variations in methods over time.

Effects/complications

The review of the clinical effectiveness of patient education models indicates that there is a significant difference in HbA_{1c} in relation to education, although the presence of other treatment aspects in the package of care may create some uncertainty over the actual cause of the difference in HbA_{1c}. However, assuming a reduction of around 0.5% in HbA_{1c}, as a result of patient education models, there are difficulties in assessing the actual clinical impact of such an effect with respect to patients' health outcomes. Methods for the modelling of disease progression and cost-effectiveness using HbA_{1c}, as a means of differentiating between patient groups, are not common and we were unable to identify methods relating to Type 1 diabetes. For Type 2 disease, one approach is that of Eastman and colleagues.[75] As with the DCCT analysis of Type 1 diabetes (i.e. conventional versus intensive insulin therapy), it is not possible to establish whether HbA_{1c} is responsible for the reduction in incidence of diabetic complications, as differences with respect to changes in diabetic treatment are present. The DCCT data do not provide a definitive assessment of the causal relationship between specific levels of glycaemic exposure (HbA_{1c}) and the risk of complications,[78] as confounding is possible from a number of sources. Therefore, it is difficult to

assess the specific impact that a reduction in HbA_{1c} will have on long-term outcomes (although there is broad acceptance that a reduction in HbA_{1c} is associated with a reduction in the incidence of long-term complications).

The DAFNE Study Group have submitted a model that uses the methods published by Eastman and colleagues for Type 2 diabetes, and have been able to apply the model to Type 1 diabetes, given data available to them from further analyses by Eastman and colleagues (personal communication). Structurally, the model reflects a disease progression model for patients with diabetes across a number of different complication areas. The probabilities used to transit patients between states are partly from the DCCT and partly from unpublished sources (for nephropathy, neuropathy and retinopathy), and the means of adjusting the probability of experiencing complications as a result of a reduced HbA_{1c} measure may be reliant on the effects of changing mode of treatment as well as the effect of improved HbA_{1c}. However, given the absence of data to inform on disease progression otherwise, the model offers some indications as to progression of disease in an intervention versus control cohort analysis.

The base analysis of the cost-effectiveness model submitted to NICE also incorporates a number of other uncertain parameter inputs. For example, we are unsure of the estimated base case clinical effect (HbA_{1c}) and the estimated impact of health outcomes and complications on health-related QoL and QALY values. We have re-run some analyses using the structured model provided by the DAFNE Study Group and present the findings below.

Southampton changes to DAFNE model assumptions

- Assume no effect on ketoacidosis – data from DAFNE [*British Medical Journal* (*BMJ*) submission] does not report a significant difference.
- Assume no difference in outpatient reviews – data from DAFNE (*BMJ* submission) does not report a significant difference.
- Assume a reduction in HbA_{1c} of 0.53% – which is the reported difference (DAFNE submission) between the DAFNE intervention group at 12 months and baseline.
- Assume annual probability of progression to ESRD is 0.05, data from DCCT.[72]
- Assume annual probability of first amputation at 0.01, data from DCCT.[72]

When these alterations are used in the DAFNE model structure, the prediction remains one of a net cost saving, although at £668 per patient (£536 when discounted) this is not as dramatic as found by the DAFNE base case analysis (based on the same cohort specifications as the submitted model); see *Table 32*.

Given the changes to the input assumptions above, the DAFNE model predicts an improvement in life years of 0.034 per patient (discounted incremental effect) and an improvement in QALYs of between 0.06 (VAS) and 0.08 (EQ-5D tariff) per patient (discounted incremental effect) – smaller benefits than those shown by the DAFNE base case analysis. While the cost-effectiveness prediction is one of cost saving, together with positive benefits, the emphasis on the predicted benefits is less important. However, should the DAFNE intervention result in additional costs, the benefits estimated within the model would need to be scrutinised further.

Given the structure of the DAFNE model and the methods used to derive the QALY values applied in the model, it is not easy to alter the input values which drive the QALY calculations. We have undertaken some sensitivity analysis on the QALY algorithm used to estimate the QALY values (VAS and EQ-5D tariff values) associated with incidence of complications. Together with the above parameter inputs and the baseline patient characteristics, we reduced the QALY decrements associated with nephropathy and neuropathy complications by 50% (of DAFNE base case inputs). The results, shown in *Table 32*, were a reduction in discounted QALYs saved within the model from 0.0609 QALYs on the VAS to 0.054 QALYs, and from 0.0776 QALYs per patient using the EQ-5D tariff to 0.063 QALYs per patient.

TABLE 32 *Cost-effectiveness results based on Southampton adjustments to the DAFNE input parameter values*

		Per patient
Incremental cost	Undiscounted	–£668
	Discounted	–£536
Incremental EQ-5D QALY	Undiscounted	0.066
	Discounted	0.063
Incremental VAS QALY	Undiscounted	0.057
	Discounted	0.054
Incremental life-years	Undiscounted	0.036
	Discounted	0.035

Given the relatively small costs associated with the DAFNE intervention, and given the 10-year time horizon for analysis, only small improvements in terms of mortality and/or health-related QoL (e.g. QALY gains) are required to enable the DAFNE intervention (and patient education generally) to appear cost-effective. For example, an additional intervention cost of £545 together with the predicted increase in insulin treatment costs of approximately £450 per patient (discounted over 10 years) would require an improvement over the same period of 0.05 QALYS to give a cost per QALY of just under £20,000, or an improvement of 0.10 QALYs to offer a cost per QALY estimate of just under £10,000. However, it may be that we are not concerned with the additional insulin costs in such a simplistic 'back calculation', given that the comparison of intensive versus conventional insulin therapy is generally regarded as a cost-effective treatment option.[10,72]

Overall, given the relatively low costs and the expectation of reduced longer term complications, the cost-effectiveness profile for the DAFNE patient education model and similar models of patient education appears to be potentially favourable. However, this is dependent on the clinical effectiveness of patient education models (i.e. improvements in HbA_{1c}).

Chapter 11
Discussion and conclusions

Implications for other parties

If patient education were effective in improving diabetic control and reducing long-term complications of diabetes there would be an impact on patients, their families and other parties. QoL may be affected in both positive and negative ways. If people with diabetes gain confidence in managing their condition, reduce their anxieties and have better outcomes, then QoL should be significantly improved. In contrast, this could be offset if, despite increased knowledge brought about by the education, they feel that they are unable to manage the disease successfully. Inability to adhere to the change in diet might be the commonest example of failure of self-management.

Factors relevant to NHS policy

There is anecdotal evidence that patients receive conflicting information from different healthcare providers. Education requires a consistent approach from all professional staff. It is therefore important that any shift of diabetes care, for example from hospital to primary care settings, should be accompanied by consistent advice (this may be covered by the forthcoming NICE guidelines on diabetes care, and is not addressed in this report). In order to implement any one common learning curriculum, it is likely that there will be a need for interprofessional education and also a need for an organisational culture that supports empowerment.

Spending more time on education will require changes in working practices for all professionals involved. Similarly, patients who have become more effective self-managers as a result of successful education may require healthcare delivery of a different style from that experienced now. One barrier to implementation may be that some practitioners may already feel that they are providing adequate 'education' for patients with diabetes. Furthermore, consideration needs to be given to the current problems of staffing in certain disciplines within the NHS (e.g. DSNs, dietitians). It is likely that most education is provided by DSNs and dietitians. Anecdotal evidence encountered in the course of this review suggests that there is a shortage of both disciplines and that funding is only part of the problem – even if funds were available, recruitment in some areas is difficult. Anecdotal evidence also suggests that there are considerable time pressures in diabetes clinics, partly due to the increases in prevalence of both types of diabetes, and that physician time may also be a constraint.

The educational 'models' that have been reviewed in this report are mainly additional to traditional informal education within clinics. If staff shortages mean that it is difficult to provide education in clinics, then that creates a significant barrier to implementation of newer models. There may need to be a hierarchy of educational needs until such time as recruitment difficulties have been overcome.

Conclusions

Statement of principal findings

The main findings of this review of patient education models for diabetes are summarised below.

Efficacy

Interventions for Type 1 diabetes

The results from studies of education for patients with Type 1 diabetes suggest that education/intensified treatment programmes can produce significant effects in terms of diabetic control. These results also indicate that these effects may be relatively long-lasting. In addition, the results of one trial with a long-term follow-up have demonstrated significant effects of the intervention on diabetic complications, such as retinopathy. However, it should be noted that this trial also provided educational support throughout the trial. Two studies reported greater knowledge and better diabetic control in educated groups (although one study did not test these differences statistically).

The benefits of diabetes control cannot be attributed solely to the education that is offered to the patients, as in all but one study patients were intensifying their treatment regimens. The educational component is part of the intensification of insulin therapy.

Interventions for Type 2 diabetes

The effects on diabetic control (e.g. HbA_{1c}, BMI, cholesterol) were limited in studies of interventions

teaching multiple topics of self-management for Type 2 diabetes. Modest effects were demonstrated in studies focusing on diet and exercise alone. These effects were not large, but those that were present did appear to be relatively long-lasting. Little evidence has been put forward for the effects of education on diabetic end-points or cognitive outcomes, although some positive effect on patient knowledge was demonstrated. In two studies reporting increased knowledge, HbA_{1c} decreased in one and use of OHAs was reduced in the other.

These inconclusive findings are unfortunate as most patients with diabetes have Type 2 diabetes and incidence is increasing. It would be impossible at this point to say definitively what characteristics of an educational programme (if any) aimed at patients with Type 2 diabetes might produce long-term positive effects.

Education for patients is already provided, although in varying amounts, and should continue as there is likely to be little negative effect (although those patients who find themselves unable to act on advice may have increased anxiety due to education). 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.

Interventions for patients with either Type 1 or Type 2 diabetes

Two CCTs that included patients with either Type 1 or Type 2 diabetes suggested that education could reduce HbA_{1c} levels. However, results from two RCTs did not demonstrate any clear effects of the educational interventions on outcomes. Two studies reported increased knowledge in educated groups, but there was no clear correspondence between increased knowledge and diabetic control.

Cost-effectiveness

This report is concerned with the cost-effectiveness of patient education models for diabetes, not the cost-effectiveness of intensive diabetic therapy. The findings from the literature review of economic evaluations do not offer any indications as to the cost-effectiveness of patient education models for diabetes. Although there are potential benefits from education models in terms of improved glycaemic control (i.e. HbA_{1c}), there are difficulties in considering the cost-effectiveness of interventions in diabetes based only on improvements in HbA_{1c}. Trials of patient education are mostly short term and important outcomes such as diabetic complications are observed in the longer term. Trials such as the SDIS provide a combination of education and treatment intensification and it is not possible to isolate the benefits of patient education. Therefore, an assessment of the cost-effectiveness of the intervention is difficult.

Intervention costs are largely direct costs of education programmes, constituting NHS staff time and subsequent capital and training requirements. Costs for the intervention are relatively small, with submissions from sponsors/consultees estimating intervention costs at £545 per patient for a 5-day DTTP in Type 1 patients to £66 per patient for an education programme aimed at newly diagnosed Type 2 patients. The upper cost estimate is a comprehensive assessment of resource use and NHS costs. Improvements in HbA_{1c} are expected to offer long-term benefits in terms of a reduced incidence of diabetic complications.

The DAFNE Study Group presents an economic evaluation that finds the DAFNE intervention cost saving over a 10-year period, with added health benefits (i.e. life-years saved, QALYs gained). Although there is uncertainty over some aspects of the economic model used to assess the cost-effectiveness of DAFNE, we would support the intervention as potentially cost-effective in Type 1 patients where the benefits in terms of improved HbA_{1c} are significant and are considered over a 10-year time horizon.

Other issues and methodological concerns

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, outwith 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 development and evaluation of RCTs for complex interventions.[96] Few of the interventions seem to have been developed in a way such that the crucial components of interventions can be teased apart from the aspects of the intervention that may be less important.

Confounding

There is likely to be confounding in some studies of this nature, for instance between intensifying insulin treatments and the education provided in those trials for Type 1 patients. Other confounds may include 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 patients were to greater or lesser extents self-selected. When patients 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. Similarly, results on 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 of these effects.

Quality of study design

Many of the studies were of poor design. 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 labelled CCTs in this report. Such design issues were often poorly reported.

Many studies were also fairly small and therefore likely to be 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 poor in most studies. The method of randomisation was not described in most studies. In addition, 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.

Most of the included studies do not include the level of detail about the intervention that would allow for replication of the study, a basic requirement of placing a study into the scientific literature. This shortcoming is important, not only scientifically but also 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 in other settings.

Another problem that relates to the poor quality of reporting is an uncertainty about the nature of the control group in many of the studies. It has been assumed in most cases that the control group was receiving 'usual care'. However, in many cases what this consists of is unclear. The extent to which the interventions actually differed from the controls is sometimes unclear. This can obscure the determination of what in the intervention may be effective and it may influence the size of effect that is shown for an intervention (either an over- or an underestimate). This can also affect the generalisability of studies if it is not clear to what extent a study resembles usual practice where the intervention might be implemented.

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 would report on interventions that were conducted and then 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 with very brief follow-up are not useful in this context. Such studies were excluded. However, studies that evaluated outcomes at least 12 months following the introduction of an intervention were included. 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 perhaps lasting for the entire year or more. 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.

Attrition

Many included studies had fairly high levels of drop-out between initial recruitment and reporting of results. This is of concern for a number of reasons. Most studies did not report that they performed an ITT analysis, instead testing 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 can also affect the results. The most likely effect is to reduce the estimate of the effectiveness of the intervention as the patients who are least motivated toward self-management and who are most ill are the mostly likely to leave the study.

High attrition rates affect the validity of study results, but they are also a 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 as a component of usual care.

Theoretical underpinning to education

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. 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 would be more likely to make swifter progress.

Transferability

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 traditions and customs, may have an impact on outcomes. Patient health beliefs and attitudes may also be different from one country to another, and finally, the healthcare context (private/state provision) may also affect outcomes.

Strengths and limitations of the review

This review has a number of strengths which lead to a minimisation of bias. The review is independent of any vested interest and it brings together the evidence for the effectiveness of patient education models for diabetes by the application of consistent methods of critical appraisal. It was guided by the principles for undertaking a systematic review and prior to undertaking the rapid review, the methods of the review were set out in a research protocol (Appendix 1). This protocol defined the research question, inclusion criteria, quality criteria, data extraction process and methods employed to undertake the different stages of the review. Finally, an advisory group has informed the rapid review from its initiation, through the development of the research protocol and completion of the report.

There were certain limitations placed on this review. Owing to differences in the design, duration, outcome measures and reporting of studies, synthesis of the included studies was through narrative review with no formal meta-analysis. Despite being guided by the principles for undertaking a systematic review, owing to time restrictions placed on the review the authors of references were not contacted for further details of their trials where data were lacking. As published papers are usually limited to 2500–5000 words, it may be that some details of the trials are not published.

Implications for further research

This report has served to highlight a shortage of high-quality information regarding the efficacy of education in diabetes. While the nature of the chronic disease demands that patients manage diabetes themselves and obviously this cannot be achieved without education, there is little good evidence to suggest exactly how patients should be educated and trained in order to facilitate good

metabolic control and high QoL. If the goal of further research is to evaluate patient education *per se*, then RCTs with the following characteristics are needed:

- long-term follow-up
- explicit tests of time-limited interventions with long-term follow-up
- designs and statistical tests appropriate to test single aspects of interventions
- detailed reporting of interventions and comparators
- careful consideration of study attrition and appropriate analysis
- explicit comparisons between study and control groups rather than within-group, before and after measures
- inclusion of validated measures of QoL and other psychological outcomes such as stress and anxiety.

If it is acknowledged that patient education is only a part of the care of patients with diabetes, then trying artificially to isolate the effects of education may not be appropriate. In this case, the MRC framework provides useful recommendations for developing evaluations of complex interventions.[96]

Diabetes education should be considered in the context of overall diabetes management including education, support and behavioural change, drug treatment and surveillance and treatment of complications. These evaluations should perhaps be considered in the broader context of understanding theory, testing intervention interactions and long-term surveillance of the programme after testing effectiveness. A broader range of outcome measures may be appropriate, for instance including behavioural outcomes that may be measured qualitatively. Qualitative research which focuses on process is particularly relevant to practice to allow a better understanding of quantitative evidence, and there is a need for research to focus on both outcomes and processes.

The goals of treatment differ for different patients. In patients with Type 2 diabetes whose BG is at a desirable level, it may be a goal to reduce or eliminate the use of oral agents or to maintain BG within a range rather than to reduce it. Trials should make such treatment goals clear and to report separately on the basis of treatment goals. Newly diagnosed patients are likely to react differently to patients who have been dealing with diabetes for some time. The natural history of Type 2 diabetes will mean that treatment goals and options are likely to change over time. Therefore, rather than reporting on mixed groups of patients who differ in these characteristics, it would be useful to determine what kinds of treatment packages are most effective for different patient subgroups.

Research should also address the problem of performing systematic reviews of complex interventions, such as diabetes treatment and teaching programmes.

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Note

A small amount of information was submitted to NICE in confidence and references to this information have been removed from this version. However, it should be noted that the Institute's Appraisal Committee had access to the full report to draw up their guidance.

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Appendix 1

Rapid review methods from the research protocol

The methods below were approved by NICE at the start of the review.

Research question

To undertake a systematic review of the clinical and cost-effectiveness of models for educating people with Type 1 and Type 2 diabetes mellitus in diabetes self-management.

Clarification of research question and scope

- Self-management in diabetes refers to achieving and maintaining BG control through diet, exercise, oral medications and insulins.
- The primary questions for this review are whether current models of diabetes self-management education are sufficiently effective in terms of clinical indices (see outcomes below) and in terms of costs and benefits; and if not, what other models might be introduced.
- The educational interventions to be considered in this review will be defined as available models for educating people with diabetes in diabetes self-management with the likelihood that these will include those passively transferring knowledge, those based on principles of empowerment, group and individual programmes and combinations thereof.
- The main comparator for this review will be usual care in clinics or primary care. This will vary among clinics and general practices, but will include informal education and unevaluated, locally developed education packages. In many existing hospital services education will be provided by DSNs or others specifically trained in diabetes education. In other cases providers may have little or no formal training. An anticipated lack of data on current education provision will mean that research results may not be directly comparable to particular existing programmes or to an 'average' existing programme. Instead, it is likely that conclusions will be limited to comparisons that exist within trials.
- Early appraisal of some literature in this area suggests that self-management interventions are generally complex, often including education as well as changes in the intensity of medical treatment. It should be noted that there may be a low likelihood of locating trials that will be informative about educational interventions *per se* (without confounding with intensity of treatment). It may be necessary to assess packages of care which combine, for example, more intensive insulin regimens with the education required to use those.
- 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.
- Potential economic benefits include reduced costs associated with the treatment of diabetes-related complications.

Search strategy

- We will search the following databases: Cochrane Systematic Reviews Database, Cochrane Controlled Trials Register, NHS CRD (University of York) databases (including DARE, NHS EED and HTA database), MEDLINE (Silverplatter), PubMed (previous 6 months – for latest publications), EMBASE, PsychLit, ERIC, National Research Register, Science Citation Index, Social Science Citation Index, EconLit, MRC Trials database, Early Warning System and Current Controlled Trials.
- Searches will include RCTs, CCTs, systematic reviews and meta-analyses for evidence of efficacy. Searches will also 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.
- Because the type of diabetes may not always be addressed in trials and some trials may include patients with both types of diabetes, diabetes

types will not be searched for individually. A broad search strategy will be used and all trials will be collated and filtered on retrieval of the abstracts and full papers.
- Searches will be limited to the years 1980 to the present. Older publications will not be sought because there are existing reviews that have captured the relevant publications prior to 1980; these reviews and their included trials will be assessed for inclusion according to the inclusion criteria (see below). Searches will also be limited to English language. Reports published only as meeting abstracts will be excluded. Unpublished master's dissertations and theses will be excluded.
- 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.
- The Cochrane Metabolic and Endocrine Diseases Group will be consulted.

Inclusion and exclusion criteria

Systematic reviews and meta-analyses of RCTs and CCTs (see below) 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 some concurrent control group.
- RCTs or CCTs that compare models of group education with individual education will be included.

Intervention

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

Reporting

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:

- what the intervention is with some description of the topics covered
- who provides instruction (e.g. post and qualification)
- how education is delivered (e.g. in person, by computer)
- group or individual
- length of intervention (length and number of sessions)
- target audience (e.g. Type 1, Type 2 or both; newly diagnosed)
- didactic or interactive instruction
- 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 1 or Type 2 diabetes using the standard diagnostic criteria in effect at the inception of the study. Both newly diagnosed and patients with established diabetes will be included. In some cases the type of diabetes may not be clearly defined in trials, in which case these will be treated as a separate subgroup of trials.
- 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 BG levels (HbA_{1c}), severe hypoglycaemic episodes, diabetes-related complications or QoL (as assessed by validated measures, e.g. SF-36).
- Additional outcomes that will be reported if available within trials that meet the other inclusion criteria will include BP, hospital admissions, relief of distress or anxiety, uptake of screening (e.g. eye screening or BP checks), patient knowledge, patient satisfaction, achievement of individual treatment goals and resource use/costs. Any psychological measures must be evaluated with validated psychometric instruments.
- Results that address individual preferred learning styles or meeting the needs of ethnic minorities or others with specific needs will be included if they are reported in studies that meet the inclusion criteria set out above.
- Inclusion and exclusion criteria will be applied by one reviewer and checked by a second. Any disagreement will be resolved by discussion.

Inclusion and exclusion criteria for papers on the cost-effectiveness of models of diabetic education

All papers that present findings on the cost-effectiveness of educational interventions (as defined above) when compared with usual care in clinics or primary care (as defined above), will be reviewed in detail, comprising a narrative review with a tabulation of results where appropriate.

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.

Appendix 2

Sources of information, including databases searched and search terms

The databases were searched for published studies and recently completed and ongoing research. All searches were limited to English language only. A flowchart outlining the identification of studies is shown in *Figure 1*.

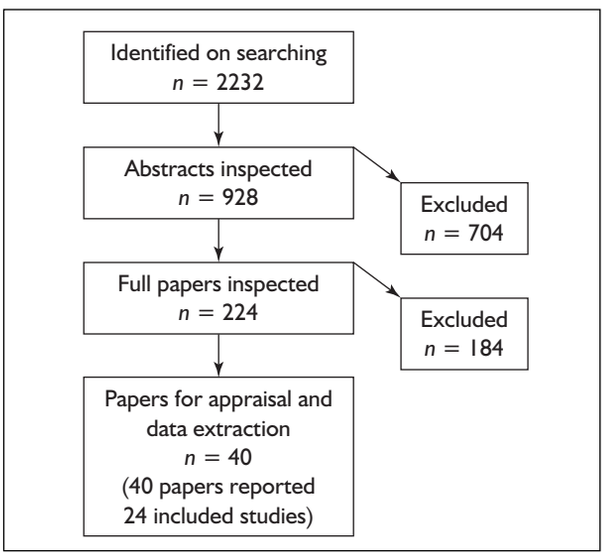

FIGURE 1 *Flowchart of identification of studies (RCTs, CCTs and systematic reviews) for clinical effectiveness systematic review. The number of references identified on initial searching includes duplicates from searches across multiple databases and also references that were obviously inappropriate. These could include studies considering conditions other than diabetes, studies* in vitro*, studies with non-educational interventions or studies in inappropriate patient populations. When duplicates and obviously inappropriate references were removed, 928 abstracts remained for further consideration. These included a few references that were located for background information outside the formal effectiveness search. On the basis of inspecting the abstracts, 704 references were excluded. Full papers for 224 references were retrieved and inspected. A few of these were retrieved for general background information rather than as potential clinical trials. From the full papers inspected, 184 were excluded. The worksheet detailing the inclusion criteria can be found in Appendix 3. A substantial number of papers that were retrieved were not reports of clinical trials, being, for instance, descriptions of educational programmes or non-systematic reviews. Those references which were reports of clinical studies of educational programmes, but which were excluded, are listed in Appendix 4 along with the reasons for their exclusion. Forty papers were included for full data extraction and inclusion in the report. These 40 papers described 24 RCTs or CCTs of education for patients with diabetes.*

Clinical effectiveness search strategies

- Cochrane Library (Issue 2, 2002) and
  #1 DIABETES-MELLITUS*:ME
  #2 (DIABET*:TI or IDDM:TI) or NIDDM:TI)
  #3 #1:TI or #2:TI)
  #4 PATIENT-EDUCATION*:ME
  #5 MODELS-EDUCATIONAL*:ME
  #6 (#1 or #2)
  #7 (#4 or #5)
  #8 ((((((EDUCAT* or LEARN*) or TEACH*) or TRAIN*) or MODEL*) or PROGRAM*) or INTERVENTION*)
  #9 (#7 or #8)
  #10 SELF-CARE*:ME
  #11 SELF-MANAGE*
  #12 (SELF next MANAGE*)
  #13 (SELF-CARE or (SELF next CARE))
  #14 (PATIENT near (((EMPOWER* or CONTROL*) or MANAGE*) or REGULAT*))
  #15 ((((#10 or #11) or #12) or #13) or #14)
  #16 (#6 and (#9 or #15)).
- National Research Register (Issue 2, 2002).
  As for the Cochrane Library (above).
- MEDLINE (WebSPIRS), 1980–2002/06
  (((((explode 'Diabetes-Mellitus'/all subheadings in MIME,MJME) or ((diabet* or IDDM or NIDDM) in TI)) and (('Patient-Education'/all subheadings in MIME,MJME) or (explode 'Learning-'/all subheadings in MIME,MJME) or ('Models-Educational'/all subheadings in MIME,MJME) or (educat* or learn* or teach* or train* or model* or program* or intervention*)) and (((pt=randomized-controlled-trial) or (pt=controlled-clinical-trial)) or (random* or (control* near (study or group or trial or usual care))))) or (((explode 'Diabetes-Mellitus'/all subheadings in MIME,MJME) or ((diabet* or IDDM or NIDDM) in TI)) and ((explode 'Self-Care'/all subheadings in MIME,MJME) or (self regulat* or self manage* or self care or self monitor*) or (BG near4 (monitor* or regulat* or manage* or control*)) or (patient* near3 (empower* or control* or manage* or regulat*))) and (((pt=randomized-controlled-trial) or (pt=controlled-clinical-trial)) or (random* or (control* near (study or group

or trial or usual care)))))) and (English in la)) or ((explode 'Diabetes-Mellitus'/all subheadings in MIME,MJME) and ((MUHLHAUSER-I in AUI:MEDS) or (BERGER-M in AUI:MEDS))).

- PubMED (Internet version), records added from 21/08/01 to 19/7/02
  1. (Diabetes Mellitus"[MESH OR diabetes OR diabetic*) AND (educational OR educate* OR intervention*)
  2. (diabetes OR diabetic*) AND (self-manage* OR self-care)
  3. (diabetes OR diabetic*) AND (education* AND model*)
  4. (diabetes OR diabetic*) AND (patient education) AND trial.
- EMBASE (WebSPIRS), 1980-2002/06 (((((explode 'diabetes-mellitus'/all subheadings) or ((diabet* or IDDM or NIDDM) in TI)) and (('patient-education'/all subheadings) or (explode 'learning-'/all subheadings) or ('education-program'/all subheadings) or ('teaching-'/all subheadings) or ((educat* or learn* or teach* or train* or model* or program* or intervention*) in TI))) or (((explode 'diabetes-mellitus'/all subheadings) or ((diabet* or IDDM or NIDDM) in TI)) and ((explode 'self-care'/all subheadings) or (self manag* or self care) or (patient near3 (empower* or control* or manage* or regulat*)))) or (((explode 'diabetes-mellitus'/all subheadings) or ((diabet* or IDDM or NIDDM) in TI)) and ((muhlhauser or berger) in AU))) and ((explode 'clinical-trial'/all subheadings) or (meta-analy* or metaanaly* or systematic review or systematic overview))) and (English in la).
- Science Citation Index, 1980–18/07/2002 diabet* and (trial* or random*) and (self-manage* or self-care or patient same education or model* same education*).
- Web of Science Proceedings, 1990 to 18/07/2002 diabet* and (trial* or random*) and (self-manage* or self-care or patient same education or model* same education*).
- PsycINFO 1980–2002/07 ((explode 'Diabetes-Mellitus' in DE) or (diabet* and (PY=1980-2002) and (English in la) and (LA=ENGLISH))) and (((patient* near education*) and (PY=1980-2002) and (English in la) and (LA=ENGLISH)) or ((model* near education*) and (PY=1980-2002) and (LA=ENGLISH)) or (self care and (PY=1980-2002) and (LA=ENGLISH)) or (self manage* and (PY=1980-2002) and (LA=ENGLISH))) and ((trial* or random*) and (PY=1980-2002) and (LA=ENGLISH)).
- CINAHL 1982–2002/05 ((explode 'Diabetes-Mellitus'/all topical subheadings/all age subheadings in DE) or (diabet* in ti,ab)) and ((((model* or patient*) near education*) or (self care) or (self manage*)) in ti,ab,sh) and (((clinical near trial) or (random*)) in ti,ab,sh).
- ERIC 1980–June 2002 diabet$ and (model$ or self-care or self care or self manage$ or self-manage$ or patient education$) and (trial$ or random$).
- BEI (British Education Index), 1986–May 2002 diabet$ and (model$ or self-care or self care or self manage$ or self-manage$ or patient education$) and (trial$ or random$).
- DARE and HTA Database (web version), searched on 18/7/02
  1. diabet$ AND education
  2. diabet$ AND self manage$
  3. diabet$ AND self care$.
- BIOSIS 1985–18 July 2002
  1. (((al: (diabet*)) and al: (self care)) and al: (random*)) or (((al: (diabet*)) and al: (self manage*)) and al: (random*))
  2. ((al: (diabet*)) and al: (education* w model*)) and al: (random*)
  3. (al: diabet* n patient education) and al: random*.

Cost-effectiveness and QoL

- MEDLINE (WebSPIRS), 1980–2002/07 ((explode 'Economics-'/all subheadings in MIME,MJME) or ((explode 'Quality-Adjusted-Life-Years'/all subheadings in MIME,MJME) or (explode 'Quality-of-Life'/all subheadings in MIME,MJME)) or (cost* or economic*) or ((quality near2 life) or QALY) or (wellbeing or well-being)) and ((((random* or (control* near trial) or (clinical near trial)) or ((PT=CONTROLLED-CLINICAL-TRIAL) or (PT=RANDOMIZED-CONTROLLED-TRIAL)) or (pt=clinical-trial) or (metaanaly* or meta-analy* or (systematic* near review) or (systematic* near overview) or (pt=meta-analysis))) and ((((explode 'Diabetes-Mellitus'/all subheadings in MIME,MJME) or ((diabet* or IDDM or NIDDM) in TI)) and (('Patient-Education'/all subheadings in MIME,MJME) or (explode 'Learning-'/all subheadings in MIME,MJME) or ('Models-Educational'/all subheadings in MIME,MJME) or (educat* or learn* or teach* or train* or model* or program* or intervention*))) or (((explode

'Diabetes-Mellitus'/all subheadings in MIME,MJME) or ((diabet* or IDDM or NIDDM) in TI)) and ((explode 'Self-Care'/all subheadings in MIME,MJME) or (self regulat* or self manage* or self care or self monitor*) or (blood glucose near4 (monitor* or regulat* or manage* or control*)) or (patient* near3 (empower* or control* or manage* or regulat*)))) or (((explode 'Diabetes-Mellitus'/all subheadings in MIME,MJME) or ((diabet* or IDDM or NIDDM) in TI)) and ((MUHLHAUSER-I in AUI:MEDS) or (BERGER-M in AUI:MEDS))))) and (English in la)).

- EMBASE (WebSPIRS), 1980–2002/06
  ((explode 'quality-of-life'/all subheadings) or ('quality-adjusted-life-year'/all subheadings) or (explode 'health-economics'/all subheadings) or (explode 'economics-'/all subheadings) or (cost* or economic*) or ((quality near3 life) or qaly or wellbeing or well-being)) and ((((((explode 'diabetes-mellitus'/all subheadings) or ((diabet* or IDDM or NIDDM) in TI)) and (('patient-education'/all subheadings) or (explode 'learning-'/all subheadings) or ('education-program'/all subheadings) or ('teaching-'/all subheadings) or ((educat* or learn* or teach* or train* or model* or program* or intervention*) in TI))) or (((explode 'diabetes-mellitus'/all subheadings) or ((diabet* or IDDM or NIDDM) in TI)) and ((explode 'self-care'/all subheadings) or (self manag* or self care) or (patient near3 (empower* or control* or manage* or regulat*)))) or (((explode 'diabetes-mellitus'/all subheadings) or ((diabet* or IDDM or NIDDM) in TI)) and ((muhlhauser or berger) in AU))) and ((explode 'clinical-trial'/all subheadings) or (meta-analy* or metaanaly* or systematic review or systematic overview))) and (English in la)).
- PubMED (Internet version, records added from 24/12/01 to 18/07/02)
  diabetes AND (cost OR costs OR economic OR economics).
- NHS EED (web version), searched on 18/07/02
  diabetes and (teaching or training or learning or management or education).

Additional searching

Bibliographies

All references to articles for which full papers were retrieved were checked to ensure that no eligible studies had been missed.

Experts

Experts were contacted for advice and peer review and to identify additional published and unpublished references and any currently ongoing studies.

Web sites

Diabetes UK website: http://www.diabetes-uk.org.uk/home.htm.

Appendix 3

Inclusion criteria worksheet

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

Appendix 4

Details of excluded studies

DAFNE

The objective of the DAFNE (Dose Adjustment for Normal Eating) trial was to evaluate whether a flexible intensive insulin regimen, combining dietary freedom with insulin adjustment training, can improve both metabolic control and QoL. Eligible patients were adults with established Type 1 diabetes with moderate or poor glycaemic control. The setting was secondary care diabetes clinics in three English health districts.

Participants were randomised into a waiting-list controlled trial. [DAFNE patients had a mean age 40 years; a long duration of diagnosis (average 17 years); poor glucose control at baseline. The study had low recruitment, with only 136 of 1000 invited joining. There had been one death, possibly related to active treatment.] The intervention group, 'immediate DAFNE', attended a training course within 1–4 months of randomisation. The control group, 'delayed DAFNE', acted as waiting-list controls. They continued to receive their usual care for 6 months, and then attended a 'delayed DAFNE' training course 6 months later. The groups were compared at baseline and 6 and 12 months. The post-course follow-up was 12 months for the immediate DAFNE group and 6 months for the delayed DAFNE group.

The primary outcome measures were HbA_{1c}, rate of severe hypoglycaemia and the ADDQoL (Audit of Diabetes-Dependent Quality of Life). Other end-points included weight, lipids, satisfaction with treatment (DTSQ) and psychological well-being (W-BQ12). HbA_{1c} levels in the immediate DAFNE group fell by 1% for the first 6 months after training. At 12 months, there had been some increase, but levels still remained significantly lower than baseline by 0.5% (95% CI 0.1 to 0.9, $p = 0.004$). One-quarter (16/67) maintained a fall in HbA_{1c} of >1.5% and four (6%) showed a rise of >1.5%. The levels in the delayed DAFNE group remained constant for the first 6 months while waiting for training, and fell 0.7% 6 months after the training. ADDQoL scores improved and were fully maintained in immediate DAFNE. In delayed DAFNE, they remained constant and then improved after training. Similar patterns of improvement to the ADDQoL were shown for the DTSQ and W-BQ12.

It was concluded that skills training was effective in promoting dietary freedom, improved QoL and glycaemic control in people with Type 1 diabetes, without worsening severe hypoglycaemia or cardiovascular risk.

This trial does not meet the reviews inclusion criteria for length of follow-up as there was no concurrent control group for the 12-month follow-up period.

The Diabetes Control and Complications Trial (DCCT)

The DCCT was a multicentre, RCT that compared intensive therapy with conventional therapy and assessed their effects on the development and progression of early vascular and neurological complications of Type 1 diabetes. All patients had an educational component at the start of the trial, and the intensive treatment group continued to visit their study centre each month and were contacted even more frequently by telephone to review and adjust their regimens. The trial does not meet this review's reproducibility inclusion criterion. The educational packages were locally developed and, therefore, differed between centres.

United Kingdom Prospective Diabetes Study (UKPDS)

The UKPDS was designed to establish whether intensive BG control in patients with Type 2 diabetes reduced the risk of macrovascular or microvascular complications. The cut-off for BG control was 14 mmol/litre in the control group and 6 mmol/litre in the intervention group. When BG exceeded the cut-off, treatment was altered to try to reduce it. All patients had a 3-month dietary run-in period where they were seen by a physician and dietitian. All patients also continued to receive dietary advice from a dietitian throughout the study period.

Although education was given to the participants, this was similar in both groups and therefore does not meet the inclusion criteria.

Other trials that were excluded from the review:

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

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Berger M. Evaluation of a teaching and treatment programme for type I diabetic patients. *Diabetes Educ* 1984;**10**(Spec no):36–8.

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Coates VE, Boore JRP. Knowledge and diabetes self-management. *Patient Educ Couns* 1996;**29**:99–108.

Constable J, Buckingham C, Bean L. Evaluating the effect of an education programme on quality of life. (Research on effectiveness of education for diabetic patients.). *J Diabetes Nurs* 2000;**4**:104–7.

Ginsberg BH, Tan MH, Mazze R, Bergelson A. Staged diabetes management: computerizing a disease state management program. *J Med Syst* 1998;**22**:77–87.

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Mühlhauser I, Bott U, Overmann H, Wagener W, Bender R, Jorgens V, *et al*. Liberalized diet in patients with type 1 diabetes. *J Intern Med* 1995;**237**:591–7.

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Ryle A, Boa C, Fosbury J. Identifying the causes of poor self-management in insulin dependent diabetics: the use of cognitive-analytic therapy techniques. 1993.

Rynne A, McKenna K. Evaluation of an outpatient diabetes education programme. (Research evaluating a four-session multidisciplinary outpatient programme. 29 refs). *Br J Occup Ther* 1999;**62**: 459–65.

ter Braak EW, de Valk HW, de la Bije YF, van der Laak MF, van Haeften TW, Erkelens DW. Response to training in blood glucose awareness is related to absence of previous hypoglycaemic coma. *Diabetes Care* 2000;**23**:1199–200.

Watson MK, McDaniel JL, Gibson MH. An innovative approach to home health education: the critical path to self-care for adults with diabetes. *Home Health Care Manag Pract* 1996;**8**:41–51.

Trials excluded owing to nature of patients (patients not type 1 or 2 and/or not adults)

Agewall S, Wikstrand J, Samuelsson O, Persson B, Andersson OK, Fagerberg B. The efficacy of multiple risk factor intervention in treated hypertensive men during long-term follow up. Risk Factor Intervention Study Group. *J Intern Med* 1994;**236**:651–9.

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Turnin MC, Bourgeois O, Cathelineau G, Leguerrier AM, Halimi S, Sandre-Banon D, *et al*. Multicenter randomized evaluation of a nutritional education software in obese patients. *Diabetes Metab* 2001; **27**(2 Pt 1):139–47.

Ward AK. Educational feedback in the management of type 2 diabetes in general practice. *Educ Gen Pract* 1996;**7**:142–50.

Trials excluded owing to nature of education (i.e. not education programme, no details education or not reproducible)

Abourizk NN, O'Connor PJ, Crabtree BF, Schnatz JD. An outpatient model of integrated diabetes treatment and education: functional, metabolic, and knowledge outcomes. *Diabetes Educ* 1994;**20**:416–21.

Abraira C, Colwell J, Nuttall F, Sawin CT, Henderson W, Comstock JP, *et al*. Cardiovascular events and correlates in the Veterans Affairs Diabetes Feasibility Trial. Veterans Affairs Cooperative Study on Glycemic Control and Complications in type II Diabetes. *Arch Intern Med* 1997;**157**:181–8.

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Boehm S, Schlenk EA, Raleigh E, Ronis D. Behavioural analysis and behavioural strategies to improve self-management of type II diabetes. *Clin Nurs Res* 1993; **2**:327–44.

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Fosbury JA, Bosley CM, Ryle A, Sonksen PH, Judd SL. A trial of cognitive analytic therapy in poorly controlled type I patients. *Diabetes Care* 1997;**20**:959–64.

Gaede P, Vedel P, Parving HH, Pedersen O. Intensified multifactorial intervention in patients with type 2 diabetes mellitus and microalbuminuria: the Steno type 2 randomised study. *Lancet* 1999;**353**:617–22.

Groeneveld Y, Petri H, Hermans J, Springer M. An assessment of structured care assistance in the management of patients with type 2 diabetes in general practice. *Scand J Prim Health Care* 2001; **19**:25–30.

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Shichiri M, Kishikawa H, Ohkubo Y, Wake N. Long-term results of the Kumamoto Study on optimal diabetes control in type 2 diabetic patients. *Diabetes Care* 2000;**23** Suppl 2:B21–9.

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Appendix 5

Quality assessment scales for RCTs and CCTs

Quality criteria for RCTs – CRD Report 4

Quality criteria for assessment of experimental studies

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

Some instructions for using a checklist for RCTs

Quality item	Coding	Explanation
1. Was the assignment to the treatment groups really random?		
Random sequence generation	Adequate Partial Inadequate Unknown	Adequate: random numbers table or computer and central office or coded packages Partial: (sealed) envelopes without further description or serially numbered opaque, sealed envelopes Inadequate: alternation, case record number, birth date, or similar procedures Unknown: just the term 'randomised' or 'randomly allocated', etc.

continued

Quality item	Coding	Explanation
2. Was the treatment allocation concealed?		
Concealment of randomisation The person(s) who decide on eligibility should not be able to know or be able to predict with reasonable accuracy to which treatment group a patient will be allocated. In trials that use good placebos this should normally be the case; however, different modes or timing of drug administration in combination with the use of small block sizes of known size may present opportunities for clinicians who are also involved in the inclusion procedure to make accurate guesses and selectively exclude eligible patients in the light of their most likely treatment allocation; in centres with very low inclusion frequencies combined with very brief follow-up times this may also present a potential problem because the outcome of the previous patient may serve as a predictor of the next likely allocation	Adequate Inadequate Unknown	Adequate: when a paper convinces you that allocation cannot be predicted [separate persons, placebo really indistinguishable, clever use of block sizes (large or variable)]. Adequate approaches might include centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system with a randomisation sequence that is not readable until allocation and other approaches with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients. Inadequate: this option is often difficult. You have to visualise the procedure and think how people might be able to circumvent it. Inadequate approaches might include use of alternation, case record numbers, birth dates or week days, open random numbers lists, serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation) and any other measures that cannot prevent foreknowledge of group allocation. Unknown: no details in text. Disagreements or lack of clarity should be discussed in the review team
3. Were the groups similar at baseline regarding the prognostic factors?		
Baseline characteristics Main aim is to enable the reviewer to see which patients were actually recruited. It enables one to get a rough idea on prognostic comparability. A real check on comparability requires multivariable stratification (seldom shown)	Reported Unknown	Consult the list of prognostic factors or baseline characteristics (not included in this appendix). Reviewer decides
4. Were the eligibility criteria specified?		
Prestratification Consult the list of prognostic factors or baseline characteristics (not included in this appendix)	Adequate Partial Inadequate Unknown	*Single-centre study* Adequate: prestratification on at least one factor from the list or no prestratification if the number of patients exceeds a prespecified number Partial: leave judgement to reviewer Inadequate: stratification on a factor(s) not on our list or no stratification whereas the number of patients is less than the prespecified number Unknown: no details in text and no way to deduce the procedure from the tables *Multicentre 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

continued

Quality item	Coding	Explanation
5. Were outcome assessors blinded to the treatment allocation?		
Blinding of assessors The assessor may be the patient (self-report), the clinician (clinical scale, blood pressure, etc.) or, ideally, a third person or a panel. Very important in judgement of cause of death but unimportant in judgement of death	Adequate Inadequate Unknown	Adequate: independent person or panel or (self-) assessments in watertight double-blind conditions Inadequate: clinician is assessor in trial on drugs with clear side effects or a different influence on lab. 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 caregivers	Adequate Partial Inadequate Unknown	Adequate: placebo described as 'indistinguishable' and procedures watertight (use your imagination with the 'cheat' in mind; e.g. statement that sensitive/unmasking lab. 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)	Adequate Partial Inadequate Unknown	Adequate: percentages of all relevant interventions in all groups Partial: one or more interventions omitted or omission of percentages in each group Inadequate: not deducible Unknown: no statements
7. Was the patient blinded?		
Blinding of patients This item is hard to define. Just the statement 'double blind' in the paper is really insufficient if the procedure to accomplish this is not described or reasonably deducible by the reviewer. Good placebos (see, hear, taste, feel, smell), tricky unmasking side-effects accounting for the subjectivity of the outcome measurements and the accessibility of co-interventions by the patient are required	Adequate Partial Inadequate Unknown	Adequate: placebo described as 'indistinguishable' and procedures watertight Partial: just 'double blind' in text and no further description of procedures or nature of the placebo Inadequate: wrong placebo Unknown: no details in text
Compliance Dosing errors and timing errors	Adequate Partial Inadequate Unknown	Unknown Adequate: Medication Event Monitoring System (MEMS or eDEM) Partial: blood samples, urine samples (use of indicator substances) Inadequate: pill count or self-report Unknown: not mentioned
Check on blinding Questionnaire for patients, care givers, assessors and analysis of the results; the (early) timing is critical because the treatment effect may be the cause of unblinding, in which case it may be used as an outcome measure	Reported Unknown	Reviewer decides

continued

Quality item	Coding	Explanation
8. Were the point estimates and measure of variability presented for the primary outcome measure?		
Results for the primary outcome measure	Adequate Partial Inadequate Unknown	Adequate: mean outcome in each group together with mean difference and its standard error (SE) or standard deviation (SD) or any CI around it or the possibility to calculate those from the paper. Survival curve with log-rank test and patient numbers at later time points Partial: partially reported Inadequate: no SE or SD, or SD without N (SE = SD/N) Unknown: very unlikely
9. Did the analysis include an intention to treat analysis?		
Intention-to-treat (ITT) analysis Early drop-out can make this very difficult. Strictest requirement is sensitivity analysis including early drop-outs	Adequate Inadequate	Reviewers should not just look for the term ITT but assure themselves that the calculations were according to the ITT principle.
Dealing with missing values The percentage missing values on potential confounders and outcome measurements (seldom given) is a rough estimate of a trial's quality. One can carry them forward, perform sensitivity analysis assuming the worst and best case scenarios, use statistical imputation techniques, etc. Note that the default option (deletion) assumes that the value is randomly missing, which seems seldom justified	Adequate Partial Inadequate Unknown	Adequate: percentage of missing values and distribution over the groups and procedure of handling this stated Partial: some statement on numbers or percentages Inadequate: wrong procedure (a matter of great debate) Unknown: no mentioning at all of missing and not deducible from tables
Loss to follow-up This item examines both numbers and reasons; typically an item that needs checking in the methods section and the marginal totals in the tables. Note that it may differ for different outcome phenomena or time points. Some reasons may be reasons given by the patient when asked and may not be the true reason. There is no satisfactory solution for this	Adequate Partial Inadequate Unknown	Adequate: number randomised must be stated. Number(s) lost to follow-up (dropped out) stated or deducible (from tables) for each group and reasons summarised for each group. Partial: numbers, but not the reasons (or vice versa) Inadequate: numbers randomised not stated or not specified for each group Unknown: no details in text

Quality criteria for assessment of CCTs – CRD Report 4

Were the groups similar at baseline in terms of prognostic factors?

Were the eligibility criteria specified?

Were outcome assessors blinded to the treatment allocation?

Were the point estimates and measure of variability presented for the primary outcome measure?

Did the analyses include an intention to treat analysis?

Were withdrawals and dropouts completely described?

Were participants likely to be representative of the intended population?

Appendix 6

Psychological instruments used in included trials

Psychometric instruments

Many different measures of psychological constructs were used to quantify knowledge, attitudes, QoL and other psychological variables. Only the results using instruments known to be or reported to be validated were data extracted. A few studies used measures that were constructed for the purposes of the study about which no validation information was provided. Unfortunately, the 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.

QoL

The diabetes quality of life measure (DQOL) was used by Trento and colleagues.[30] The measure was originally designed for use in the DCCT. 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 as well as an overall well-being scale. The items are answered on a five-point scale. Test–re-test reliability ranges from 0.78 to 0.92. The test has also been shown to have good internal consistency in patients with either Type 1 or Type 2 diabetes.

QoL was tested by Kaplan and colleagues[35] 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.

QoL was measured by Gilden and colleagues[47] with questions focused on self-care skills. The self-care skills included diet, exercise, medication administration, monitoring blood tests and three general items. QoL was subdivided into two subscales (QLa and QLb). QLa indicated more demanding and intensive lifestyle changes due to diet, exercise and other general factors. QLb reflected less demanding behaviours including medication compliance and self-testing. It seems that the knowledge, QoL, stress and family involvement scales used in this study may have been tested for internal consistency together yielding a Cronbach's α of 0.93.

Other measures of psychological status

Gilden and colleagues[47] assessed stress using nine items adapted from another validated scale. The nine items were answered on a three-point scale with a higher score indicating less stress.

Depression was assessed in the Gilden study[47] using Zung's Mood Scale. The scale consists of 20 items. The total index and four subscales were scored: pervasive affective disturbance, physiological disturbance, psychomotor disturbance and psychological disturbance. Scores range from 25 to 100 with lower scores reflecting less depression.

Knowledge

The knowledge questionnaire used in the Mühlhauser study[23] was a 37-item illustrated questionnaire. It included general aspects of diabetes, metabolic self-monitoring, rules for changing insulin dose, treatment and prevention of hypoglycaemia and diet. The internal reliability of the questionnaire was 0.8. A Russian version of the same questionnaire was used in the Starostina study.[24]

The Diabetes Knowledge Scale – form A (DKNA)[97] is a 15-item scale with Cronbach's $\alpha > 0.82$. The scale was used by Campbell and colleagues.[29] The multiple-choice questions include questions on the normal range for BG, the causes of hypoglycaemia, insulin requirements during illness

and the status of rice as a carbohydrate food. Additional items test basic survival information and other valid content.

Knowledge of diabetes was tested by Trento and colleagues[30] 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[34] 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.

Gilden and colleagues[47] measured knowledge using a 24-item questionnaire including general knowledge, nutrition and pharmacy.

Bloomgarden and colleagues[44] assessed knowledge in a standardised manner with an interviewer. Eight questions were used and were assumed to be validated as a Centers for Disease Control publication on diabetes knowledge measures was cited as their source. The knowledge score was simply the sum of correct answers.

Measures of adoption of educational recommendations and satisfaction

Attitudes to diabetes and its treatment were assessed by Cooper and colleagues (see footnote to *Table 12*) using the Diabetes Integration Questionnaire. The questionnaire measures the integration of diabetes and its treatment into the lifestyle and personality of the patient. It is a 19-item scale. Higher summary scores are related to better psychological adjustment to diabetes. The questionnaire is reported to be reliable and valid.

Treatment effectiveness was assessed by Cooper and colleagues (see footnote to *Table 12*) using a questionnaire derived from an interview tool. Patients respond to seven items (two on treatment effectiveness in relation to self-care, three on seriousness, and two on personal control) on a five-point scale. Patients were also asked about self-care treatment effectiveness for 11 areas (e.g. physical activity, not smoking, glucose testing). For each of these areas patients were asked the degree to which that area was believed important in controlling diabetes and the degree to which that area will prevent future complications. An overall treatment effectiveness score was created by averaging scores across all the treatment effectiveness questions. This questionnaire was reported to be reliable and valid.

Satisfaction was assessed by Campbell and colleagues[29] using an 18-item scale developed and validated by the authors. It was shown to have good internal consistency and reliability.

Health behaviours were evaluated by Trento and colleagues[30] using the Condotte di Riferimento (CdR). The questionnaire consisted of 16 items that posed hypothetical situations of the form 'what would you do if …'. The test evaluated whether patients were able to identify underlying health problems and react correctly. The questionnaire was checked for internal consistency using Cronbach's α and internal validity was checked by cluster analysis.

Glasgow and colleagues[45] assessed patient diet using the Kristal Food Habits Questionnaire (FHQ). The FHQ is a 20-item scale that measures four dimensions of fat related dietary habits. A summary score across the four dimensions was used in the analyses. The FHQ has been validated.

Other validated instruments used

A number of additional instruments were used in various studies. These instruments are not being described, 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 Samaras trial.[40] An apparent variation of this scale was also used by Ridgeway.[37]

The Beck Depression Inventory was used by Wing.[39] Although this is a valid psychometric instrument, the use of the instrument has been questioned in patients who are not depressed.

Ridgeway[37] used the Life Skills cognitive knowledge of diabetes test provided by the Diabetes Education Society and approved by the American Diabetes Association.

Appendix 7

Data extraction: Type 1 diabetes

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Reichard *et al.*, 1988–96[21,98–107] Source: published Country: Sweden Setting: outpatient clinic Language: English Trial design: RCT	Called the Stockholm Diabetes Intervention Study (SDIS) **Treatment intervention:** intensified conventional treatment (ICT) with structured education. Patients attended singly or in pairs Topics: intermediate metabolism, especially the role of insulin, insulin substitution, effect of insulin substitution by varying food intake and exercise, hypoglycaemia and counter regulation, microvascular complications, performing and interpreting BG tests and principles of insulin substitution in relation to test results. Recommended multiple insulin injections and frequent home BG monitoring. Goals for home BG levels individually set. Goal was to reduce HBA_{1c} to 7% Tutoring: initial tutoring performed with telephone contacts at least every 2 weeks. Patients suggested solutions to problems but physician intervened if dangerous. Patients used daily glucose tests and wrote down results. Initially phone contacts every 2 weeks or more often if needed. If patients did not call, physician called them. As they grew more confident, called every 3–4 weeks. Continuous tutoring on demand started when metabolic control was optimal. Patients could reach physician at any time of day via pager Provider: physician	Eligibility exclusion criteria: born 1930 or later (in 1982); IDDM appearing at age ≤ 30, and with insulin dependency within 1 year from diagnosis; no known abuse of alcohol or drugs; non-proliferative retinopathy of any degree present (including preproliferative retinopathy), no previous photocoagulation; normal serum creatinine; unsatisfactory BG control according to physician in charge of patient How selected: 111 patients asked to participate, 102 accepted (they did not beforehand have to accept the intensified programme if randomised to such a treatment) Numbers involved: total *N* = 102: Intervention *N* = 48; control = 54. Nos on insulin: all Tablets: Diet alone: Type of diabetes: Type 1 Duration of diabetes in years: mean (SD): Intervention=17.9 (6.4); control =16.3 (4.9) Baseline measurements of outcome parameters: see results as recalculated over time following drop-outs Gender: Intervention: male *N* = 26, female *N* = 22; control: male *N* = 28, female *N* = 26	Primary outcomes used: HbA_{1c}, hypoglycaemic episodes, ketoacidotic incidents, diabetic retinopathy, neuropathy, nephropathy Secondary outcomes used: mortality, hospital admissions, BP, well-being, BMI, foot ulcers, time and number of patient visits, risk factors for complications, dietary intake, cognitive function and neuropsychological function Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: HbA_{1c} = 4–6%; mild retinopathy = level 2.2 or less; UAER rates: normoalbuminuria: <20 μg/min; microalbuminuria: 20–200 μg/min Nephropathy: >200 μg/min Nerve conduction velocities = lower normal method was 41 m/s How outcomes assessed: HbA_{1c}: by lab. measurement (altered over trial period but high correlation between methods) Retinopathy: grading system as used in ETDRS (Early Treatment Diabetic Retinopathy Study), mean of 2 ophthalmologists grading Nephropathy: UAER, analysed in 24-h urine samples Neurophysiological assessment: conduction

continued

Reference and design	Intervention	Participants	Outcome measures
	Length and no. of sessions: 2 education sessions, 3 and 2 h long, respectively. Seen in the clinic every second month. Had frequent phone contact with the physician – reachable at any time of day via a pager. After 7.5 years ICT patients returned to routine diabetes care Mode: Treatment changes: yes Training of trainers: Theory: **Control intervention:** advised to monitor their BG. Visited the clinic every fourth month. Given instructions on how to use home BG testing and insulin doses were adjusted to achieve lower BG. Test results discussed at clinic visits. Treatment goal was to reduce BG without giving rise to serious hypoglycaemia. Many patients had frequent contact with physician after 7.5-year period. **Protocol changes to both groups:** protocol changed twice: after 3 years, in order to achieve lower BG levels in the control group and after 7.5 years, in order to let intensively treated patients return to routine diabetes care Duration of intervention: 7.5 years	Age, mean (SD): Intervention = 30.0 (7.5); control = 31.7 (7.3) ethnic groups: not reported Losses to follow-up: At 3 years, 97 patients remained Intervention $N = 44$, control $N = 53$. At 5 years 96 remained Intervention $N = 44$ and control $N = 52$, At 7.5 years 89 remained, At 10 years 43 remained. Compliance: no data available	velocities determined in the peroneal, tibial and sural nerves Hypoglycaemia: patient reports. Serious hypoglycaemic episodes defined as requiring help from someone else or resulting in a coma Risk factors for microvascular complications: patients with HbA_{1c} during study ≥ 9% were compared with patients with levels below this Neuropsychological and cognitive tests: a battery of computerised tests from the Automated Psychological Test (APT) system, not reported here Well-being: not a validated measure, not reported here Dietary intake: analysed by a dietitian. A non-judgemental 48-h recall used with patient unprepared Validated: yes Timing of outcomes same for both groups: assume yes Length of follow-up: for 7.5 years during the education programme, then returned to normal care – followed up for 2.5 more years

Results: Values given for outcomes are the mean of all the values measured at approximately 4-month intervals over the specified time period. Mean (SEM) given, unless stated otherwise.

HbA_{1c} (%):

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	9.5 (0.2)	7.5 (from graph)	9.4 (0.2)	9.0 (from graph)	$p = 0.0005$
3 years	9.5 (0.2)	7.4 (0.1)	9.4 (0.2)	9.0 (0.2)	$p = 0.00001$
5 years	9.5 (0.2)	7.2 (0.1)	9.4 (0.2)	8.7 (0.1)	$p < 0.001$
7.5 years	9.5 (1.3)	7.1 (0.7)	9.4 (1.4)	8.5 (0.7)	$p = 0.001$
10 years	9.5 (1.4)	7.2 (0.6)	9.4 (1.2)	8.3 (1.0)	$p < 0.001$
After 3 years: the number of patients with mean HbA_{1c} levels above the initial mean of 9.5% was reduced from 20 to 0 in ICT group and from 27 to 10 in RT group.					

Retinopathy:
Number of patients demonstrating mild retinopathy at 18 months

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	27	28	26	18	$p = 0.011$

Changes in mean retinopathy level: number of patients at 18 months

	Intervention group	Control group	Difference between groups
Better	6	5	
Unchanged	26	19	
Worse	16	30	0.024

Sum of patients with preproliferative or proliferative changes in at least one eye (level 5, <5 or worse)

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	3	7	4	15	

Percentage of patients demonstrating serious retinopathy

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
7.5 years	NA	27	NA	52	$p = 0.01$
10 years	0	33	0	63	$p = 0.003$

Mean retinopathy level (12 grade scale 0.5–6.0)

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	2.4 (0.1)	2.8 (0.2)	2.6 (0.1)	3.2 (0.2)	
3 years	2.4 (0.1)	3.2 (0.2)	2.6 (0.1)	3.6 (0.2)	NS
5 years	2.4 (0.1)	3.5 (0.2)	2.6 (0.1)	4.1 (0.2)	$p < 0.05$
After 5 years: proliferative retinopathy appeared in at least one eye in 10 ICT patients and 15 RT patients (NS).					

Visual acuity (percentage of patients)

Time	Intervention group	Control group	Difference between groups
7.5 years	14	35	$p = 0.02$

Visual deterioration (percentage of patients)

Time	Intervention group	Control group	Difference between groups
10 years	18	37	$p = 0.04$

Normoalbuminuria: number of patients

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	34	35	36	27	
3 years	34	35	35	30	
7.5 years	34	33	33	26	

Microalbuminuria: number of patients

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	11	9	13	19	
3 years	8	6	13	13	
7.5 years	8	8	13	11	

Nephropathy: number of patients

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	3	4	3	6	
3 years	2	3	3	8	
7.5 years	2	3	3	12	$p = 0.01$

Nephropathy: percentage of patients

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
10 years	5	7	7	26	$p = 0.012$

Mean UAER levels (μg/minute)

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
3 years (diff. from below)	1.3 (0.1)	1.3 (0.1)	1.4 (0.1)	1.6 (0.1)	$p = 0.031$
5 years	55.7 (26.7)	46.0 (26.1)	74.3 (31.0)	239.9 (129.7)	$p < 0.05$
7.5 years	56 (175)	45 (110)	63 (206)	119 (219)	$p = 0.04$

GFR: glomerular filtration rate (ml/minute)

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
3 years	122 (3)	115 (3)	126 (3)	119 (3)	
5 years	122 (3)	112 (3)	126 (3)	115 (4)	
7.5 years	122 (19)	109 (19)	126 (21)	110 (27)	NS
10 years	123 (19)	110 (18)	127 (22)	109 (25)	NS

Neuropathy: number (percentage) of patients who exhibited neuropathy

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
5 years	13	16	17	34	$p < 0.01$
7.5 years	5 (12%)	6 (14%)	8 (17%)	13 (28%)	NS
10 years	12%	14%	16%	32%	$p = 0.041$

Neurophysiology: Nerve Conduction Velocities: peroneal nerve

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	42.5 (0.7)	42.3 (0.6)	42.1 (0.7)	40.5 (0.7)	
3 years	43.0	43.4	42.1	40.8	NS
5 years	43.0 (0.7)	42.8 (0.6)	42.1 (0.7)	39.3 (0.7)	$p < 0.01$
7.5 years (from graph)	43.2	43.0	42.0	38.5	
10 years	42.9 (4.4)	41.3 (3.8)	41.9 (4.7)	36.2 (11.6)	$p = 0.007$

Tibial nerve

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	41.2 (0.7)	41.6 (0.6)	40.2 (0.7)	39.1 (0.8)	
3 years	41.3	42.7	40.4	40.5	NS
5 years	41.3 (0.8)	42.1 (0.6)	40.4 (0.7)	37.7 (0.8)	$p < 0.001$
7.5 years (from graph)	41.3	42.5	40.4	37.8	
10 years	41.3 (5.4)	41.1 (4.2)	40.4 (5.0)	35.1 (11.8)	$p = 0.002$

Sural nerve

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	45.1 (0.7)	44.1 (0.8)	45.3 (0.8)	43.1 (0.8)	
3 years	44.3	44.0	42.8	37.9	NS
5 years	44.2 (1.3)	40.3 (1.8)	42.6 (1.7)	36.5 (2.0)	$p < 0.05$
7.5 years (from graph)	44.5	42.5	43.0	34.2	
10 years	44.2 (8.6)	39.7 (12.0)	42.5 (12.3)	30.8 (18.4)	$p = 0.008$

Hypoglycaemia:
Percentage of patients experiencing at least one serious hypoglycaemic episode in the time period

Time	Intervention group	Control group	Difference between groups
18 months	48	22	$p = 0.003$
3 years	57	23	$p = 0.001$
5 years	77	56	$p < 0.05$
7.5 years	80	58	$p < 0.05$
10 years	86	73	NS

Total number of serious hypoglycaemic episodes in the time period

Time	Intervention group	Control group	Difference between groups
18 months	41	28	
3 years	102	28	
5 years	242	98	

Number of patients requiring emergency room visits

Time	Intervention group	Control group	Difference between groups
18 months	8	8	
3 years	11	3	
During last 2.5 years (from 7.5 to 10 years)	8	8	NS

Mean total number of serious hypoglycaemic episodes per patient per year

Time	Intervention group	Control group	Difference between groups
5 years	1.1	0.4	
7.5 years	1.1	0.4	
10 years	1.06	0.47	$p = 0.003$
After 5 years: patients unconscious at least once: ICT= 41% (18) RT= 19%, (10) $p < 0.05$			

Ketoacidosis: number of patients experiencing an episode

Time	Intervention group	Control group	Difference between groups
7.5 years	1	2	
10 years	1	4	

Blood pressure: systolic (mmHg)

	Intervention group		Control group		
Time	Baseline	Follow-up	Baseline	Follow-up	Difference between groups
3 years	129.2 (2.0)	127.0 (2.3)	133.2 (2.0)	131.8 (2.1)	
5 years	129 (2)	126 (2)	133 (2)	133 (2)	
10 years	129.3 (13.5)	124.9 (15.4)	133.2 (15.8)	132.2 (15.7)	$p = 0.029$

Blood pressure: diastolic (mmHg)

	Intervention group		Control group		
Time	Baseline	Follow-up	Baseline	Follow-up	Difference between groups
3 years	77.5 (1.4)	78.0 (1.2)	78.5 (1.0)	81.2 (1.2)	
5 years	77 (1)	77 (1)	79 (1)	78 (1)	
10 years	79.4 (9.4)	74.1 (8.6)	78.4 (8.4)	77.3 (8.7)	$p = 0.085$

Number of patients receiving treatment for hypertension

Time	Intervention group	Control group	Difference between groups
5 years	7	11	
7.5 years	11	17	

Body mass index

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
18 months	22.6 (0.3)	22.9 (0.3)	22.8 (0.3)	22.9 (0.3)	
3 years	22.6 (0.3)	23.4 (0.4)	22.8 (0.3)	23.0 (0.3)	
5 years	22.5 (0.3)	23.8 (0.4)	22.8 (0.3)	22.8 (0.3)	
7.5 years	22.5 (0.3)	23.9 (0.5)	22.8 (0.4)	23.3 (0.4)	NS
10 years	22.5 (2.0)	24.2 (3.4)	22.8 (2.5)	23.9 (2.9)	NS

Energy intake (kcal/day)

	Intervention group		Control group		
Time	**Baseline**	**Follow-up**	**Baseline**	**Follow-up**	**Difference between groups**
3 years	1812 (82)	1768 (99)	1829 (77)	1758 (63)	NS

Mortality:
Number of patients who had died

Time	Intervention group	Control group	Difference between groups
3 years	4	0	
5 years	4	1	
7.5 years	4	3	
10 years	4	3	
After 3 years: 4 patients in intervention group had died. After 5 years: one control patient had died. After 7.5 years: 4 patients in intervention group and 3 in control group had died. After 10 years: 4 patients in intervention group and 3 in control group had died.			

Time and number of patient visits
After18 months: patients in the ICT group required a mean of 45 minutes per patient per month for education, visits and telephone contacts, compared with 10 minutes per patient per month for patients in the RT group. Between 3 and 5 years after the start of the study there were no longer any differences between the groups

Neuropathic foot ulcers
After 7.5 years: number of patients who developed neuropathic foot ulcers: ICT = 0, RT = 3

Risk factors for complications
After 3 years: patients with $HbA_{1c} \geq 9\%$ (the mean value for RT group) were compared with those with lower values. There was significantly more deterioration in the former (retinopathy $p = 0.028$; nephropathy, $p = 0.025$, neuropathy, $p = 0.018$)
22 ICT patients (50%, 95% CI 34 to 66%) and 27 RT patients (73%, 95% CI 61 to 84%) deteriorated with respect to one complication or more ($p = 0.024$)

Methodological comments
Allocation to treatment groups: partial
Blinding of outcome assessors: all investigators (ophthalmologist, neurophysiologist, laboratory personnel) except the physician in charge of the study were unaware of the treatment group of the individual patients
Allocation concealment: randomisation performed with closed identical envelopes
Analysis by ITT: no

Comparability of treatment groups: yes
Method of data analysis: hypothesis tests (*t*-tests, Wilcoxon tests and Mann–Whitney *U*-tests). Contingency tables analysed by chi-squared test. Linear regression used when appropriate. For multivariate analyses used logistic regression. Some results expressed as means with 95% CI, majority mean and SEM.
Sample size/power calculation: no
Attrition/drop-out: numbers and reasons given

General comments
Generalisability: inclusion criteria defined. Do not know what proportion of eligible patients in population participated
Conflict of interests: Swedish Division of Novo-Nordisk, Boehringer Mannheim Scandinavica, Swedish Medical Research Council, Groschinsky Foundation
Other: values given are mean values over the whole study period at 1.5, 3, 5, 7.5 and 10 years. States that after 3 years an effort was made to reduce Hba_{1c} below 9% in all control patients, ? how

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Terent *et al.*, 1985[22] Source: published Country: Sweden Setting: community Language: English Trial design: RCT	4 Groups: A = Education + SMBG B = SMBG C = Education D = Control **Treatment intervention:** education (for Groups A & C) individual Provider: physician and dietitian Topics: special model constructed to explain interplay between food consumption, BG levels, insulin and urinary glucose excretion. Also taught about hypoglycaemic episodes, hyperglycaemic episodes, foot care, injections and urine testing Sessions: six hourly lessons during 1 month Treatment changes: self-monitoring, see below Training of trainers: Theory: Mode: Given questionnaire at 1 and 6 months after end of the course to test knowledge of diabetes and related issues **SMBG:** Groups A & B had extra visit at outpatient dept at start of phase II. SMBG demonstrated by physician. SMBG groups "encouraged to change their insulin dose to achieve preprandial values <7 mmol/litre and postprandial values <10 mmol/litre" **Control intervention:** Standard therapy. Groups B (phase I) and D (phases I–III) continued their pre-trial checking habits. Fasting BG and 24-h urinary glucose values measured every 3rd month at outpatients. Physical exam. 6 monthly. All patients had device for monitoring urinary glucose **Duration of intervention:** 1 month	Eligibility. All adult patients (aged ≥17) with Type 1a diabetes in municipality, diagnosed ≤20 years. How selected: from survey of diabetes in area. *N* = 37, first randomised into 2 groups: formal education group *N* = 19, standard therapy *N* = 18. After 6 months of education (phase I) a second randomisation performed. Teaching of SMBG completed in 6 months (phase II) and patients followed for further 6 months (phase III) Numbers involved: *N* = 37 in 4 groups Group A *N* = 10 education + SMBG Group B *N* = 8 usual care + SMBG Group C *N* = 9 education + education Group D *N* = 10 usual care + usual care Nos on insulin: all Type of diabetes: type 1 Duration of diabetes (years) (mean ± SD): Group A 11.6 ± 6.2, Group B 13.0 ± 3.8, Group C 5.0 ± 3.9, Group D 12.5 ± 5.1 Baseline measurements of outcome parameter: HbA_1 (mean ± SD): Group A 12.3 ± 3.2, Group B 11.8 ± 1.4, Group C 11.2 ± 2.0, Group D 11.1 ± 2.3 Gender (M/F): Group A 6/4, Group B 3/5, Group C 4/5, Group D 8/2 Ages (mean ± SD): Group A 28.5 ± 6.2, Group B 27.6 ± 6.8, Group C 25.7 ± 5.4, Group D 25.0 ± 4.6 Ethnic groups: not given Losses to follow-up: none Compliance: all attended education sessions. The number of urinary glucose testers in education groups A	Primary outcomes used: HbA_1, hypoglycaemic episodes, ketoacidotic incidents Secondary outcomes used: diabetes knowledge Individual preferred learning style addressed: no Any sub-groups: no Normal range(s) for outcomes: 95% CI for HbA_1 4.7 to 8.0% How outcomes assessed: HbA_1 by lab. (column chromatography), knowledge by questionnaire, hypoglycaemic episodes by medical record Validated: yes for HbA_1, no for knowledge Timing of outcomes same for both groups: Length of follow-up: 18 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
		& C increased from 9 (47%) to 15 (79%). For SMBG in groups A & B, proportion of weekly testers was 89% in phase II and 78% in phase III. Adherence to SMBG equally good in Groups A and B. For SMBG patients, average number of visits to Outpatient dept was 6 in phase II and 5 in phase III	

Outcome	Group A (education + SMBG)	Group B (SMBG)	Group C (education)	Group D (control)
HbA_1 levels (mean ± SD): no significance testing between groups only within	12 months = 11.0 ± 2.6 18 months = 10.2 ± 1.9	12 months =10.8 ± 1.0 18 months = 9.8 ± 3.0	12 months =9.9 ± 2.5 18 months = 10.2 ± 2.1	12 months = 9.5 ± 3.2 18 months = 10.4 ± 2.1
Hypoglycaemic episodes: (no statistical analysis)	7 in groups A + B		14 in groups C + D	
Ketoacidosis: (no statistical analysis)	2		3	

Knowledge about diabetes, insulin, oral hypoglycaemics, testing and physical exercise: not validated measure. Knowledge about food exchange and good distribution over the daytime: not validated measure

Methodological comments
Allocation to treatment groups: not stated
Blinding of outcome assessors: yes (HbA_1 values not accessible to investigators or patients until end of study)
Allocation concealment: not stated
Analysis by ITT: no drop-outs
Comparability of treatment groups: duration of diabetes significantly shorter in Group C
Method of data analysis: within-group comparisons, no analysis between groups
Sample size/power calculation: no
Attrition/drop-out: none

General comments
Generalisability: good – only 4 eligible patients in the community excluded – reasons given
Conflict of interests: funding support not mentioned
Other: very small number of patients in each group

Quality criteria (CRD Report 4) RCTs

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?	Partial
7. Did the analyses include an ITT analysis?	No drop-outs
8. Were withdrawals and drop-outs completely described?	No drop-outs

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Mühlhauser *et al.*, 1987[23] Source: published Country: Romania Setting: hospital-based Language: English Trial design: prospective controlled trial (3 groups) CCT	**Treatment interventions:** IDTTP (intensive treatment and teaching programme): Düsseldorf model Provider: 2 nurses trained in Düsseldorf Topics: BG as normal as possible; metabolic self-monitoring (blood or urine); self-adaptation of insulin dose; recording self-monitoring, doses and hypoglycaemic episodes; liberalised diet Sessions: 5 days in groups of about 10 patients Treatment changes: IDTTP used different insulins as well as different therapy Training trainers: Theory: Mode: BDTTP (basic treatment and teaching programme): adaptation of IDTTP Provider: 2 teaching nurses Topics: aglucosuria without significant hypoglycaemic reactions; simple rules for self-adjustment of insulin; matching diet to insulin preparation used Sessions: 4 days Treatment changes: Training trainers: Theory: Mode: Control intervention: standard treatment of hospital (no self-adjustment or self-monitoring, rigid diet, individual disease management instruction by physician in charge) **Duration of intervention:** Initially 1 year for all groups. For second year the control entered IDTTP and IDTTP followed for 2 years. BDTTP only 1 year	Eligibility: ketosis-prone, insulin-dependent diabetic patients, aged 15–40 years. Excluded if: admission primarily for severe acute or chronic disorder unrelated to diabetes, mental retardation or psychiatric diseases that would interfere with participation in group teaching programme, clinically overt diabetic nephropathy, proliferative retinopathy or blindness, severe foot complications How selected: consecutive admissions to hospital for diabetic metabolic decompensation or newly diagnosed diabetes Numbers involved: 300 (IDTTP 100, BDTTP 100, Control 100) Type of diabetes: 1 Duration diabetes (median years): IDTTP 6, BDTTP 5, control 5 Baseline measurements of outcome parameter (mean ± SEM): HbA_1: IDTTP 12.3 ± 0.2, BDTTP 11.7 ± 0.2, Control 12.5 ± 0.2 BMI (kg/m^2): IDTTP 21.8 ± 0.2, BDTTP: 21.5 ± 0.2, control: 21.7 ± 0.3 Knowledge: IDTTP 16 ± 1, BDTTP: 17 ± 1, control: 16 ± 1 No. hospitalised in year before study: IDTTP 5, BDTTP 46, control 53 Gender (M/F, %): IDTTP: 57/43, BDTTP 54/46, control 60/40 Age (years) (mean ± SEM): 26 ± 1 Ethnic groups: not reported Losses to follow-up (year 1): IDTTP 2%, BDTTP 8%, control 7%	Primary outcomes used: HbA_1, hypoglycaemic episodes, ketoacidotic incidents Secondary outcomes used: knowledge, hospital admissions, BMI, insulin dose (U/kg weight), insulin injections, frequency of self-monitoring Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: HbA_{1c} (mean ± 2SD in 50 healthy subjects): 5.4–7.6% How outcomes assessed: HbA_{1c}: lab. Hypoglycaemic and ketoacidotic episodes: interview and record review Knowledge: questionnaire Hospital admissions: baseline = self-report; record review Validated: no info. on validity, adequate reliability Timing of outcomes same for both groups: yes Length of follow-up: 1 year from inception reported here. IDTTP followed for 2 years

continued

Outcome (1 year)	IDTTP (n = 98 unless stated otherwise)	BDTTP (n = 92 unless stated) otherwise)	Control (n = 93 unless stated) otherwise)	Difference between groups
HbA_1 (estimated from graph; mean)	9.3%**[b]	11.2%	12.8%	**sig. to control $p < 0.01$ [b]sig. to BDDT, $p < 0.01$
Severe hypoglycaemia (total no. of patients with at least one episode)	12	5	6 (n = 97)	
(total number of episodes)	27	5	9 (n= 97)	
Ketoacidosis (no of patients with at least one episode)	2**	3*	13 (n = 97)	*sig. to control, $p < 0.05$ **sig. to control $p < 0.01$
(total no. of episodes)	2**	4*	16 (n = 97)	*sig. to control, $p < 0.05$ **sig. to control $p < 0.01$
Knowledge (mean ± SEM)	32 ± 1**[a]	26 ± 1**	24 ± 1	**sig. to control $p < 0.01$ [a]sig. to BDTTP $p < 0.05$
Hospitalisations (no. of patients hospitalised)	42**[a]	57**	84	**sig. to control $p < 0.01$ [a]sig. to BDTTP $p < 0.01$
(total no. of hospital admissions and days)	67**[a]; 630 days**[a]	100**; 967 days**	173; 1447 days	**sig. to control $p < 0.01$ [a]sig. to BDTTP $p < 0.01$
Number of daily insulin doses (1/2/>3)	0/44/56**[b]	9/76/15	19/71/9	**sig. to control $p < 0.01$ [b]sig. to BDDT, $p < 0.01$
Daily insulin dose (U/kg weight) (mean ± SEM)	0.70 ± 0.02 (n = 85)	0.67 ± 0.02 (n = 83)	0.65 ± 0.03 (n = 80)	
BMI (mean ± SEM)	23.3 ± 0.3*[a]	22.6 ± 0.2	22.4 ± 0.3	*sig to control, $p < 0.05$ [a]sig to BDTTP $p < 0.05$
Frequency of self-monitoring (data not presented)				

Methodological comments

6-month HbA_{1c} data reported

Allocation to treatment groups: consecutive patients to each group. Reports that the order of conditions was chosen randomly, but patient groups not recruited concurrently rather consecutively. This may have resulted in more ill patients entering control group because they were recruited first and might be more likely to be hospitalised

Blinding of outcome assessors: not reported

Allocation concealment: no

Analysis by ITT: deaths in control group accounted for in hypoglycaemia and ketoacidosis analyses, otherwise not reported
Comparability of treatment groups: BDTTP group significantly lower in HbA_1 at baseline
Method of data analysis: hypothesis tests, confidence intervals not provided. Procedure adopted to adjust for baseline differences in HbA_{1c}
Sample size/power calculation: none
Attrition/drop-out: numbers and reasons for drop-outs reported

General comments
Generalisability: patient population seems appropriate
Conflict of interests: partial support from Boehringer Mannheim, Novo-Industri and Becton-Dickinson
Other: none

Quality criteria (CRD Report 4) CCTs

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?	Partially
Did the analyses include an ITT analysis?	Unknown
Were withdrawals and drop-outs completely described?	Partial
Were participants likely to be representative of the intended population?	Yes

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Starostina *et al.*, 1994[24] Source: published Country: Russia Setting: National Research Centre for Endocrinology (Moscow) Language: English Trial design: CCT (prospective controlled trial)	**Treatment intervention:** DTTP Topics: (based on Düsseldorf method) Two programmes used – one based on BGSM and one on UGSM. Patients advised to monitor blood or urine glucose 3–4 times daily before main meals and at bedtime. If insulin treatment is intensified, patients can liberalise their diet. As more liberalised, more frequent self-monitoring and injections of insulin and adaptation of dosage Provider: DTTP performed by 2 physicians Sessions: 5-day inpatient treatment and teaching programme Delivery: Treatment changes: patients adapt insulin dosage themselves Training of trainers: Theory: **Control intervention:** usual care: no structured education, no metabolic self-monitoring, no rules for self-adjustment of insulin dosages, but with conventional strict dietary prescriptions Duration of intervention: 5 days	Eligibility: 121 consecutive type I diabetic patients, aged 15–45, admitted to the National Research Centre for Endocrinology for inpatient treatment. Excluded if: significant loss of vision, renal insufficiency, severe concomitant orders unrelated to diabetes How selected: following a group randomisation protocol, first consecutive 61 to UGSM and next 60 to BGSM. Additional 60 patients fulfilling the inclusion criteria recruited to control group Numbers involved: $N = 181$, $N = 61$ UGSM (urine glucose self-monitoring), $N = 60$ BGSM (BG self-monitoring), $N = 60$ control Nos on insulin: all Type of diabetes: type I Duration of diabetes (years ± SE): UGSM 11 ± 0.9, BGSM 10.9 ± 0.8, control 10.9 ± 0.9 Baseline measurements of outcomes: HbA_1 (mean ± SE): UGSM 12.5 ± 0.2, BGSM 12.6 ± 0.2, control 12.2 ± 0.2 Severe hypoglycaemia: UGSM 2, BGSM 6, control 6 Ketoacidosis: UGSM 9, BGSM 10, control 17 BMI: UGSM 23.6, ± 0.5, BGSM:= 22.4 ± 0.3, control 22.3 ± 0.3 Knowledge (mean ± SE): UGSM 11 ± 0.1, BGSM 11 ± 0.1, control 11 ± 1 Hospitalisation (diabetes related year up to intervention) (mean days/patient ± SE): UGSM 9.8 ± 2.6, BGSM 9.0 ± 3.4, control 11.6 ± 2.6 Sick leave (diabetes related) (mean ± SE): UGSM: 7.8 ±	Primary outcomes used: HbA_1 Secondary outcomes used: costs, hypoglycaemia, ketoacidosis, diabetes-related hospitalisation days, diabetes-related sick leave days, knowledge Individual preferred learning style addressed: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes; HbA_1 5–8% How outcomes assessed: HbA_{1b} lab. test, knowledge by questionnaire, others not stated Validated: knowledge test Russian version of a standardised questionnaire. Unclear if re-validated Timing of outcomes same for both groups: no – longer for intervention than control Length of follow–up: intervention groups 24 months, control group 12 months

continued

Reference and design	Intervention	Participants	Outcome measures
		3.2, BGSM 11.1 ± 4.2, control 10.6 ± 2.3 No daily insulin injections: UGSM 1.9 ± 0.1, BGSM 2.3 ± 0.1, control: 2.2 ± 0.1 Daily insulin dose: UGSM 0.67 ± 0.03, BGSM 0.73 ± 0.04, control 0.68 ± 0.03 Gender (M/F): UGSM 31/30, BGSM 29/31, control 26/34 Age ranges (years ± SE): UGSM 28.7± 1.1, BGSM 29.1 ± 1.1, control 29 ± 1.2 Ethnic groups: not given Losses to follow-up: 16 (9%) (6 from UGSM, 8 from BGSM and 2 control) (reasons given) Compliance: not mentioned	

Outcome (mean ± SE unless noted otherwise)	UGSM (*n* = 55)	BGSM (*n* = 52)	Control (*n* = 58)	Difference between groups[a]
HbA_1	1 year: 9.4 ± 0.2 2 year: 9.2 ± .0.2	1 year: 9.3 ± 0.2 2 year: 9.2 ± 0.2	1 year: 12.3 ± 0.2	
Hypoglycaemia (cases)	1 year: 2 2 year: 8	1 year: 6 2 year: 4	1 year: 8	
Ketoacidosis (cases)	1 year: 1 2 year: 0	1 year: 0 2 year: 0	1 year: 16	
BMI	1 year: 24.4 ± 0.5 2 year: 24.4 ± 0.5	1 year: 23.3 ± 0.3 2 year: 23.2 ± 0.3	1 year: 22.6 ± 0.3	
Knowledge	1 year: 25 ± 1 2 year: 25 ± 1	1 year: 26± 1 2 year: 26 ± 1	1 year 11 ± 1	Increase comparable in UGSM and BGSM
Hospitalisation days/patient (diabetes related)	1 year: 0.8 ± 0.6 2 year: 1.1 ± 0.7	1 year: 0.4 ± 0.4 2 year: 1.7 ± 0.8	1 year: 14.3 ± 3.6	Decrease comparable in UGSM and BGSM
Sick leave/patient (diabetes related)	1 year: 0.2 ± 0.2 2 year: 1.0 ± 0.7	1 year: 0 2 year: 0.7 ± 0.5	1 year: 10.7 ± 2.0	Decrease comparable in UGSM and BGSM
No. of daily insulin injections	1 year: 2.9 ± 0.1 2 year: 2.9 ± 0.1	1 year 2.9 ± 0.1 2 year: 3.2 ± 0.1	1 year 2.2 ± 0.1	Increase comparable in UGSM and BGSM
Daily insulin dose (IU/kg)	1 year: 0.75 ± 0.03 2 year: 0.70 ± 0.03	1 year: 0.74 ± 0.03 2 year: 0.69 ± 0.02	1 year: 0.70 ± 0.03	

[a] No comparisons between intervention and control groups reported.

Methodological comments
Allocation to treatment groups: reported as group randomisation for UGSM and BGSM. Control group unclear
Blinding of outcome assessors: not stated
Allocation concealment: no
Analysis by ITT: no
Comparability of treatment groups: yes
Method of data analysis: data expressed as means and ±SEM. Comparisons with parametric and non-parametric tests for unpaired data, analysis of variance (ANOVA) for repeated measure, other hypothesis testing methods
Sample size/power calculation: no
Attrition/drop-out: 9%
Participants may not have been comparable to usual care in the UK – high initial HbA_1 levels

General comments
When UGSM used the savings from discontinuing ineffective drugs outweighed the costs of test strips and produced net savings. When BGSM was used, net costs were incurred
Generalisability: yes – consecutive patients admitted to Research Centre. Consecutive assignment may result in differences due to history, etc., but all recruited within 5 months
Conflict of interests: financial support from Boehringer Mannheim, Germany
Other: not sure how control group were recruited – insufficient detail given

Quality criteria (CRD Report 4) CCTs

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

Appendix 8

Data extraction: Type 2 diabetes

Interventions of multifaceted self-management education

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Brown *et al.*, 2002[28,108] Source: published Country: USA Setting: community Language: English Trial design: RCT	**Treatment intervention:** Culturally referenced diabetes self-management group education intervention using didactic and interactive approach, delivered in person. 4 cohorts over 1 year Topics: nutrition, self-monitoring, exercise, hygiene, illness days, foot care, complications (short and long term). Promotion behaviour changes through problem solving, food preparation demonstrations and social support Provider: Mexican American nurses, dietitians and community workers Sessions: 52 contact hours (3 months of weekly 2-h sessions, 6 months of biweekly + 3 months of monthly 2-h support group sessions) Theory: based on results of four meta-analytic reviews and 6 years of development and piloting of intervention. Delivery: groups with each participant bringing a 'support' person Treatment changes: Training of 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 Mode: written materials limited owing to low literacy rates. Language predominantly Spanish with a	Eligibility criteria: Type 2 diabetes (defined p. 260) diagnosed after 35 years of age, aged between 35 and 70 years, willing to participate. Excluded 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, 128 control) Nos on insulin: intervention 25, control 26 Tablets: intervention 83, control 86 Diet alone: intervention 10, control 7 Oral and insulin: intervention 8, control 7 Type of diabetes?: 2 Mean duration of diabetes (years): intervention 7.6 (SD 5.8), control 8.1 (SD 6.9) Baseline measurements of outcome parameter (mean ± SD): HbA_{1c} intervention 11.810% ± 3%, control 11.80% ± 3.02% BMI: intervention 32.33 ± 5.97, control 32.12 ± 6.35 Cholesterol: intervention 211.83 ± 45.34, control 203.57 ± 48.82	Primary outcomes used: HbA_{1c} Secondary outcomes used: diabetes-related knowledge, fasting BG, BP, total cholesterol, HDL and LDL cholesterol, triglycerides, health beliefs, home glucose monitoring, BMI, costs Individual preferred learning style addressed?: no Any sub-groups: age and gender Normal range(s) for outcomes: none reported How outcomes assessed?: no details reported Validated?: physiological measures yes, knowledge and health beliefs unclear Timing of outcomes same for both groups: yes Length of follow-up: 12 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
	blend of English and each participant nominated a family member as a support person. Ref. 16 in trial gives more detail of intervention plus Table 1, p. 261 **Control intervention:** Usual care by physicians or local clinics (wait-list controls) **Duration of intervention:** 12 months	Triglycerides: intervention 215.35 ± 130.07, control 195.58 ± 118.95 Gender (M/F): intervention 51/75, control 40/86 Mean age (years): intervention 54.7 (SD 8.2), control 53.3 (SD 8.3) Ethnic groups: all Mexican Americans Losses to follow-up: not reported. Baseline data on 126 intervention and 126 control patients, 12-months data based on 112 intervention and 112 control patients Compliance: attendance at 1st 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	

Outcome (mean ± SD)	Intervention group	Control group	Difference between groups
HbA_{1c} (n = 112)	10.89% (2.56), adjusted 10.87%*	11.64% (2.85), adjusted 11.66%	*$p < 0.05$
FBG (n = intervention 114, control 113)	194.95 (63.27)*	210.51 (66.55)	*$p < 0.05$
Cholesterol (n = intervention 112, control 113)	189.88 (36.35)	187.64 (42.66)	
Triglycerides (n = 113)	214.43 (194.93)	198.65 (148.38)	
BMI (n = intervention 113, control 114)	32.17 (6.45)	32.28 (6.52)	

Knowledge/beliefs not reported as not a validated measure. 3- and 6-months data reported
Costs: total for eight subjects/group = US$3070; total per person = US$384

Methodological comments
Allocation to treatment groups: reports that individuals allocated to groups and then later that groups were randomly assigned to experimental or control conditions. In 'data analysis' section also states that 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: multilevel modelling (within-subjects and between-subjects analysis) which estimates for a given subject from available data and thus does not eliminate those with missing data
Standard deviation reported, no confidence intervals
Sample size/power calculation: not reported
Attrition/drop-out: not reported except numbers in results tables

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

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Campbell *et al.*, 1996[29] Source: published Country: Australia Setting: unclear Language: English Trial design: RCT	4 programmes: minimal instruction (1), individual education (2), group education (3), behavioural programme (4). All encouraged to bring a support person Provider: programmes 1, 2 +3 were delivered by staff in the diabetes education service, including 5 nurse educators and 3 dietitians. A single nurse delivered programme 4 **Treatment intervention 1 (apparently individual) = minimal education:** Sessions: two 1 h sessions within 2 weeks of referral Topics: (same topics but less detail than others); the portion exchange dietary system, exercise, use of OHAs, practical instruction in urine testing, foot care and recommendations to consult an ophthalmologist and podiatrist **Treatment intervention 2 = individual education:** Sessions: 2 sessions for 1 h within 2 weeks of referral, then 30-minute sessions approximately monthly until 12 months Topics: same but more detail than for intervention 1 and included information on the causes, symptoms, mechanisms and complications of diabetes **Treatment intervention 3 = group education:** Sessions: at least 2 individual sessions and a 3-day small group education course. (Individual monthly sessions were continued until a course could be scheduled) Mode: course involved lectures, small group exercises, practical sessions Topics: same topics as the other programs. 2-h follow-	Eligibility exclusion criteria: <80 years, Type 2 for <5 years, speak and write English, had received no previous formal instruction, not taking >75% of the maximum dose OHAs, had no terminal illness How selected: patients referred by general practitioner. Numbers involved: total *N* = 238, groups 1 59, 2 57, 3 66, 4 56 Nos on insulin: none Tablets: group 1 19, 2 22, 3 24, 4 23. Diet alone: groups 1 40, 2 35, 3 42, 4 33. Type of diabetes?: 2 Duration of diabetes (mean years ± SE): group 1 0.5 (0.1), 2 0.9 (0.2), 3 0.4 (0.1), 4 0.36 (0.1) Baseline measurements of outcome parameter: HbA_1: groups 1 11.9% (SE 0.6), 2 12.2% (0.5), 3 12.1% (0.6), 4 13.3% (0.6) Knowledge: group 1 5.7 (0.4), 2 5.3 (0.4), 3 5.5 (0.4), 4 4.6 (0.5) Systolic BP: groups 1 136.9 (2.4), 2 135.5 (3.0), 3 137.5 (2.7), 4 145.8 (3.3) Diastolic: group 1 80.7 (1.3), 2 81.6 (1.2), 3 81.7 (1.4), 4 91.7 (1.7) Gender (M/F): groups 1 22/37, 2 33/24, 3 35/31, 4 24/32 Mean age (years): groups 1 58.2 (1.3), 2 56.8 (1.5), 3 58.4 (1.4), 4 60.9 (1.4) Ethnic groups: not reported Losses to follow-up: group 2 40% attrition, group 3 42%, group 4 9% Compliance:	Primary outcomes used: HbA_1 Secondary outcomes used: BP, knowledge, satisfaction, uptake podiatry, ophthalmology, hospitalisations, BMI Individual preferred learning style addressed?: no Any sub-groups: no Normal range(s) for outcomes: HbA_1 <8.5%, knowledge? How outcomes assessed?: HbA_1 lab., knowledge, satisfaction, hospitalisations self-report, BP unclear Validated?: HbA_1, knowledge (DKNA) yes, satisfaction reported to have shown good internal consistency and reliability Timing of outcomes same for both groups: Length of follow-up: 12 months (minimal instruction only 6 months) from inception

continued

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

Outcomes (mean change ± SE unless noted otherwise)	Group 1 (minimal education)	Group 2 (individual education)	Group 3 (group education)	Group 4 (behavioural)	Difference between groups
HbA_1 (%): *n* = ?/25/19/39	No follow-up	–3.3% (0.9)	–3.0%(1.1)	–4.8%(0.7)	
Knowledge: *n* = ?/29/26/35	No follow-up	4.4 (0.6)	4.2(0.5)	5.6(0.6)	
Systolic BP (mgHg): *n* = ?/16/11/37	No follow-up	–6.8(5.8)	–12.4(6.8)	–16.9(3.8)	
Diastolic BP (mgHg): *n* = ?/16/11/37	No follow-up	–5.3(3.0)*	–5.0(4.0)*	–7.9(2.6)	*sig. from group 4, $p < 0.05$
BMI *n* = ?/30/25/41	No follow-up	–2.0 (0.4)	–1.4 (0.5)	–2.6 (0.5)	
Cholesterol (mmol/l) *n* = ?/23/19/34	No follow–up	0.12 (0.20)	0.16 (0.16)	–0.33(0.15)	
HDL cholesterol (mmol/l) *n* = ?/21/16/27	No follow-up	0.02 (0.04)	0.18 (0.10)	0.06 (0.08)	

continued

Outcomes (mean change ± SE unless noted otherwise)	Group 1 (minimal education)	Group 2 (individual education)	Group 3 (group education)	Group 4 (behavioural)	Difference between groups
Cholesterol risk ratio (total/HDL) *n* = ?/21/15/25	No follow-up	–0.25 (0.03)	–0.35 (0.46)	–0.59 (0.20)	
Treatment intensity: *n* = ?/29/27/42	No follow-up	% unchanged: 75 % decreased: 17 % increased: 7	% unchanged: 70 % decreased: 22 % increased: 8	% unchanged: 74 % decreased: 17 % increased: 10	
Satisfaction (actual score + SE): *n* = ?/25/25/30	No follow-up	74.8(2.2)	77.9(2.0)	77.0(2.3)	
Proportion consulting ophthalmology (%): *n* = ?/38/37/47	No follow-up	97	95	89	
Proportion consulting podiatry (%): *n* = ?/31/30/42	No follow-up	55	73	74	

3- and 6-month data reported.

Methodological comments

Allocation to treatment groups: not described
Blinding of outcome assessors?: not described
Allocation concealment?: not described
Analysis by ITT?: no
Comparability of treatment groups: significant differences in levels of education, duration since diagnosis, diastolic BP, smoking
Method of data analysis; continuous data – change scores were calculated and compared by ANCOVA (covariance analysis) with *t*-tests as *post hoc* tests, categorical data – chi-squared and pair-wise comparisons, mean and standard error given
Sample size/power calculation: no
Attrition/drop-out: percentages reported

General comments

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

Quality criteria (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?	Reported

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Trento *et al.*, 2001[30] Source: published Country: Italy Setting: university clinic Language: English Trial design: RCT	**Treatment intervention:** Topics: observation phase, educational diagnosis, definition of goals and development of plan including methods and setting in which to deliver. Data collected on patients baseline education, health beliefs. undesirability of being overweight, meal planning, improving and checking metabolic control and preventing complications (more detail in Table 1). Homework diaries for weight and food intake were given out at the end of each meeting, and discussed at beginning of next Provider: 1 or 2 physicians and educationalist. Also GP, 2 postgrad. medical students, clinical psychologist and psychometrist helped design programme Sessions: 4 sessions, over 1 h each. Sessions apparently repeated every 3 months Patients in need/wishing to have clinical attention were seen on a one-to-one basis at the end. 4-session cycle repeated for a second year Delivery: 6 groups of 9–10 people, in person, both didactic and interactive (hands-on activities, group work, problem-solving activities, real-life simulations and role play Treatment changes: none mentioned Training of trainers: Theory: **Control intervention:** 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.	Eligibility/exclusion criteria: Type 2 diabetes treated with either diet alone or diet and OHAs, who had attended clinic for at least 1 year How selected: no details Numbers involved: total 112 (56 intervention, 56 control) Nos on insulin: none Tablets: 50 intervention, 46 control Diet alone: 6 intervention, 10 control Type of diabetes: 2 Duration diabetes: intervention 9.4 (1–23) years, control 9.8 (1–39) years Baseline measurements of outcome parameter (mean ± SD): HbA_{1c}: intervention 7.4% ± 1.4%, control 7.4% ± 1.4%, QoL (DQOL): intervention 67.6 ± 19, control 66.7 ± 25 Retinopathy (none/mild/more severe): intervention 42/8/6, control 38/13/5 Knowledge: intervention 14.9 ± 7.9, control 20.2 ± 7.4 BMI: int: 29.7 ± 4.5, cont: 27.8 ± 4.1 No. hypertensive: intervention 34, control: 25 Health conduct (CdR): intervention 11.1 ± 2.7, control: 12.0 ± 4.3 Weight (kg): intervention 77.4 ± 13.1, control 78.2 ± 14.6 Fasting BG (mmol/l): intervention 9.8 ± 2.6, control 10.0 ± 3.1 Cholesterol (mmol/l): intervention 5.8 ± 1.1, control 5.5 ± 0.9 HDL cholesterol (mmol/l): intervention 1.2 ± 0.3, cont 1.3 ± 0.3	Primary outcomes used: HbA_{1c}, QoL (DQOL), retinopathy Secondary outcomes used: knowledge, BMI, health conduct, weight, FBG, cholesterol, triglycerides, creatinine, albumin, foot ulcers, hypoglycaemic medications Individual preferred learning style addressed?: no Any sub-groups: no Normal range(s) for outcomes: not given How outcomes assessed?: not given Validated?: HbA_{1c} yes. QoL with DQOL (slightly modified with 6 questions omitted from the worry, social/vocational section as pertinent to young Type 1 patients) Retinopathy: unsure Knowledge by education study group of the Italian Society of Diabetes (reported to be valid) Health conduct assessed by CdR: validated Timing of outcomes same for both groups: yes Length of follow-up: 2 years from inception

continued

Reference and design	Intervention	Participants	Outcome measures
	Individual education sessions from same educationalist, with special reference to eating habits, home monitoring of glucose and prevention of complications Duration of intervention: intervention patients averaged 7.9 visits (7–8) and control 8.2 (5–11) in 2 years	Triglyceride (mmol/l): 2.6 (0.7–11.5), control 1.7 (0.5–5.2) Creatinine (μmol/l): 91.6 ± 14.2, control 90.0 ± 14.0 Albuminuria (none/micro or macro): intervention 32/24, control 37/19 Foot ulcers (never/past/active); intervention 54/0/2, control 53/2/1 Hypoglycaemic treatment (intervention/control): diet only: 6/10, sulphonylureas 27/21, metformin 5/6, sulphonylureas + metformin 18/19, insulin 0/0 Gender (M/F): intervention 27/29, control 34/22) Age ranges (years): intervention 62 (35–80), control 61 (43–78) Ethnic groups: no details Losses to follow up: intervention: 13 (3 deaths, 10 moved), control: 9 (1 death, 5 moved, 3 lost to follow-up)	

Outcome (mean ± SD)	Intervention group (n = 43)	Control group (n = 47)	Difference between groups
HbA_{1c}	7.5 ± 1.4%	8.3 ± 1.8%	$p < 0.002$
DQOL	55.6 ± 15.9	80.8 ± 31.5	$p < 0.001$
Diabetic retinopathy (none/mild/more severe)	35/5/3	33/7/7	NS
GISED (knowledge)	24 ± 6.6	17.4 ± 8.6	$p < 0.001$
BMI	29.0 ± 4.4	27.6 ± 4.2	$p = 0.06$
No. hypertensive	26	22	NS
Health conduct (CdR)	15.8 ± 2.9	11.3 ± 4.3	$p = 0.01$
Weight (kg)	76.0 ± 13.4	77.1 ± 14.7	NS
Fasting BG (mmol/l)	9.9 ± 2.6	9.2 ± 2.9	NS
Total cholesterol (mmol/l)	5.7 ± 1.2	5.6 ± 1.2	NS
HDL cholesterol (mmol/l)	1.4 ± 0.4	1.3 ± 0.3	$p < 0.05$
Triglycerides (mmol/l)	2.1 (0.7–6.9)	1.7 (0.6–3.9)	$p = 0.53$
Creatinine (μmol/l)	88.8 ± 16.5	87.8 ± 17.2	NS
Albuminuria (none/micro or macro)	20/21	19/22	NS

continued

Outcome (mean ± SD)	Intervention group (*n* = 43)	Control group (*n* = 47)	Difference between groups
Foot ulcers (never/past/active)	42/1/0	45/1/1	NS
SMBG	10	14	NS
Hypoglycaemic treatment:			
Diet only	2	5	NS
Sulphonylureas	18	13	NS
Metformin	3	6	NS
Sulphonylureas + metformin	18	25	NS
Insulin	2	5	NS

Methodological comments
Allocation to treatment groups: random number tables
Blinding of outcome assessors?: not reported (N/A for HbA_{1c})
Allocation concealment?: not reported
Analysis by ITT?: no
Comparability of treatment groups: control participants had higher levels of education and better knowledge of diabetes
Method of data analysis: generalised linear model for repeated measures, and correlation coefficients
Standard deviation and significance levels only, no confidence intervals reported
Sample size/power calculation: no
Attrition/drop-out: reported as above

General comments
Generalisability: HbA_{1c} seems relatively low from outset
Conflict of interests: Turin University research grant
Other: publication of first-year results as preliminary results

Quality criteria (CRD Report 4)

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Cooper *et al.*, unpublished[a] Source: manuscript submitted Country: UK Setting: multicentre – 2 hospitals and 1 health centre Language: English Trial design: randomised wait-list design	**Treatment intervention:** Diabetes Look After Yourself (DLAY) course: Topics: self-management (nutrition, physical activity, relaxation, screening, management of complications [foot care, sick-day rules (personal communication of author)] exploration of feelings, how to make best use of health service) Provider: DSNs Sessions: 8 weekly sessions of approximately 2 h each. Delivered at staggered intervals over 14 months Delivery: largely interactive, small and plenary group discussions, problem-based learning, goal setting, exercise, relaxation and practice of skills Treatment changes: assume none Training of trainers: nurse trainers trained together and provided manual Theory: empowerment Ran in 3 different centres **Control intervention:** Randomised but on the wait list for 12 months Group A (n = 30): had outcomes measured after 6 and 12 months on DLAY Group B (n = 23): had short-term control period for 6 months and outcomes measured after 6 and 12 months on DLAY Group C (n = 36): long-term control period for 12 months before starting DLAY Duration of intervention: 8 weeks	Eligibility criteria: Type 2 diabetes diagnosed for at least 1 year, able to give written consent, undergoing regular diabetes screening. Excluded if: under 21 and over 75 years old, persistent defaulters, alcohol problem, language problem, and a physical handicap which precludes them from the activity/exercise programme (more details in Table 1) How selected: Numbers involved: N = 89, intervention N = 53, control N = 36 Nos on insulin: none Tablets: intervention 75%, control 66% Diet alone: intervention 25%, control 34% Type of diabetes: all 2 Duration of diabetes (mean years and range since diagnosis): intervention 5.7 (1–28); control 5.7 (1–30) Baseline measurements of outcome parameters (mean ± SD): HbA_{1c}: intervention: 7.9 ± 1.7%, control: 7.0% ± 1.6% Attitudes: intervention 73.1 ± 11.9, control 74.6 ± 11.0 Treatment effectiveness (median): intervention 4.4, control 4.0 BMI: intervention 32.5 ± 6.7, control: 32.1 ± 6.1 Diet: intervention 71.6 ± 18.2, control 69.6 ± 15.5 Exercise: intervention 50.8 ± 25.5, control 48.8 ± 31.6 Self-monitoring (%): intervention 67, control 47 Gender (M/F) (%): intervention 57/43, control 58/42 Age (years) (mean and range): intervention 58.2 (30–70), control 58.4 (35–73)	Primary outcomes used: HbA_{1c} Secondary outcomes used: Summary of Diabetes Self-Care Activities Questionnaire. Diabetes Integration Questionnaire (attitudes to diabetes and its treatment). Personal Models of Diabetes Questionnaire (treatment effectiveness). (qualitative outcomes not reported here) Individual preferred learning style addressed: no Any sub-groups: no Normal range(s) for outcomes: HbA_{1c}: 4–6% How outcomes assessed: HbA_{1c} by lab., others self-report Validated: quantitative measures validated Timing of outcomes same for both groups: yes between evaluations, but final evaluation in group B 6 months later Length of follow-up: 12 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
		Ethnic groups: not stated Losses to follow up: $n = 11$ (12%), 5 deaths (3 intervention/2 control) and 6 drop-outs (3 intervention/4 control) (*sic*.) Compliance: 76% attended 7 or more sessions. (A significant correlation between attendance rates and reductions in HbA_{1c} levels at 12 months)	

Outcome (mean ± SD)	Intervention group	Control group	Difference between groups
HbA_{1c}	7.9 ± 2.1	7.2 ± 1.6	NS
Attitudes (scale 0–100%, higher = better)	75.1 ± 11.0	70.5 ± 11.0	$p = 0.01$
Treatment effectiveness (median on Likert scale 0–5, higher = better)	4.5	4.1	NS
BMI	31.3 ± 5.7	30.5 ± 3.9	NS
Diet (scale: 0–100%, higher = better)	76.5 ± 12.2	68.0 ± 17.8	NS
Exercise (scale: 0–100%, higher = better)	62.5 ± 25.3	55.9 ± 25.0	NS
Self-monitoring (% blood testing)	92	63	$p = 0.002$

[a] See footnote to Table 12.

Methodological comments

Allocation to treatment groups: 'blindly and randomly assigned'
Blinding of outcome assessors: not reported
Allocation concealment: 'blindly and randomly assigned'
Analysis by ITT: not reported
Comparability of treatment groups: higher mean HbA_{1c} level in trial group compared with control after attrition (7.9% vs 7.0%) – adjusted for in analysis
Method of data analysis: used both quantitative and qualitative analysis. Means, SDs and p values reported. Regression analysis was used in the calculation of changes in baseline HbA_{1c} levels – to account for significant differences in baseline values of trial and control groups
Sample size/power calculation: yes – calculated that 48 patients needed to detect a 1% change in HbA_{1c} This gave a power level of 95% significance at the 5% level
Attrition/drop-out: 12%

General comments

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

Quality criteria (CRD Report 4) RCTs

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?	Partial

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Heller *et al.*, 1988[31] Source: published Country: UK Setting: hospital Language: English Trial design: RCT	**Treatment intervention:** group weight loss intervention of 4–6 patients with a spouse or friend. Each given a target weight Topics: aim was to lose weight, what foods to eat and those to avoid, aetiology of diabetes, self-monitoring, self-care, diabetic complications, the importance of eye examinations and foot care. Self-monitoring of urine taught (twice a day) Provider: one of two diabetes nurses and one dietitian Sessions: 3 90-minute sessions at weekly intervals with follow-up visits (90 min) at 3 and 6 months **Materials:** video which explained foods to eat, etc., a board for plotting weights so the group could see progress and a book on diabetes for patients Delivery: group education Treatment changes: Training of trainers: Theory: Mode: Persistent symptoms glycosuria or random BG >15 mmol/l were withdrawn At 3 months patients visited for 90 minutes and lunched with nurse and dietitian, followed by a group discussion with critical discussion of food choice. At 6 months 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 dietitian, 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: all newly diagnosed Type 2 patients (defined), overweight (BMI >27 kg/m^2), 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 40, control 47 Nos on insulin: none Tablets: none Diet alone: assume all Type of diabetes: 2 Duration diabetes: newly diagnosed Baseline measurements of outcome parameter: HbA_1 (mean + 95% CI): intervention 12.3% (11.4 to 13.2), control 12.7% (11.9 to 13.5) Gender (M/F): intervention 20/16, control 16/23 Age ranges (years) (mean + 95% CI): intervention 56.6 (55 to 58), control 56.4 (53 to 59.9). Ethnic groups: not reported Losses to follow-up: intervention 4, control 8 (reasons given) Compliance: 1 control + 2 intervention did not attend 3-month follow-up, 1 intervention did not attend 6-month follow-up	Primary outcomes used: HbA_1 Secondary outcomes used: knowledge, fasting BG, weight Individual preferred learning style addressed? No Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: HbA_1: 5.0–7.5%, knowledge (max. score 36) How outcomes assessed?: knowledge self-report, lab. for HbA_1 Validated?: HbA_1 yes, knowledge no details of validation Timing of outcomes same for both groups: yes Length of follow-up: 12 months from inception

continued

Outcome (mean ± 95% CI)	Intervention group (n = 36)	Control group (n = 39)	Difference between groups
HbA_1	9.0% (8.2 to 9.8)	9.9% (8.9 to 10.9)	
Proportion of patients HbA_1 <7.5%	36%	28%	
FBG (mmol/l)	9.1 (7.9 to 10.3)	10.3 (8.8 to 11.8)	
Weight loss (kg)	–5.5 (4 to 6.5)	–3 (2 to 4)	$p < 0.05$
Knowledge: not reported as not validated 3 and 6 months data reported.			

Methodological comments
Allocation to treatment groups: not reported
Blinding of outcome assessors?: not reported
Allocation concealment?: not reported
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% confidence intervals; *t*-tests, Mann–Whitney's and chi-squared tests used
Sample size/power calculation: no
Attrition/drop-out: drop-outs reported

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 (CRD Report 4) RCTs

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?	Unknown
8. Were withdrawals and drop-outs completely described?	Reported

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

continued

Reference and design	Intervention	Participants	Outcome measures
		Age ranges (years): intervention 51.1 (SD 8.1), control 53.7 (SD 12.8) Ethnic groups (Israel/Asia + Africa/Europe + America): intervention 8/7/8, control 3/10/13 Losses to follow-up: 2 intervention patients did not participate in the education programme, or keep appointments Compliance: 23 patients participated in the first meetings, 21 in the second and 18 in the third and fourth	

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

Methodological comments
Allocation to treatment groups: patients stratified according to mean values of pre- and postprandial glucose and HbA_{1c} and randomised. No details of method
Blinding of outcome assessors?: labs 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-squared between groups. No point estimates or confidence intervals given
Sample size/power calculation: not given
Attrition/drop-out: drop-outs reported

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

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Domenech *et al.*,1995[33] Source: published Country: Argentina Setting: community Language: English Trial design: CCT	Patients had previously received dietary advice from their physicians and/or had been treated with OHAs. **Treatment intervention:** group intervention of up to 8 patients incorporating group discussion and teaching Provider: physicians who had previously participated in a 2-day instruction of the teaching programme Sessions: 4 teaching units (90–120 min 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 Every 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 twice per day, 2 h after food **Control intervention:** usual care **Duration of intervention:** 1 month	Eligibility/exclusion criteria: excluded if newly diagnosed Type 2 diabetes, aged over 60 years, presence of advanced microangiopathic complications and presence of other severe diseases (e.g. cancer) How selected: the first 6–7 patients consulting each physician were selected for inclusion. In the control groups a larger number were included as were expecting a larger drop-out and in order to obtain a better match by age, gender and duration of diabetes Numbers involved: total $N = 124$, intervention 53, control 71 NB: baselines based on those completing study Nos on insulin: not reported, assume nil Tablets: intervention 29, control 32 Diet alone: assume intervention 11, control 7 Type of diabetes: 2 Duration of diabetes (years): intervention 6.9 (±0.7), control 6.3 (±1.3) Baseline measurements of outcome parameter: HbA_1 intervention 9% (±2.6), control 9% (±2.2) Gender (M/F): intervention 18/22, control 17/22 Age ranges (years): intervention 52.7 (SE 3.1), control 53.1 (SE 1.1) Ethnic groups: not reported Losses to follow up: intervention 13, control 32 (details given for intervention group only)	Primary outcomes used: HbA_1 Secondary outcomes used: knowledge weight (kg), daily intake OHAs Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: HbA_1 <7.5% How outcomes assessed?: lab., knowledge by self report Validated?: HbA_1 yes, knowledge no Timing of outcomes same for both groups: yes Length of follow-up: 12 months from inception

continued

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

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

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-out: 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 (CRD Report 4) CCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Kronsbein *et al.*, 1988[34] Source: published Country: Germany Setting: general practices Language: English Trial design: CCT, conditions implemented by practice	**Treatment intervention:** Provider: specially trained physicians' assistants Topics: basic information, metabolic self-monitoring, reasons for raised BG levels, OHAs, diet, foot care, physical activities, sick-day rules, late complications Sessions: 90–120 minutes each week for 4 weeks; groups of 4–6 patients; focus on group interaction with each session including experiential, theoretical and practical aspects Treatment changes: Training trainers: Theory: Mode: **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 sulphonylureas **Duration of intervention:** 4 weeks	Eligibility: WHO criteria for NIDDM Exclusion: physical or mental handicaps that prevented them from following the intervention programme How selected: 8 GPs attending teaching programme volunteered to introduce programme – 5 practices immediately, 3 after 1 year. Intervention participants: all consecutive patients who participated in first three courses Numbers involved: Starting total 127; intervention 65, control 62 Total (those completing follow-up) 99; intervention 50, control 49 Type of diabetes: 2 Duration of diabetes (years ± SD): Intervention 7 ± 5, control 7 ± 6 Baseline measurements of outcome parameter (mean ± SD): HbA_{1c}: intervention 7.1 ± 1.6%, control 6.5 ± 1.6% Weight (kg): intervention 76.5 ± 12.6, control 75.1 +12.9 Knowledge: intervention 9 ± 3, control 9 ± 3 No. without glucose-lowering medications: intervention (%) 32%, control 39% Gender (M/F) (%): intervention 42/58, control 39/61 Age ranges (years) (mean ± SD): intervention 65 ± 9, control 63 ± 8 Ethnic groups: not reported Losses to follow-up: intervention 15, control 13	Primary outcomes used: HbA_{1c} Secondary outcomes used: knowledge score no. on BG lowering medications, treatment with insulin, frequency self-monitoring urine, bodyweight Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): No Normal range(s) for outcomes: HbA_{1c} up to 5.6% How outcomes assessed: HbA_{1c} by lab., knowledge by specially designed questionnaire, no. on medications not reported, self-report glycosuria testing Validated: knowledge questionnaire assumed validated, reference provided Timing of outcomes same for both groups: Length of follow-up: 1 year from inception

continued

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

*Difference between groups, $p < 0.05$; **difference between groups, $p < 0.0001$.

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 confidence intervals for within-group and between-group differences
Sample size/power calculation: reported power required ~55 patients per group
Attrition/drop-out: yes

General comments

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

Quality criteria (CRD Report 4) CCTs

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

Interventions of focused self-management education

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Kaplan *et al.*, 1987[35] Source: published Country: USA Setting: unclear Language: English Trial design: RCT	Four groups: diet education (group 1), exercise education (group 2), diet and exercise education (group 3) and control education (control) All given the exchange diet (1200 cal) recommended by ADA and each received an exercise prescription based on baseline exercise test. A deposit of $40 was requested with return if attend and meet predetermined goals. Treatment interventions incorporated behavioural modification (stretching and walking and target heart rate) and strategies to increase compliance. The control did not Sessions: groups 2 h once per week for 10 weeks **Treatment intervention:** *Group 1 (diet):* Provider: Dietitian explained the diet Topics: identification of goals, used principles of modern learning theory. Diary monitoring of eating behaviour. Identification of external cues that lead to over/inappropriate eating Theory: used positive reinforcement. Also recorded own cognitions (positive and negative self-statements) and discussed in group. Also brief relaxation. Ref. 11 for more details Treatment changes: Training trainers: Mode: *Group 2 (exercise):* Provider: Topics: goal setting, planning for exercise, self-monitoring introduced, completion of diary, question answering and group exercise sessions. Used positive feedback, and gave suggestions for managing problems	Eligibility/exclusion criteria: confirmed diagnosis, fasting plasma glucose >3.62 mmol/l How selected: radio + newspaper advertisements and physicians Numbers involved: total $N = 87$, unsure of group numbers Nos on insulin: 19 Tablets: 29 Diet alone: 28 Type of diabetes: 2 Duration diabetes: not recorded Baseline measurements of outcome parameter: HbA_{1c}, group 1 8.97% (SD 2.82), group 2 8.16% (3.44), group 3 9.18% (2.46), control 8.21 (1.54) Gender (M/F): 32/44 Age ranges (years): group 1 54.87 (SD 12.32), group 2 53.81 (8.04), group 3 56.96 (8.95), control 54.5 (8.83) Ethnic groups: not reported Losses to follow-up: 11 (reasons given) Compliance: average attendance >80% for all groups	Primary outcomes used: HbA_{1c}, QoL Secondary outcomes used: weight (kg) Individual preferred learning style addressed?: Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: see appendix in text How outcomes assessed?: HbA_{1c} lab., QoL self-report questionnaire Validated?: QoL yes Timing of outcomes same for all groups: yes Length of follow-up: 18 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
	Treatment changes: Training of trainers: Theory: Mode: *Group 3 (diet and exercise):* Provider: Topics: modified dietary intervention for 5 weeks, then focused on exercise, self-monitoring, foot care and stretching, then followed exercise and behaviour modification format Treatment changes: Training of trainers: Theory: Mode: *Control intervention: (education):* Provider: exposed to health care specialists including an endocrinologist, podiatrist, ophthalmologist, psychologist, dietitian, 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 of trainers: Theory: Mode: Duration of intervention: 10 weeks		

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

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

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-out: 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

Quality criteria (CRD Report 4)

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Uusitupa *et al.*, 1992–6[36,109–113] Source: published Country: Finland Setting: hospital outpatient Language: English Trial design: RCT	**Basic education to both groups:** prior to randomisation for 3 months, both groups received basic education (basic knowledge of NIDDM, dietary advice to lose weight, reduce intake of saturated fat and cholesterol, and increase the use of unsaturated fat and unrefined carbohydrates) Both groups, after the 1-year intervention period, were advised to visit local health centres at 3-month intervals and the research centre at 21 and 27 months. **Treatment intervention:** Topics: 1. individualised intensified dietary education (principles of the diabetic diet, fat, carbohydrate, fibre, sweeteners, special diabetic products, behaviour modification, review of important things in diet, food preparation), recommended an individually tailored diet, compliance measured by food records and fatty acids of serum lipids 2. exercise training: oral and written instructions – proposed walking, jogging, cycling, swimming, cross-country skiing. Recommended heart rate during sessions 110–140 beats per minute. Recommended 3–4 times per week for 30–60 minutes Provider: physician, DSN(s), clinical nutritionist Length and no. of sessions: six visits to the clinic (at 2-month intervals) Recommended frequency of exercise training 3–4 sessions per week of 30–60 minutes each. Mode: given in person at the local health centre Treatment changes: no Training of trainers: Theory:	Eligibility criteria: obese, newly diagnosed Type 2 patients aged 40–64 years, FBG levels of ≥ 6.7 mmol/l How selected: physicians working in five rural and one urban health centre in Kuopio, referred all newly diagnosed patients from 1987 to 1989 Numbers involved: total $N = 86$, intervention 40, control 46 Nos on insulin: none Tablets: 7 (intervention = 2, control = 5) (1 in trial 2283) Diet alone: assume 79 (85 in trial 2283) Type of diabetes: 2 Duration of diabetes: all newly diagnosed Baseline measurements of outcome parameters: mean (SD): Weight (kg): intervention 88.3 (14.1), control 88.8 (14) BMI: intervention 32.0 (5.2), control 31.6 (4.8) FBG: (mmol/l): intervention 6.6 (1.9), control 7.5 (2.9) FBG adjusted: (mmol/l): intervention 7.0, control 7.2 % patients with FBG ≤ 6.7 mmol/l: intervention 37.5, control 26.1 HbA_{1c} (%): intervention 7.1 (1.8), control 7.8 (2.0) HbA_{1c} adjusted (%) intervention 7.4, control 7.8 % patients with HbA_{1c} ≤7.0%: no data reported Total cholesterol (mmol/;): intervention 6.1 (1.2), control 6.3 (1.0) HDL cholesterol (mmol/l): intervention 1.07 (0.25), control 1.17 (0.29) Non-HDL cholesterol (mmol/l): intervention 5.1 (1.3), control 5.1 (1.0)	Primary outcomes used: HbA_{1c} Secondary outcomes used: BP FBG, weight, BMI, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, food intake, apolipoproteins A1 and B, HDL cholesterol/total cholesterol, drug treatment, aerobic capacity Individual preferred learning style addressed: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: not reported How outcomes assessed: bodyweight measured with electric scale; physiological measures by lab., BP nurse measured (mean of 3 measurements), food intake self-report Validated: yes, except self-report measures Timing of outcomes same for both groups: yes Length of follow-up: after the 1-year intervention period, patients followed up for a further 12 months

continued

Reference and design	Intervention	Participants	Outcome measures
	Control intervention: Usual education given at the local health centres that originally referred them. They visited at 2–3-month intervals, plus twice visited the outpatient clinics Duration of intervention: 12 months	Triglycerides (mmol/l): intervention 2.50 (1.44), control 2.26 (1.33) BP systolic (mmHg): intervention 140 (16), control 137 (16) BP diastolic (mmHg): intervention 87 (11), control 83 (9) Gender (M/F): intervention 21/19, control 28/18 Age ranges (years): 40–64. Mean (SD) ages at diagnosis: intervention 52.2 (6.5), control 54.2 (6.5) Ethnic groups: not reported Losses to follow-up: at 2-year follow-up 2 lost in each group. Reasons not given	

Outcome (24 months: intervention *N* = 38, control *N* = 44) mean ± SD	**Intervention group**	**Control group**	**Difference between groups**
HbA_{1c} (%)			
12 months	6.6 (1.6)	7.5 (1.7)	
24 months	7.2 (1.9)	8.0 (1.6)	
HbA_{1c} adjusted (%)			
12 months	6.7	7.3	
24 months	7.4	7.9	
% patients with $HbA_{1c} \leq 7.0\%$			
12 months	74.4%**	47.8%	**$p = 0.005$
24 months	55.3%[a]	31.8%	[a]$p = 0.016$
BMI			
12 months	31.4 (5.0)	31.9 (4.6)	
24 months	31.9 (5.0)	32.2 (4.5)	
Blood pressure systolic (mmHg)			
12 months	137 (16)	144 (18)	
24 months	146 (19)	150 (22)	
Blood pressure diastolic (mmHg)			
12 months	83 (9)	85 (9)	
24 months	88 (10)	87 (9)	
Total cholesterol (mmol/l)			
12 months	6.0 (1.0)	6.4 (1.0)	
24 months	6.4 (1.3)	6.5 (1.1)	
HDL cholesterol (mmol/l)			
12 months	1.20 (0.29)	1.21 (0.28)	
24 months	1.17 (0.24)	1.19 (0.29)	
Non-HDL cholesterol (mmol/l)			
12 months	4.8 (1.0)		
24 months	5.2 (1.0)		

continued

Outcome (24 months: intervention *N* = 38, control *N* = 44) mean ± SD	**Intervention group**	**Control group**	**Difference between groups**
Triglycerides (mmol/l)			
12 months	1.96 (0.89)	2.33 (1.19)	
24 months	2.34 (1.19)	2.25 (1.25)	
Weight (kg)			
12 months	86.5 (13.7)	90.2 (14.3)	
24 months	Men (*n* = 20) 91.8 (10.7); Women (*n* = 18) 83.1 (14.2)	Men (*n* = 26) 95.1 (10.3); Women (*n* = 18) 84.8 (18.1)	
FBG (mmol/l)			
12 months	6.2 (1.8)	7.5 (2.2)	
24 months	7.1 (2.4)	8.2 (2.3)	
FBG adjusted (mmol/l)			
12 months	6.4*	7.3	*$p < 0.02$
24 months	7.4	8.0	
% patients with FBG ≤6.7 mmol/l			
12 months	75**	52.2	**$p = 0.005$
24 months	55.3[a]	31.8	[a]$p = 0.016$
Apoliprotein A1			
12 months	1.38 (0.19)	1.41 (0.18)	
Apoliprotein B			
12 months	1.13 (0.24)*	1.26 (0.27)	*$p < 0.02$
HDL cholesterol/total cholesterol			
12 months	0.20 (0.05)	0.19 (0.05)	
Drug treatment (percentage taking)			
24 months	12.5**	34.8	**Significant from control $p = 0.005$
Most of the comparisons reported were within groups. Only comparisons between groups are reported below. Self-report outcomes not reported here.			

Methodological comments

Allocation to treatment groups: unclear, only reports 'randomised'
Blinding of outcome assessors: not relevant
Allocation concealment: not reported
Analysis by ITT: not reported
Comparability of treatment groups: intervention group lower for FBG and HbA_{1c} – difference not tested statistically. Values were adjusted as covariates into MANOVA (multivariate analysis of variance) procedures and into the two-way covariance analysis (ANCOVA)
Method of data analysis: MANOVA, ANCOVA, *t*-tests. Analysis of variance used to test differences between groups. *p* values reported. Variables expressed as mean (SD)
Sample size/power calculation: no
Attrition/drop-out: 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 bodyweight, FBG and HbA_{1c} during 3 months of basic education before randomisation

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Ridgeway *et al.*, 1999[37] Source: published Country: USA Setting: community ambulatory clinic Language: English Trial design: RCT	**Treatment intervention:** Topics: dieting and exercise were emphasised as important in the control of diabetes. Diet and exercise prescriptions and goals set individually. Contracts made to emphasise patient participation and personal responsibility Provider: registered nurse and a dietitian 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 Changes to treatment: OHA medication started or increased 1 intervention, 4 control, stopped or decreased 1 intervention, 0 control, insulin increased 2 intervention, 2 control; OHA replaced by insulin 0 intervention, 3 control	Eligibility/exclusion criteria: 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 (FBG >150 mg/dl and HbA_{1c} above normal range) How selected: computerised audit was conducted and yielded 150 patients of whom 56 met inclusion criteria Numbers involved: total $N = 56$, intervention 28, control 28 Nos on insulin: intervention 3, control 3 Tablets: intervention 12, control 13 Diet alone: intervention 3, control 4 Type of diabetes: 2 Duration of diabetes (years): intervention 10=, control 13 Baseline measurements of outcome parameter (mean ± SD): GHb: intervention 12.3 ± 2.2%, control 12.3 ± 3.0% Knowledge intervention ($n = 17$) 74.2, control not reported QoL not reported Diabetes symptoms: intervention 43.8 ± 14.7, control 44.5 ± 19 FBG: intervention 215, control 210 Total cholesterol: intervention 259, control 224 HDL cholesterol: intervention 40, control 40 Triglycerides: intervention 634, control 381 LDL cholesterol: intervention 133, control 119	Primary outcomes used: GHb, QoL (MOS SF-36 and DRP questionnaires), symptoms Secondary outcomes used: knowledge (life skills test), FBG, total cholesterol, HDL cholesterol, triglycerides, LDL cholesterol Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): Normal range(s) for outcomes: GHb 4.8–7.8%. Knowledge scored as percent of correct answers. No values for QoL How outcomes assessed?: GHb by lab. Others by questionnaire, presume self-report Validated: GHb yes, MOS SF-36 unclear whether validated; unclear whether DRP and life skills tests validated Timing of outcomes same for both groups: assume yes Length of follow-up: 12 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
		Gender (M/F): intervention 6/12, control 5/15 Mean age (years): intervention 62, control 65 Ethnic groups: not reported NB: baseline characteristics based on those completing study Losses to follow-up: intervention 10, control 8 (reasons given) Compliance: intervention at least 5 classes	
Outcome (12 months)	**Intervention group (*n* = 18)**	**Control group (*n* = 20)**	**Difference between groups**
GHb	11.52%	11.64%	NS
QoL	No data presented		
Knowledge	85.7	No 12-month data presented	
Symptoms	No data presented		
Weight (lb)	186	186	NS
FBG	205	185	NS
Total cholesterol	219	234	$p = 0.09$
HDL cholesterol	36	37	NS
Triglycerides	485	336	NS
LDL cholesterol (in patients with triglyceride <400)	130	125	NS

Methodological comments
Allocation to treatment groups: states randomly assigned in text but no details of method of any randomisation also states that education was recommended to patients after 'randomisation' which all in education group accepted
Blinding of outcome assessors?: not reported
Allocation concealment?: not reported
Analysis by ITT?: no
Comparability of treatment groups: groups similar on baseline characteristics
Method of data analysis: *t*-tests. Standard error (difference within groups) given. No other measure of variance reported. No confidence intervals
Sample size/power calculation: not calculated, reported to be likely numbers available in a small general internal medicine group practice
Attrition/drop-out: 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 dept of medicine
Other: cost estimate for programme $95 for educational materials and salaries, excluding laboratory costs

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Wing *et al.*, 1985[38] Source: published Country: USA Setting: community Language: English Trial design: RCT 3 groups	**Treatment intervention:** *Behaviour modification:* Provider: behavioural psychologist and nutritionist Topics: info. on nutrition, exercise, diabetes, behavioural strategies Self-monitor diet Caloric goal for exercise and group exercise Contingency contract refunded $3 per lb of weight loss Changing eating environment Changing cognitions Sessions: weekly for 16 weeks in groups Treatment changes: Training of trainers Theory: Mode: lecture + discussion on topic related to diet and exercise. *Nutrition education:* Provider: as above Topics: diet – follow exchange list eating plan closest to caloric goal Nutrition topics Importance of exercise No requirement to self-monitor either diet or exercise No contingency contract for weight loss Sessions: weekly for 16 weeks in groups Treatment changes: Training of trainers Theory: Mode: as above **Control intervention:** treatment program identical in content with nutrition education except only 4 monthly meetings **Duration of intervention:** intervention for 16 weeks and follow-up for 1 year after intervention	Eligibility criteria: 30–70 years of age, 20% or more above ideal weight for height, diabetes being treated by diet only or by OHA medication, Type 2 diabetes by criteria specified by National Diabetes Data Group How selected: recruited via newspaper advertisements and articles and letters to physicians Numbers involved: total 53, no. in each group not reported Nos on insulin: none Tablets: 75% Diet alone: 25% Type of diabetes: 2 Duration of diabetes: 5.9 years Baseline measurements of outcome parameter: HbA_1: 9.3 ± 0.3 (mean ± SEM) BMI: 34.8 ± 7 BDI: 11.2 Gender (M/F): 20/33 Age (years) (mean ± SEM): 55.1 ± 1 Ethnic groups: not reported Losses to follow-up: 3	Primary outcomes used: HbA_1 Secondary outcomes used: BP, Beck depression inventory (BDI), BMI, insulin, total cholesterol, total triglycerides, HDL cholesterol, FBG, activity, food frequency, eating behaviour inventory Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: not reported How outcomes assessed: lab., nurse measure and self-report Validated: yes except activity, food frequency, eating behaviour inventory Timing of outcomes same for both groups: yes Length of follow-up: 12 months post-intervention (16 months from inception)

continued

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

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

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

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

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Wing *et al.*, 1986[39] Source: published 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 $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 of trainers: Theory: Mode: **Control intervention** = weight control group. Focused on weight reduction. BG levels checked at each meeting so adjusts could be made to medication, but no praise or reinforcement was given for BG control. Sessions as intervention group. **Duration of intervention:** 12 weeks	Eligibility: Type 2 diabetes, between 35 and 65 years; 20% above ideal weight for height; use of OHA medication or insulin for control of BG; diagnosis ≥ 30 years. Exclusion criteria: patients having prior experience with home monitoring of BG How selected: About 2/3 were self-referred; 1/3 referred by their physicians Numbers involved: $N = 50$, (25 weight control group, 25 glucose monitoring group) Nos on insulin: weight control = 48%, glucose monitoring = 52% Type of diabetes: all 2 Duration of diabetes: not given Baseline measurements of outcome parameter: FBG: weight control group ($N = 22$) 207 ± 70.5, glucose monitoring group ($N = 22$) 209.2 ± 69.7 HbA_1 (%): weight control group ($N = 21$) 10.86 ± 2.00, glucose monitoring ($N = 22$) 10.19 ± 2.51 Weight (kg), mean ± SD: weight control group ($N = 22$) 96.35 ± 23.57 Gender (% male): weight control group = 20%, glucose monitoring group = 24% Overall 39 women/11 men Age (years): overall average 54 years; weight control group = 54.0, glucose monitoring group = 53.5 Ethnic groups: not given Losses to follow-up: 5 (10%): 3 from weight control group and 3 from glucose monitoring group	Primary outcomes used: glycosylated haemoglobin (HbA_1) Secondary outcomes used: self-reported depression, weight (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 sub-groups (e.g. ethnic groups): Normal range(s) for outcomes: FBG levels = 60–120 mg/dl, $HbA_1 = 6.5 \pm 0.5\%$ How outcomes assessed: Beck depression inventory scale for depression (self-report), BP nurse, lab. physiological measures, self-report compliance Validated: yes Timing of outcomes same for both groups: yes Length of follow-up: 12 months from inception

continued

Reference and design	Intervention	Participants	Outcome measures
		Compliance: assessed by self-report records and by a 'marked item' technique. Patients used 89.1% of the assigned strips during treatment and 70.2% during the follow-up period. They detected 86.7% of the marked items during treatment and 62.8% during follow-up	
Outcomes	**Weight control group (*n* = 22)**	**Glucose monitoring group (*n* = 23)**	**Difference between groups**
HbA_1 (%)	10.44 ± 2.16	10.19 ± 2.29	
Beck depression inventory	No data provided		
FBG (*n* = 22)	210 ± 73.1	216.2 ± 58.7	
Decreases in medication (%)	Oral agents 64 Insulin 64	Oral agents, 73 Insulin 83	NS
Serum lipids did not differ between groups. Analysis for BP, triglyceride levels, total cholesterol levels, 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 B/P, HbA_1 not applicable, others unclear
Allocation concealment: not stated
Analysis by intention to treat: no
Comparability of treatment groups: no significant differences between groups reported
Method of data analysis: repeated-measures analysis of variance used to compare physiological changes in patients in the two groups. *p* values given
Sample size/power calculation: no
Attrition/drop-out: reports 10%, however, numbers for outcomes also reduced but no details

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

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Samaras *et al.*, 1997[40] Source: published Country: Australia Setting: community – hospital outpatient clinic Language: English Trial design: RCT	**Treatment intervention:** Topics: initially a needs assessment undertaken using focus groups of outpatients where contributing factors for exercise non-compliance were identified and classified. Strategies to overcome barriers, build self-esteem and motivation and provide professional and peer support. Safe exercise, exercise-specific education to improve confidence, coping with diabetes and exercise, self-esteem issues, decision making, goal setting and achieving mastery and enjoyment in exercise Provider: designed and undertaken by nurse educator, also involved exercise physiologist, dietitian, group facilitator and physician Sessions: monthly sessions for 1 h followed by a moderately paced aerobic exercise session. Delivery: group intervention, in person Treatment changes: unclear Training of trainers: Theory: health promotion model 'proceed-precede' (ref. given) **Control intervention:** usual treatment with assessment visits at baseline, 6 and 12 months and routine clinic visits Duration of intervention: 6 months (after programme exercise sessions still available to intervention group)	Eligibility/exclusion criteria: Type 2 diabetes, aged 40–70 years, performing less than 1 h exercise per week. Excluded if history or signs of ischaemic heart disease, current smoker, poor comprehension of English How selected: endocrinologists completed questionnaires on all their patients 40–70 years old at routine clinic for 2 months Numbers involved: $N = 26$ (intervention 13, control 13) Nos on insulin: intervention 3, control 4 Sulphonylurea: intervention 5, control 5 Metformin or diet alone: intervention 5, control 4 Type of diabetes: 2 Duration of diabetes: not reported Baseline measurements of outcome parameter (mean ± SE): HbA_{1c}: intervention 5.6% ± 0.3, control 6.8% ± 0.6 (not significant) BMI: intervention 32.3 ± 1.1, control 35.7 ± 1.6 Weight: intervention 83 ± 3.6, control 98.2 ± 3.4 Skinfolds: intervention 99.4 ± 6.0, control 119.4 ± 9.4 % Body fat: intervention 40.3 ± 1.7, control 40.3 ± 2.4 Waist:hip: intervention 0.94 ± 0.1, control 0.94 ± 0.08 Activity score: intervention 164 ± 28, control 168 ± 16 Total cholesterol: intervention 5.6 ± 0.3, control 5.6 ± 0.2 HDL cholesterol: intervention 1.1 ± 0.1, control 1.1 ± 0.1 Triglycerides: intervention 3.1 ± 1.1, control 2.3 ± 0.3	Primary outcomes used: HbA_{1c}, QoL (SF-36) Secondary outcomes used: BMI Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): those managed with metformin or diet alone and those taking sulphonylurea or insulin therapy Normal range(s) for outcomes: not reported How outcomes assessed: physiological measures lab., QoL self-report, activity = meter Validated?: HbA_{1c} yes, QoL by SF36: yes. Timing of outcomes same for both groups: yes Length of follow-up: 12 months from baseline

continued

Reference and design	Intervention	Participants	Outcome measures
		FBG: intervention 9.3 ± 1.0, control 7.9 ± 0.7 Fasting insulin: intervention 22.4 ± 4.1, control 21.4 ± 2.2 Gender (M/F): intervention 4/9, control 6/7 Age ranges (years): intervention 60.5= (SE 7.8), control 60.5= (SE 2.1) Ethnic groups: not reported, varied cultural backgrounds Losses to follow-up: assume nil Compliance: full	

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

Methodological comments

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

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

Quality criteria (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?	No losses reported
8. Were withdrawals and drop-outs completely described?	No losses reported

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Wing *et al.*, 1988[41] Source: published Country: USA Setting: unclear Language: English Trial design: RCT	**Common procedure to both groups:** weight control programme. Participated in a lecture-discussion on behavioural weight control, given individualised calorie goals and recorded all intake. Taught about caloric values of food groups and trained in portion size estimation. Exercise (walking) was stressed, and given gradually increasing exercise goals. Other lessons focused on behavioural strategies for controlling cues for eating, dealing with social situations involving food, changing cognitions about food, motivation and self-reinforcement and problem solving. Deposited money at start, and refunded for every pound of weight lost and for attending Both groups given free glucometers and asked to monitor BG 12 times/week. Trained in its use **Intervention 1: self-regulation education:** Topics: extensive training in how to use SMBG information; this info. was given gradually over the course of the programme. Meetings 1–5 given homework tasks to demonstrate the effect of diet and exercise on BG control, and given examples, these were then discussed at later group meetings. Meetings 6–9 given goals for BG which were good and fair. Monitored how many within each range. Then taught to use the readings to self-regulate their behaviours using reinforcement. Meetings 10–13 refunded deposit money for behaviour changes and other criteria used in previous phases. Not asked to adjust treatments in response to SMBG Provider:	Eligibility criteria: >20% overweight, 30–65 years, met NDDG (1979) criteria for Type 2 How selected: newspaper advertisements used to recruit Numbers involved: total $N = 20$, intervention 1 =10, intervention 2 = 10 Nos on insulin: none Tablets: 16 Diet alone: 4 Type of diabetes: 2 Duration of diabetes: not reported Baseline measurements of outcome parameter (mean ± SE): HbA_1: intervention 1 10.57 ± 0.44%, intervention 2 10.54 ± 0.55% BMI: 35.4 ± 1.05 Gender (M/F): 7, 13 Age ranges (years): average 53.3 (range 38–60). Ethnic groups: not reported Losses to follow-up: 3 in total, 1 in intervention 1, 2 in intervention 2 (1 death, 2 refusals) Compliance: all attended all 16 weeks	Primary outcomes used: HbA_1 Secondary outcomes used: BMI Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: HbA1 6.1 ± 0.5% How outcomes assessed?: lab. Validated?: yes Timing of outcomes same for both groups: yes Length of follow-up: 68 weeks from inception

continued

Reference and design	Intervention	Participants	Outcome measures
	Sessions: 13 sessions Delivery: in person Treatment changes: treatment changes in both groups monitored by physician and followed standard algorithm Training of trainers: Theory: **Intervention 2: self-monitoring education:** No additional training in using SMBG information (as intervention 1 group had). **Duration of both interventions:** 13 meetings over 16 weeks (held weekly for 10 weeks and every 2 weeks for the following 6 weeks). Follow-up meetings held every 2 weeks for the next 3 months and at monthly intervals for the following 3 months. 10 months total. Were care programmes identical: unclear		
Outcome (mean ± SE)	**Intervention group 1 (*n* = 9)**	**Intervention group 2 (*n* = 8)**	**Difference between groups**
HbA_1 (%)	10.8 ± 0.8	9.71 ± 0.78	Time × condition interaction, NS (based analysis on baseline of those attending for follow up)
Weight (kg) (BMI not reported at follow-up)	86.6 ± 5.6	94.8 ± 5.9	Time × condition interaction, NS (based analysis on baseline of those attending for follow-up)

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

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

Quality criteria (CRD Report 4) RCTs

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

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Gilliland *et al.*, 2002[42] Source: published Country: USA Setting: community Language: English Trial design: CCT (3 groups)	**Intervention 1: family and friends (FF):** Topics: culturally appropriate diabetes education materials, skill building, social support. Three core areas: exercise, diet and support. Sessions named: get more exercise; eat less fat; eat less sugar; together we can (how to get/receive support); staying on the path (maintenance of lifestyle changes) Intervention used Native American values, Native American foods, information on diet and exercise and videos featuring Native Americans. Consistent with Native American learning, stories and prayers were used. There were written materials, as well as 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, ~6 weeks apart for ~2 h Delivery: in person in groups with family and friends 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 approximately 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: 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 UC Nos 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: 2 Duration of diabetes (mean ± SD): FF 8.1 (5.3), OO 8.3 (6.4), UC 10.0 (6.6) Baseline measurements of outcome parameter (mean ± SD): HbA_1: FF 8.3 (1.9), OO 9.2 (2.3), UC 7.9 (2.0) BMI: FF 31.0 (5.6), OO 31.2 (6.8), UC 32.0 (6.1) Weight (lb): FF 174.6 (35.4), OO 172.2 (37.2), UC 168.9 (33.8) Diastolic BP (mmHg): FF 80 (9), OO 81 (12), UC 78 (10) Cholesterol (mg/dl): FF 199 (51), OO 218 (50), UC 193 (43) Triglycerides (mg/dl): FF 224 (147), OO 290 (214), UC 214 (154) Sex (M/F); FF 9/23, OO 10/29, UC 3/30 Age (years) (mean ± SD): FF 60.2 (12.1), OO 59.9 (13.4), UC 60.2 (11.8) Ethnic groups: all participants Native American	Primary outcomes used: HbA_{1c}, weight Secondary outcomes used: diastolic BP, cholesterol, triglycerides Individual preferred learning style addressed?: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: HbA1 not reported How outcomes assessed: laboratory Validated: yes Timing of outcomes same for both groups: yes Length of follow-up: ~1 year from inception

continued

Reference and design	Intervention	Participants	Outcome measures
	Duration of both interventions: sessions conducted during 10 month period Were care programmes identical: yes	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 (mean ± SD)	FF intervention group	OO intervention group	Control – usual care	Difference between groups (across 3 arms)
HbA_1 adjusted mean change	+0.5 (0.3)	+0.2 (0.3)	+1.2 (0.4)	$p < 0.05$ Combined interventions vs control, $p < 0.05$
Weight (lb)	–2.0 1.5)	–1.8 (1.5)	+1.7 (1.8)	NS Combined interventions vs control, $p = 0.05$
Diastolic BP (mmHg)	–6.5 (2.0)	–0.4 (1.7)	–0.3 (2.1)	$p < 0.05$ Combined interventions vs control, NS
Cholesterol	–22 (11)	–20 (11)	–10 (16)	NS Combined vs control, NS
Triglycerides	–178 (78)	–48 (48)	–69 (63)	NS Combined vs control, NS

Methodological comments
Allocation to treatment groups: by community
Blinding of outcome assessors: not reported, not of concern for laboratory measures
Allocation concealment: N/A
Analysis by ITT?: no
Comparability of treatment groups: at baseline groups differed in HbA_{1c}, in number of patients receiving OHAs, in hypertension. These differences were incorporated into statistical analyses
Method of data analysis: ANOVA for continuous variables, chi-squared or Fisher's exact tests for discrete variables. ANCOVA for intervention differences in HbA_{1c} 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-out: More women than men and more obese than non-obese participants were evaluable
Participants in usual care were more likely to drop-out

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

Quality criteria (CRD Report 4) CCTs

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 9

Data extraction: patients with either Type 1 or Type 2 diabetes

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Bloomgarden *et al.*, 1987[44] Source: published Country: USA Setting: diabetes clinic at a teaching hospital Language: English Trial design: RCT	**Treatment intervention:** Providers: nurse educator and nutritionist Topics: understanding diabetes, foot skin and dental hygiene, insulin administration, emergencies, risk factors for macrovascular disease. Nutrition sessions covered: individual diet instruction, basic nutrition, weight loss and the diabetic diet, food purchasing and meal planning Sessions: Treatment changes: Training of trainers: Theory: Mode: usual care plus 9 group education sessions offered to each patient. Separate sessions in Spanish. Used card games, films and slides **Control intervention:** Usual care – available to all patients in both groups. Patients had contact at each visit with their physician and a nurse who reviewed medications and specific problems **Duration of intervention:** Programme lasted 1.6 ± 0.3 years in education group and 1.5 ± 0.3 years in control group	Eligibility: all insulin-treated patients. None were excluded by design of the study How selected: all insulin-treated diabetics on the clinic registry as of September 1979 Numbers involved: 345 agreed to participate 302 returned for examination by physician: 145 in education group, 157 in control group Nos on insulin: all Type of diabetes: 2, intervention 76%, control = 65% Duration of diabetes (years) (± SD): intervention 13 ± 8, control: 14 ± 9 Baseline measurements of outcome parameter (mean ± SD): HbA_{1c}: intervention 6.8 ± 2.1, control 6.6 ± 2.0 Knowledge: intervention 5.3 ± 1.6, control 5.3 ± 1.7 Gender (M/F): intervention 50/77, control 72/67 Age ranges (years) (± SD): intervention 56 ± 12, control 59 ± 13 Ethnic groups: intervention white = 6%; black = 41%, Hispanic = 31%; control white = 6%; black = 29%, Hispanic = 35% Losses to follow-up: 79 (38 in intervention and 41 in control). 345 agreed to	Primary outcomes used: HbA_{1c} Secondary outcomes used: development of foot lesions, diastolic and systolic BP in hypertensive subgroup, use of medical care, BMI, foot lesions scores, FBG, behaviour score, triglycerides, HDL and LDL cholesterol, insulin dosage Individual preferred learning style addressed: not stated Any sub-groups: graduates and non-graduates. Hypertensives Normal range(s) for outcomes: 1.8–4.8% total Hb.? Knowledge and behaviour score How outcomes assessed: knowledge and behaviour scores derived from previous literature Validated: knowledge score – possible? Timing of outcomes same for both groups: longer in education group by 1 month Length of follow-up same as duration of intervention: 1.6 ± 0.3 years in education group and 1.5 ± 0.3 years in control group

continued

Reference and design	Intervention	Participants	Outcome measures
		participate and 266 completed final assessment $n = 127$ intervention, 139 control Compliance: of the 145 patients in the intervention group, 82 attended at least 7 classes and regarded as graduates of the programme; 20 attended 3–6 classes, 30 attended 1–2 classes and 17 failed to attended any	

Outcome (mean ± SD)	Intervention group ($n = 127$)	Control group ($n = 139$)	Difference between groups
HbA_{1c}	6.1 ± 2.0	6.3 ± 2.0.	
Knowledge score	5.8 ± 1.6	5.3 ± 1.7	$p < 0.007$
BMI	Men: 29.1 ± 4.6 Women: 32.1 ± 6.9	Men: 27.7 ± 4.3 Women: 32.9 ± 7.0	
Glucose (mg/dl)	179 ± 73	185 ± 76	
Foot lesions (none/minor/severe)	61/56/10	48/75/16	
Behaviour score	4.3 ± 1.6	4.1 ± 1.6	

No differences between groups for sick days, hospitalisations, emergency room visits, outpatient visits, triglycerides, HDL and LDL cholesterol, insulin dosage (data not shown).
No differences in HbA_{1c} in those attending ≥7 sessions and those <7 sessions.
Among hypertensive patients, no differences between groups (no data shown).

Methodological comments
Allocation to treatment groups: method of randomisation not stated
Blinding of outcome assessors: not stated
Allocation concealment: not stated
Analysis by ITT: no
Comparability of treatment groups: control group had more frequent foot lesions; education group had higher FBG and number of hospitalisations in previous year
Method of data analysis: hypothesis tests (*t*-test, ANOVA). Standard deviations and *p* values given
Sample size/power calculation: yes. Large enough to detect a difference in means between the groups in HbA_{1c} of >1% with $\alpha = 0.5$ and a power of 0.95
Attrition/drop-out: reported

General comments
Generalisability: no participants tended to be older (>70), required assistance to travel to the clinic, more likely to be male
Conflict of interests: none mentioned
Other:

Quality criteria (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?	Unknown
8. Were withdrawals and drop-outs completely described?	Partially

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Glasgow *et al.*, 1997[45] Source: published Country: USA Setting: in the office of 2 internists who are primary care providers and part of a large medical group Language: English Trial design: RCT	**Treatment intervention:** Providers: researcher seen after physician visit Topics: patient-centred goal setting and problem solving, and dietary self-help materials. Produced individualised goal-setting plan to lower fat intake based on patients' eating habits and barriers to dietary self-management. Patients with higher self-efficacy score received a take-home video. Patients with lower efficacy levels returned for a 30-minute interactive video, more personalised Sessions: 20 minute initially, then telephone follow-up at 1 and 3 weeks, and 3 and 6 months to review progress, adjust strategies and mail maintenance information. At 9 months received a copy of a book 'On the human side of diabetes'. Intervention delivered by research staff Treatment changes: Training of trainers: Theory: Mode: an additional 5–10 minute touchscreen dietary barriers assessment which generated immediate feedback forms **Control intervention:** Usual care = quarterly medical care (regular assessment and follow-up, plus the initial touchscreen computer assessment), telephone contact; 3 weeks, 6 months, given book at 9 months **Duration of intervention:** 9 months	Eligibility criteria: having Type 1 or 2 diabetes, at least 40 years old, being primarily responsible for one's own diabetes dietary self-management How selected: those scheduled for visit received a letter encouraging participation. Randomised from the physician practice Numbers involved: 206 total intervention $N = 108$, control $N = 98$ Nos on insulin: intervention 68%, control 66% Type of diabetes: 2, intervention 76%, control 81% Duration of diabetes (years): intervention 13.0 (9.9), control 13.7 (12.2) Baseline measurements of outcome parameter: HbA_{1c}: intervention 7.9, control 7.9 Food questionnaire: intervention 2.26, control 2.20 BMI: intervention 30.4, control 30.5 Cholesterol: intervention 217, control 223 Gender (M/F) (%): intervention 37/63, control 40/60 Age ranges (years): intervention 61.7 (SD 12.1), control 63.1 (SD 10.5) Ethnic groups: not given Losses to follow-up: 16% (16.7 vs 15.3) Compliance: assume 100%	Primary outcomes used: HbA_{1c} Secondary outcomes used: patient satisfaction, BMI, dietary self-management questionnaire, serum cholesterol Individual preferred learning style addressed: no Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: not given How outcomes assessed: Patient Satisfaction instrument contained 7 items assessing the office visit. Food Habits Questionnaire (FHQ) measuring four dimensions of fat-related dietary habits Validated: the Kristal FHQ is validated. Patient Satisfaction Methods was developed for this study (not reported) Timing of outcomes same for both groups: yes Length of follow-up: 12 months from inception

continued

Outcomes	Intervention group	Control group	Difference between groups
HbA_{1c} levels (N = 161)	7.8	7.8	
BMI (N = 164)	30.5	30.4	
Serum cholesterol (N = 167)	208	226	$p < 0.01$
Food Habits Questionnaire (FHQ) (n = 170)	2.06	2.26	$p < 0.01$

Methodological comments
Allocation to treatment groups: randomised using a table of random numbers
Blinding of outcome assessors: not stated
Allocation concealment: not stated
Analysis by ITT: no
Comparability of treatment groups: well matched – no significant differences on any variables
Method of data analysis: a series of MANCOVA and ANCOVAs to identify specific measures on which there were treatment effects. p values given. No measure variance
Sample size/power calculation: no
Attrition/drop-out: 16% – no differences between groups

General comments
Generalisability: 61% of eligible patients (those that had scheduled an outpatient visit) agreed to participate
Conflict of interests: (funding support mentioned?)
Other: Costs for the Brief Intervention were $137 per participant. As there were no significant effects on HbA_{1c} an economic analysis not conducted. ? normal range for diet questionnaire. Different Ns for different outcomes

Quality criteria (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?	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?	Unknown

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Raji *et al.*, 2002[46] Source: published Country: USA Setting: unclear Language: English Trial design: RCT	**Intervention 1 (intensive group education):** Topics: core elements recommended by ADA (see ref.) Provider: physician, nurse, nutritionist, pharmacist, exercise physiologist, social worker, diabetes educator Sessions: 3.5 days Treatment changes: Training of trainers: Theory: Mode: structured curriculum through lectures, group discussions and supervised exercise. Two meals and snacks provided to reinforce the nutritional instruction. Patients then returned to usual care. Groups of 4–6 participants **Intervention 1 (passive education):** Topics: general diabetes management, nutrition, coronary artery disease, foot care Provider: Sessions: Treatment changes: Training of trainers: Theory: Mode: educational materials mailed to participants, homes every 3 months, for 12 months including booklets (15–45 pages) **Control intervention:** also used data from another 56 matched patients from those who declined randomisation, but not randomised. Matched on age, sex and baseline HbA_{1c} to passive group. Hb measured at 12 ± 3 months from screening **Duration of intervention:** intervention 1 3.5 days, intervention 2 once every 3 months for 12 months	Eligibility criteria: elevated HbA_{1c} (>8.5%) within 30 days randomisation, ≥18 years, able to exercise, available to participate, able to understand written and spoken English. Excluded if: significant eye disease limiting visual acuity, urine protein >2g/dl, coronary artery disease symptoms and/or lower extremity amputation that limited exercise capacity How selected: hospital lab. data screened for patients with HbA_{1c} >8.5% Numbers involved: 106 (intervention 1: 50, intervention 2: 56) Nos on insulin: 39% Tablets: 46% Combination: 15% Type of diabetes: not reported, assume mixed Duration diabetes: not reported Baseline measurements of outcome parameter: HbA_{1c} intervention 1: 10%, intervention 2: 9.9% Gender: 99% male Mean age (years) : 60 ± 3 Ethnic groups: not reported Losses to follow-up: intervention 1, 1 (no reason given); no report for intervention 2 Compliance: not reported	Primary outcomes used: HbA_{1c} Secondary outcomes used: numbers on oral medication, insulin, combination Individual preferred learning style addressed? no Any sub-groups: no Normal range(s) for outcomes: not reported How outcomes assessed?: HbA_{1c}, lab., assume medication from patient records Validated?: yes Timing of outcomes same for both groups: yes Length of follow-up from inception: 12 months

continued

Outcome	Intervention 1 group	Intervention 2 group	Non-randomised control	Difference between groups
HbA_{1c}	8.0	8.0		NS
HbA_{1c} joint intervention versus control	8.0 (SD 1.4)		8.6 (SD 1.8)	$p < 0.03$
Numbers on medication: Oral monotherapy Oral combination Insulin/oral combination insulin	Pie chart only with no indication of gauge			

Methodological comments
Allocation to treatment groups: not reported
Blinding of outcome assessors?: not applicable
Allocation concealment?: not reported
Analysis by ITT?: yes
Comparability of treatment groups: baseline characteristics only given for total group, except HbA_{1c} which was not different
Method of data analysis: point estimates only, used hypotheses tests
Sample size/power calculation: not reported
Attrition/drop-out: reported for intervention 1 only, assume nil for intervention 2

General comments
Generalisability: majority male
Conflict of interests: from research bodies, not commercial
Other: method of recruitment means high motivated patients. Possible that medical therapy intensified during trial

Quality criteria (CRD Report 4) RCTs

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?	Unknown
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?	Adequate
8. Were withdrawals and drop-outs completely described?	Reported

Reference and design	Intervention	Participants	Outcome measures
Surname and year: Gilden *et al.*, 1992[47] Source: published Country: USA Setting: diabetes clinic, Veterans Affairs Medical Center Language: English Trial design: CCT, three groups matched for age and duration of diabetes	**Group A: education and support group education:** Providers: diabetologist, nurse educator, dietitian, social worker, psychologist, podiatrist, pharmacist Topics: general knowledge of diabetes, nutritional and drug management, social work support services, stress management, self-care techniques (SMBG, general health habits, foot care) Sessions: six, one per week Support group: Provider: self-directed by patients but additional education by providers listed above Topics: continuing education, coping skills, group discussion, structured social activities Sessions: monthly for 18 months (ref. 2 describes education) Treatment changes: Training of trainers: Theory: Mode: **Group B: education only as described above** **Group C: no intervention**	Eligibility/exclusion criteria: no eligibility criteria reported How selected: attended same clinic Numbers involved: total: 32 Group A (treatment): 11 Group B (treatment): 13 Group C (control): 8 Nos on insulin: not reported Tablets: not reported Diet alone: not reported Type of diabetes: not reported Duration of diabetes (years): 10 ± 2, range 3–6 Baseline measurements of outcome parameter (Group A only; mean ± SEM): Knowledge: 36 ± 4 QoL: QLa 22 ± 2, QLb 38 ± 10, QLt 62 ± 13 Stress: 12 ± 3 Family involved: 28 ± 5 Social activity: 9 ± 4 Gender: all male Age ranges (years): mean 68 ±1.3 (SEM), range 57–82 Ethnic groups: not reported Losses to follow-up: not reported States patients not included in analysis if participants in other education programmes during 2 years, suggests numbers may not be correct	Primary outcomes used: HbA_{1c}, QoL (two subscales, QLa, QLb) Secondary outcomes used: knowledge, stress, family involvement, social activities, depression (Zung's Mood Scale) Individual preferred learning style addressed?: No Any sub-groups (e.g. ethnic groups): no Normal range(s) for outcomes: HbA_{1c} 3.0–6.1%, depression 25–50 = normal, others not reported How outcomes assessed: all measures except HbA_{1c} were self-report Validated: questionnaires reported as validated (reference given) Timing of outcomes same for both groups: yes Length of follow-up: 2 years from programme inception

Outcome (mean ± SEM) 2 years	Group A (education and support)	Group B (education)	Group C (control)	Difference between groups
HbA_{1c}	6.6 ± 0.3	6.5 ± 0.2	8.4 ± 0.7*[a]	*from group A, $p < 0.05$ [a]from group B, $p < 0.05$
Knowledge	38 ± 1	36 ± 1*	34 ± 1*	*from group A, $p < 0.05$
QLa	26 ± 1	25 ± 1	23 ± 1**	**from Group A, $p < 0.01$

continued

Outcome (mean ± SEM) 2 years	Group A (education and support)	Group B (education)	Group C (control)	Difference between groups
QLb	53 ± 5	45 ± 5	41 ± 2**	**from Group A, $p < 0.01$
QL total	78 ± 5	71 ± 6*	64 ± 3**	*from group A, $p < 0.05$ **from Group A, $p < 0.01$
Stress	14 ± 1	14 ± 1	11 ± 1*	*from group A, $p < 0.05$
Family involvement	26 ± 1	28 ± 3**	24 ± 2*	*from group A, $p < 0.05$ **from Group A, $p < 0.01$
Social activities	8 ± 1	10 ± 1	12 ± 1**	**from Group A, $p < 0.01$
Depression (higher = more depression)	43 ± 6	51 ± 3	56 ± 2	
Pervasive affective disturbance (higher = more depression)	2.3 ± 0.2	2.7 ± 0.2*	3.4 ± 1**	*from group A, $p < 0.05$ **from Group A, $p < 0.01$

QLa = more demanding and intensive life-style changes due to diet, exercise and other general factors. QLb = less demanding behaviours including medication compliance and self-testing. Higher scores indicate better knowledge and better perception of QoL.

Methodological comments

Allocation to treatment groups: matched for age and diabetes duration. No additional information
Blinding of outcome assessors: not reported
Allocation concealment: not reported
Analysis by ITT: not reported
Comparability of treatment groups: "no significant differences on questionnaire variables between Groups A and B prior to support group intervention". No other information
Method of data analysis: *t*-tests and ANOVA, SEM, no confidence intervals
Sample size/power calculation: no power calculation reported
Attrition/drop-out: no information on attrition

General comments

Generalisability: no information about inclusion criteria. Owing to small groups, setting and all male participants, generalisability may be limited
Conflict of interests: no mention

Quality criteria (CRD Report 4) CCTs

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

Appendix 10

List of reviews and systematic reviews retrieved

Albano MG, Jacquemet SP. Patient education and diabetes research: a failure. Going beyond the empirical approaches. *Acta Diabetol* 1998;**35**:207–14.

Beebe C, O'Donnell M. Educating patients with type 2 diabetes. *Nurs Clin North Am* 2001;**36**:375–86.

Brown SA. Effects of educational interventions in diabetes care: a meta-analysis of findings. *Nurs Res* 1988;**37**:223–30.

Brown SA. Studies of educational interventions and outcomes in diabetic adults: a meta-analysis revisited. *Patient Educ Couns* 1990;**16**:189–215.

Brown SA. Meta-analysis of diabetes patient education research: variations in intervention effects across studies. *Res Nurs Health* 1992;**15**:409–19.

Brown SA, Hedges LV. Predicting metabolic control in diabetes: a pilot study using meta-analysis to estimate a linear model. *Nurs Res* 1994;**43**:362–8.

Clement S. Diabetes self-management education. *Diabetes Care* 1995;**18**:1204–14.

Corabian P, Harstall C. Patient diabetes education in the management of adult type 2 diabetes. Alberta Heritage Foundation for Medical Research; 2001. No. HTA 23: Series A.

Diabetes UK. Patient education for effective diabetes self-management. London: Diabetes UK; 2002.

Eakin EG, Bull SS, Glasgow RE, Mason M. Reaching those most in need: a review of diabetes self-management interventions in disadvantaged populations. *Diabetes Metab Res Rev* 2002;**18**:26–35.

Fain JA, Nettles A, Funnell MM, Charron D. Diabetes patient education research: an integrative literature review. *Diabetes Educ* 1999;**25**:7–15.

Goodall TA, Halford WK. Self-management of diabetes mellitus – a critical review. *Health Psychol* 1991;**10**:1–8.

Griffin S, Kinmouth AL, Skinner C, Kelly J. Educational and psychological interventions for adults with diabetes. London: British Diabetic Association; 1998.

Huang ES, Meigs JB, Singer DE. The effect of interventions to prevent cardiovascular disease in patients with type 2 diabetes mellitus. *Am J Med* 2001;**111**:633–42.

Krishna S, Balas EA, Spencer DC, Griffin JZ, Boren SA. Clinical trials of interactive computerized patient education: implications for family practice. *J Fam Pract* 1997;**45**:25–33.

Montani S, Bellazzi R, Quaglini S, D'Annunzio G. Meta-analysis of the effect of the use of computer-based systems on the metabolic control of patients with diabetes mellitus. *Diabet Technol Ther* **3**:347–56.

Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care* 2001;**24**:561–87.

Padgett D, Mumford E, Hynes M, Carter R. Meta-analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. *J Clin Epidemiol* 1988;**41**:1007–30.

Thomas N. Assessment: the crucial stage in diabetes education. *Adv Clin Nurs* 1999;**3**:67–74.

Whittemore R. Strategies to facilitate lifestyle change associated with diabetes mellitus. *J Nurs Scholarsh* 2000;**32**:225–32.

Appendix 11

Internal/external validity of economic evaluations

Internal validity of economic evaluations[a]

Item	Kaplan *et al.*, 1987[65]	Glasgow *et al.*, 1997[45]
1. Well-defined question	✓	✓
2. Clear description of alternatives	✓	✓
3. Reasonable study type	✓	? Cost-effectiveness results not related to health outcomes
4. Effectiveness established	Effectiveness data used from the study undertaken, with statistically significant differences in the outcomes measures used	Effectiveness data used from the study undertaken, with statistically significant differences in the outcomes measures used
5. Estimates related to population risks	?	?
6. Relevant costs and consequences identified	✓ Intervention costs	✓ Intervention costs
7. Costs and consequences measured accurately	✓ Costs for intervention based on resource use documented in the trial reported	✓ Costs for intervention based on resource use documented in the trial reported.
	✓ Consequences from trial data	✓ Consequences from trial data
8. Costs and consequences valued credibly		✓ × Costs valued credibly, consequences not
9. Differential timing considered	Analysis within trial period only (11–18 months)	1-Year analysis
10. Incremental analysis performed	✓	✓
11. Sensitivity analysis performed	✓	×
12. Modelling conducted reasonably	Modelling of health benefits only, from previous study	?

[a]? means unclear or unknown; ✓ means item included or judged as acceptable to be internally valid; × means factor not included or judged unacceptable to be internally valid.

External validity of economic evaluations[a]

Item	Kaplan *et al.*, 1987[65]	Glasgow *et al.*, 1997[45]
1. Patient group – are the patients in the study similar to those of interest in England and Wales?	? Efficacy obtained from patients with NIDDM, in USA. Self-selecting patient group	? Efficacy obtained from patients having Type 1 or 2 diabetes, at least 40 years old, being primarily responsible for one's own diabetes dietary self-management
2. Health care system/setting – comparability of available alternatives?; similar levels of resources?; no untoward supply constraints?; institutional arrangements comparable?	× US health care provider setting	× US primary care providers forming part of a large medical group. Analysis from the perspective of the health care organisation
3. Treatment – comparability with clinical management?	? Treatment in US hospital setting	? Treatment US centres.
4. Resource costs – comparability between study and setting/population of interest?	× US cost data	? US cost data
5. Marginal versus average costs – what difference does this make?	×	?

[a]? means unclear or unknown; ✓ means judged item suitable to generalise to England and Wales with or without some re-adjustment; × means factor judged not suitable as either not possible to see how an adjustment could be made easily in short/medium term or relevant data unavailable.

Appendix 12

Data extraction of economic evaluations

Reference and design	Intervention	Subjects	Outcome measures
Surname and year: Glasgow *et al.*, 1997[45] Source: published – patient education and counseling Country: USA Setting: in the office of 2 internists who are primary care providers and part of a large medical group Language: English Trial design: RCT Economic evaluation/type: cost-effectiveness analysis	**Treatment intervention:** **Providers:** researcher seen after physician visit **Topics:** patient-centred goal setting and problem solving and dietary self-help materials **Sessions:** 20 minutes initially, then telephone follow-up at 1 and 3 weeks and 3 and 6 months to review progress, adjust strategies and mail maintenance information. At 9 months received a copy of a book 'On the human side of diabetes'. Intervention delivered by research staff **Control intervention:** Usual care = quarterly medical care (regular assessment and follow-up, plus the initial touch-screen computer assessment) telephone contact; 3 weeks, 6 months, given book at 9 months. **Duration of intervention:** 9 months See data extraction form in Appendix 9 for further detail	Eligibility criteria: having Type 1 or 2 diabetes, at least 40 years old, being primarily responsible for one's own diabetes dietary self-management How selected: those scheduled for visit received a letter encouraging participation. Randomised from the physician practice Numbers involved: total *N* = 206, intervention *N* = 108, control *N* = 98 Nos on insulin: intervention 68%, control 66% Type of diabetes: 2, intervention 76%, control 81% Duration of diabetes (years): intervention 13.0 (9.9), control 13.7 (12.2) Compliance: assume 100% See data extraction form in Appendix 9 for further detail.	Primary outcomes used: HbA_{1c} Secondary outcomes used: patient satisfaction, BMI, dietary self-management questionnaire, serum cholesterol Individual preferred learning style addressed: no How outcomes assessed: Patient Satisfaction instrument contained 7 items assessing the office visit. FHQ measuring four dimensions of fat-related dietary habits. Length of follow-up: 12 months from inception See data extraction form in Appendix 9 for further detail

Methods – economic evaluation (see Appendix 9 for clinical data extraction)
Base year prices: not stated
Perspective: healthcare organisation
Costs: included costs for intervention package (computer hardware, software), materials including handouts, pamphlets, supplies, labour costs for health educators, nurses, physicians and support staff, postage and telephone charges. Capital costs depreciated over year one. Did not include facility space and labour costs for training (of educators) (these were considered in sensitivity analyses)
Outcomes: from the study undertaken and reported (see above and Appendix 9 for clinical detail)
Discounting: no discounting undertaken (costs occurred within 1 year)

Results – economic evaluation (see Appendix 9 for clinical data extraction)
Base case: costs for the delivery of the Brief Intervention were reported at US$137 per participant. Costs were combined with outcomes data on fat consumption, saturated fat consumption and serum cholesterol (there were no significant effects on HbA_{1c}). The marginal cost per unit improvement in these outcomes were:

$62 per reduction of each per cent in dietary fat

$105 per percentage reduction in saturated fat
$8 per mg/dl reduction in serum cholesterol

Cost-effectiveness estimates were also presented for three different-sized potential patient groups, to reflect economies of scale (these were similar to the study estimates above)

Sensitivity analysis: not formally presented for the economic evaluation; however, authors do state that where costs were set to include cost of facility space and training, whilst reducing equipment costs by depreciating equipment costs over 3 years, increases the research model costs by 11% (and a dissemination model cost by 1%)

Methodological comments – economic evaluation (see Appendix 9 for clinical data extraction)
Outcomes used in cost-effectiveness analysis are intermediate outcomes and are not related by the authors to health outcomes (e.g. events or complications of disease)

Sensitivity analysis is not reported formally for the economic evaluation.

Caveat: research staff delivered the intervention package

General comments
Conflict of interests: project supported by the National Institute of Diabetes, Digestive and Kidney Diseases (USA)

Reference and design	Intervention	Subjects	Outcome measures
Surname and year: Kaplan *et al.*, 1987[35,65] Source: published – health promotion Country: USA Setting: unclear Language: English Trial design: RCT Economic evaluation/type: cost utility analysis, alongside an RCT	Patients randomly assigned to one of four experimental conditions: diet, exercise, diet plus exercise or education control See data extraction form in Appendix 8 for detail	Eligibility/exclusion criteria: confirmed diagnosis, fasting plasma glucose >3.62 mmol/litre. Numbers involved: Total *N* = 87, unsure of group numbers Nos on insulin: 19 Tablets: 29 Diet alone: 28 Type of diabetes: 2 Duration of diabetes: not recorded Gender (M/F): 32/44 Compliance: average attendance >80% for all groups See data extraction form in Appendix 8 for further detail	Primary outcomes used: HbA_{1c}, QoL Secondary outcomes used: weight in kg Individual preferred learning style addressed?: How outcomes assessed?: HbA_{1c}, laboratory; QoL, self-report questionnaire, the QWB Length of follow-up: 18 months from inception

Methods – economic evaluation (see Appendix 8 for clinical data extraction)
Base year prices: 1986 clinical charges
Perspective: not stated (assume that of the healthcare provider)
Costs: costs estimated using 1986 clinical charges in San Diego County, USA. Costs comprised: history and physical examination, laboratory charges, charges for behaviour modification sessions and charges for medical consultations. No side-effects noted, so costing of these not undertaken
Outcomes: QWB scores at initial interview and 3, 6, 12 and 18 months (QWB score reflects a mean value over 4 days prior to assessment). QWB scores used to reflect outcomes in terms of well-years. Study uses QWB weights derived from community surveys to reflect social preference or utility (0 = dead to 1 = optimum function). Analysis does not cover any issues related to long-term complications
Discounting: no discounting reported

Results – economic evaluation (see Appendix 8, for clinical data extraction)

Base case: total costs for the programme are estimated at ~US$1000. Benefit stated as 0.092 well-years (see note below). Cost–utility estimate presented as $10,870 per well-year.

Sensitivity analysis: sensitivity analysis undertaken on effectiveness parameter, assuming 50% of benefit observed, providing an estimate of $21,740 per well-year; sensitivity analysis undertaken on effectiveness, assuming benefits last for an additional year, providing an estimate of $5435 per well-year.

Methodological comments – economic evaluation (see Appendix 8 for clinical data extraction)

Based on observations from the reported experimental study.
Calculation of benefits using the QWB is an indirect derivation of benefit, based on data reported and modelled in a previous study. An appendix is presented at the end of the paper to detail the generic methodological approach taken to derive 'well-life' scores via the QWB – no study-specific scores are discussed in the appendix
Analysis does not cover any issues related to long-term complications
Patient numbers across groups will be small, and patients in the trial were self-selecting
Unsure of the numbers in each of the intervention and control groups

General comments
Conflict of interests: funding support for one of the authors from National Institutes of Health, USA

Appendix 13

Critical appraisal of health economic modelling studies in area of diabetes

Title Authors Year	Model of complications of NIDDM. I Model construction and assumptions Eastman *et al.*[75] 1997	Estimated benefits of glycaemic control in microvascular complications in Type 2 diabetes Vijan *et al.*[114] 1997	Lifetime benefits and costs of intensive therapy as practised in the diabetes control and complications trial DCCT[72] 1996	The cost-effectiveness of different management strategies for type I diabetes: a swiss perspective Palmer *et al.*[73] 2000
Modelling assessments should include:				
1 A statement of the problem	Analysis of prevention strategies for Type 2 diabetes using modelling	To evaluate the efficacy of glycaemic control in Type 2 diabetes patients	To examine cost-effectiveness of alternative approaches to the management of Type 1 diabetes	The overall objective of this study was to determine the health outcomes and economic consequences of different combinations of diabetes interventions in newly diagnosed patients with Type 1 diabetes in Switzerland
2 A discussion of the need for modelling vs alternative methodologies	Implied by the lack of empirical economic evidence though not stated directly	Implied by the lack of empirical economic evidence though not stated directly	Implied by the lack of empirical economic evidence, although not stated directly	Implied by the lack of empirical economic evidence, although not stated directly
3 A description of the relevant factors and outcomes	Factors included: disease incidence and progression, hazard rates (dependent on age and clinical factors), ethnicity adjustments, mortality sub-model, CVD sub-model. Costs of screening, treatment and disability also included. This model covers end-stage disease progression. QALYs suggested	Factors included: model covers early-stage complication only. Lifetime risk, absolute reduction in risk for blindness covered, no costs included	Factors included: mortality incorporated within disease states. Costs of therapy (all direct medical included) stated but not included. Also includes average years free from complications, cumulative incidence, QALYs suggested. Model covers end-stage disease progression	Factors included: cumulative incidence, mortality incorporated into complication sub-models, end-stage disease progression (dependent on demographic and clinical factors). Costs of event + 12-month follow-up. Life expectancy and cost per life-year gained also included as outcome.

continued

Title	Model of complications of NIDDM. I Model construction and assumptions	Estimated benefits of glycaemic control in microvascular complications in Type 2 diabetes	Lifetime benefits and costs of intensive therapy as practised in the diabetes control and complications trial	The cost-effectiveness of different management strategies for type I diabetes: a swiss perspective
Authors	**Eastman *et al.*[75]**	**Vijan *et al.*[114]**	**DCCT[72]**	**Palmer *et al.*[73]**
Year	**1997**	**1997**	**1996**	**2000**
Modelling assessments should include:				
4 A description of the model including reasons for this type of model and a specification of the scope including; time frame, perspective, comparators and setting. Note: *n* = number of health states within sub-model	3 complications + CVD: retinopathy (*n* = 5), neuropathy (*n* = 3), nephropathy (*n* = 4), CVD (*n* = 2). State transition model used to simulate the progression of Type 2 diabetes patients aged 25–74. Comparators used: conventional vs intensive glycaemic control. Perspective: based on published data and Medicare reimbursement rates (1994 US$). Costed from viewpoint of single payer responsible for all direct medical costs. Costs and QALYs discounted at 5 and 7% per year	2 complications showing early-stage disease only: nephropathy (*n* = 5), retinopathy (*n* = 5). State transition model used to simulate the progression of Type 2 diabetes patients aged 45–75 (assumed). Hypothetical drug used. No costs	3 complications modelled. Retinopathy(*n* = 5), Neuropathy (*n* = 3), Nephropathy (*n* = 4). State transition model used to simulate the progression of type I diabetes patients aged 13–39. Perspective: Healthcare perspective used for cost-effectiveness (all direct medical costs). 1994 US$. Both costs and effects discounted at 3% per year.	7 complications modelled: neuropathy (*n* = 5), nephropathy (*n* = 10), retinopathy(*n* = 5), AMI(*n* = 8), stroke (*n* = 5), hypoglycaemia (*n* = 3), Ketoacidosis (n=3). State transition model used to simulate the progression of male Type 1 diabetes patients aged 19 years (Swiss median age at onset). Comparators used: conventional insulin therapy, screening, intensive insulin therapy and ACE inhibitors used in combination. Perspective: Swiss health insurance payer. 1996 Swiss CHF. Costs discounted at 3, 5 and 6% per year
5 A description of data sources (including subjective estimates), with a description of the strengths and weaknesses of each source, with reference to a specific classification or hierarchy of evidence	Progression rates and cohort: DCCT, WESDR, REP. All hazard rates are provided	Progression and cohort: DCCT, WESDR, REP	Progression rates and cohort: DCCT, WESDR	Progression rates and cohort: DCCT, published sources
	Costs: published data and/or prevailing Medicare reimbursement rates	Costs: N/A	Costs: resources based on DCCT trial, Medicare reimbursement	
	Other: VA cooperative study, Metformin Cooperative Trial	Other: mortality retrieved from US Department of Vital Statistics		

continued

Title Authors Year	Model of complications of NIDDM. I Model construction and assumptions Eastman *et al.*[75] 1997	Estimated benefits of glycaemic control in microvascular complications in Type 2 diabetes Vijan *et al.*[114] 1997	Lifetime benefits and costs of intensive therapy as practised in the diabetes control and complications trial DCCT[72] 1996	The cost-effectiveness of different management strategies for type I diabetes: a swiss perspective Palmer *et al.*[73] 2000
Modelling assessments should include:				
6 A list of assumptions pertaining to the structure of the model (e.g. factors included, relationships, and distributions) and the data	All major assumptions systematically reviewed	All major assumptions addressed but not in a systematic manner	All major assumptions addressed but not in a systematic manner	All major assumptions addressed but not in a systematic manner
7 A list of parameter values that will be used for a base case analysis, and a list of the ranges in those values that represent appropriate confidence limits and that will be used in a sensitivity analysis	Disease progression rates derived from DCCT and published sources. Certain prevalence rates consistent with WESDR	Rates of early disease based on DCCT findings. Cohort data used for rates of subsequent progression to later disease. Incidence – DCCT, Microalbuminuria Collaborative Study and REP	Base-case rates of progression retrieved from DCCT and published sources. Formulae shown within literature	Base-case rates of progression retrieved from DCCT and published sources. Non-exhaustive list provided within the text
8 The results derived from applying the model for the base case	Results derived from applying the model to the base case are systematically reported	Results derived from applying the model to the base case are systematically reported	Results derived from applying the model to the base case are systematically reported	Results derived from applying the model to the base case are systematically reported
9 The results of the sensitivity analyses. Unidimensional; best/worst case; multidimensional (Monte Carlo/parametric); threshold	Not described within the literature	3-way sensitivity analysis considering the impact of improved glycaemic control on lifetime risk for blindness. Main conclusions hold true	Sensitivity analysis conducted to examine the sensitivity of results to changes in incidence and progression of complications. Decreasing the incidence of microalbuminuria by 50% in the conventional group increased the incremental cost per life-year gained to $79,883	1-way sensitivity analysis on all cost and probability parameters was performed, varying one parameter at a time by ±10%. 1-way sensitivity analysis showed the annual cost of intensive therapy had the greatest impact on the total lifetime costs. Reduced risk of AMI and incidence and progression of MAU with intensive therapy had the greatest impact on life expectancy

continued

Title	Model of complications of NIDDM. I Model construction and assumptions	Estimated benefits of glycaemic control in microvascular complications in Type 2 diabetes	Lifetime benefits and costs of intensive therapy as practised in the diabetes control and complications trial	The cost-effectiveness of different management strategies for type I diabetes: a swiss perspective
Authors	**Eastman *et al.*[75]**	**Vijan *et al.*[114]**	**DCCT[72]**	**Palmer *et al.*[73]**
Year	**1997**	**1997**	**1996**	**2000**
Modelling assessments should include:				
10 A discussion of how the modelling assumptions might affect the results, indicating both the direction of the bias and the approximate magnitude of the effect	Where applicable, all assumptions are systematically reported and analysed	Where applicable, all assumptions are systematically reported and analysed	Where applicable, all assumptions are systematically reported and analysed	Where applicable, all assumptions are systematically reported and analysed
11 A description of the validation undertaken, including concurrence of experts, internal consistency, external consistency, predictive validity	Validity could be strengthened by data on progression rates and costs from clinical trials but these were not available – results are an approximation only. Therefore reported results are conservative	Sensitivity analysis resulted in a range of outcomes that do not substantially affect the main conclusions	Results of the analysis extend the findings of the DCCT trial	Not described within the literature.
12 A description of the settings to which the results of the analysis can be applied and a list of factors that could limit the applicability of the results	Settings described within the systematic review	Settings described within the systematic review	Settings described within the systematic review	Settings described within the systematic review
13 A description of research in progress that could yield new data that could alter the results of the analysis	Data on progression rates and costs and resource usage from actual clinical trials could strengthen any study	Data on progression rates and costs and resource usage from actual clinical trials could strengthen any study	Data on progression rates and costs and resource usage from actual clinical trials could strengthen any study	Data on progression rates and costs and resource usage from actual clinical trials could strengthen any study

Reproduced from Chilcott J, Wight J, Lloyd Jones M, Tappenden P. The clinical effectiveness and cost-effectiveness of pioglitazone for Type 2 diabetes mellitus: a rapid and systematic review. *Health Technol Assess* 2002;**5**(19).

Appendix 14

Summary of educational interventions and comparators, with outline estimates on UK staffing costs

Study	Educational intervention/ control group	Resource implications	Estimated additional resource input for education and outline cost estimate covering UK staffing costs (2001–2)[a]
Type 1 studies included in the review of clinical effectiveness			
Stockholm Diabetes Intervention Study (SDIS): Reichard *et al.*, (multiple publications) 1988–96[21] (SDIS) RCT Patients: adult – Type 1	Two groups: 1. Usual care: instructed to use SMBG and visited clinic every 4th month, many had frequent contact over study period 2. Self-management ed. with intensified treatment. Physician provided 2 sessions of education to individuals or pairs of 2–3 h. Regular contact over study period via telephone	*Usual care:* patients continued with routine diabetes care *Intervention:* physician tutoring was through 2 initial education sessions and frequent face-to-face telephone contact, initially every 2 weeks then at greater intervals. Physician available to patients 'on demand' using a pager system	No cost estimates reported by authors. **Southampton estimate** *Staffing Resource Inputs:* Minimum 5 h physician time per patient (assuming individual education). Estimate an additional 2 h physician time per patient per year *Estimated minimum costs per patient:* Minimum staff costs (year 1) £506 Minimum staff costs (year 2 onwards) £145 Education materials per patient Not known Additional costs for training of educators Not known Additional capital/set-up costs and on-going quality assurance costs Not known
Terent *et al.*, 1985[22] RCT Patients: adult – Type 1	Four groups: 1. Usual care 2. Self management ed. + SMBG 3. Self management ed. 4. SMBG Groups 2–3 provided by physician and dietitian for six hourly lessons during 1 month. SMBG groups had additional session. Then seen every 3rd month. Group 4 seen in clinic every 3rd month	*Usual care:* pre-trial checking habits *Interventions (groups 2–4):* in addition to standard therapy, education was delivered by a physician and dietitian in six 1-h individual sessions. Patients in SMBG groups (2 and 4) attended an additional session by physician for training in SMBG. Patients received photocopies of materials used	No cost estimates reported by authors **Southampton estimate** *Staffing resource inputs:* Minimum 6 h physician time and 6 h of dietitian time, per patient *Estimated minimum costs per patient:* Minimum staff costs (year 1) £567 Education materials per patient Not known Additional costs for training of educators Not known Additional capital/set-up costs and on-going quality assurance costs Not known

continued

Study	Educational intervention/ control group	Resource implications	Estimated additional resource input for education and outline cost estimate covering UK staffing costs (2001/02)[a]
Mühlhauser *et al.*, 1987[23] (Geneva–Düsseldorf model) CCT Patients: adult – Type 1	Three groups: 3. Usual care. Under care of physician 1. IDTTP: self-management with intensified treatment. Group education over 5 days, run by diabetes nurses 2. BDTTP: self-management with simple rules for insulin adjustment but 'conventional treatment'. Group education over 4 days, run by diabetes nurses	*Usual care:* comprised that of the Bucharest Hospital. Individual instruction by physician regarding management of disease. Insulin prescribed by the outpatient unit *Interventions:* IDTTP – delivered by 2 teaching nurses in a structured 5-day inpatient education course. Groups consisted of ~10 patients. IDTTP patients were followed up exclusively by the training team of 2 physicians and nurses. IDTTP – may also result in the intensification of insulin therapy BDTTP – delivered by two teaching nurses over 4 days. Follow-up in general diabetic outpatient unit. Patients could contact the two physician and two nurse treatment and teaching team	No cost estimates reported by authors Note: methods a little outdated given today's standard methods for self-management in diabetes **Southampton estimate** *Staffing resource inputs:* IDDTP and BDTTP required 2 teaching nurses for minimum of 5 days, covering ~10 patients *Estimated minimum costs per patient:* IDTTP – Minimum staff costs (year 1) £163 BDTTP – Minimum staff costs (year 1) £130 Education materials per patient (estimate, based on DAFNE data) £ 94 Additional costs for training of educators Not known Additional capital/set-up costs and on-going quality assurance costs Not known Note: the standard treatment in the UK would not include a 4- or 5-day inpatient stay to initiate insulin therapy, therefore that cost would be incurred where education (IDDTP or BDDTP) was delivered on an inpatient basis

continued

Study	Educational intervention/ control group	Resource implications	Estimated additional resource input for education and outline cost estimate covering UK staffing costs (2001/02)[a]
Starostina *et al.*, 1994[24] (Geneva–Düsseldorf model) CCT Patients: adult – Type 1	Three groups: 1. Usual care 2. Self-management with intensified treatment + SMBG 3. Self-management with intensified treatment + urine testing Groups 2 and 3, 5-day group education provided by 2 physicians	*Usual care:* the study reports that diabetic patients in Russia and other former USSR countries are treated by endocrinologists in district policlinics and as inpatients in special endocrinology departments. The structural differences between the UK should be noted *Interventions (groups 2–3):* consisted of a 5-day inpatient based education programme. Intervention groups were inpatient admissions, admitted for treatment of diabetes. The DTTP methods were identical with those described in Mühlhauser *et al.*, 1987 (as above), except that teaching was delivered by 2 physicians	Cost data reported by authors in Russian roubles[b] **Southampton estimate** *Staffing resource inputs:* The DTTP required 2 physicians for a minimum of 5 days, covering ~10 patients *Estimated minimum costs per patient:* Minimum staff costs (year 1) £578 Education materials per patient (estimate based on DAFNE data) £94 Additional costs for training of educators Not known Additional capital/set-up costs and on-going quality assurance costs Not known Note: the standard treatment in the UK would not include a 5-day inpatient stay to initiate insulin therapy, therefore that cost would be incurred where education (IDDTP or BDDTP) was delivered on an inpatient basis

continued

Study	Educational intervention/ control group	Resource implications	Estimated additional resource input for education and outline cost estimate covering UK staffing costs (2001/02)[a]
Other selected studies discussed in the review			
DAFNE Study Group, 2002 Submission to NICE[115] Patients: adult – Type 1	Two groups: 1. Usual care. 2. DAFNE Education Group	*Usual care:* the cost-effectiveness analysis presented by the DAFNE Study Group assumes that standard care reflects the current standard practice of two or three pre-specified insulin dose injections per day *Intervention:* 5-day DTTP delivered by a DSN and dietitian, on an outpatient basis. Patients are also greeted by a physician and a physician participates in some of the group sessions. In practice, the DTTP involves all patients being on a regime of multiple daily injections (i.e. those on twice-daily insulin injections are switched to multiple injections)	Cost data reported by DAFNE Study Group. Fully inclusive cost estimate provided, based on all costs averaged over 120 patients attending education programmes per centre per year: estimated cost per patient £545 **Southampton estimate** *Staffing resource inputs:* The DTTP requires 1 DSN and 1 dietitian for a minimum of 5 days, covering ~8 patients. We also assume 2 h of physician time per programme. *Estimated minimum costs per patient:* Minimum staff costs (year 1) £223 Education materials per patient (estimate based on DAFNE data) £ 94 Additional costs for training of educators Not known Additional capital/set-up costs and on going quality assurance costs Not known

[a] Assuming physician time at £72.29 per hour, nurse time at £21.75 per hour and dietitian time at £22.23 per hour (see the table below for detailed assumptions).
[b] See the section 'Results of the systematic search economic evaluations of patient education models for diabetes' (p. 53).

Calculations of NHS staff costs

Costs/staff	Consultant physician (assume Discretionary Point 3 on salary scale)	DNS (assume G Grade nurse; top of salary scale, point 5)	Dietitian (assume Senior Dietitian, Grade 1; top of salary scale, point 6)
Annual salary (£)	76700	26056	25145
Employer's National Insurance Contribution (£)	8119	1994	1910
Employer's pension contribution (£)	5262	1730	1675
Overheads[a] (£)	24320	2216	2216
Capital overheads[a] (£)	4161	2263	3606
Total annual costs (£)	118562	34259	34552
Working time	41 weeks × 40 h	42 weeks × 37.5 h	42 weeks × 37 h
Cost per hour (£)	72.29	21.75	22.23
Cost per day (£)	578.35	163.14	164.53

Source: salary scales from Southampton General Hospital Trust (2001–2).
[a] Overhead estimates based on data from PSSRU.[116]

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The HTA Programme and the authors would like to know your views about this report.

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We look forward to hearing from you.

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