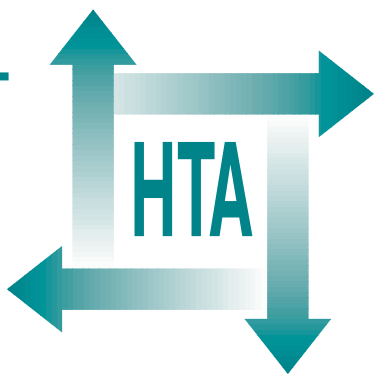
Health Technology Assessment 2001; Vol. 5: No. 10

Review

Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review

SE Hampson
TC Skinner
J Hart
L Storey
H Gage
D Foxcroft
A Kimber
K Shaw
J Walker

Health Technology Assessment
NHS R&D HTA Programme



How to obtain copies of this and other HTA Programme reports.
An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (http://www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public **and** private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

– fax (with **credit card** or **official purchase order**)
– post (with **credit card** or **official purchase order** or **cheque**)
– phone during office hours (**credit card** only).

Additionally the HTA website allows you **either** to pay securely by credit card **or** to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch
c/o Direct Mail Works Ltd
4 Oakwood Business Centre
Downley, HAVANT PO9 2NP, UK

Email: orders@hta.ac.uk
Tel: 02392 492 000
Fax: 02392 478 555
Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can only be purchased for the current or forthcoming volume.

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in **pounds sterling**, made payable to *Direct Mail Works Ltd* and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of *HTA on CD*?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. *HTA on CD* is currently free of charge worldwide.

The website also provides information about the HTA Programme and lists the membership of the various committees.

Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review

SE Hampson[1*]
TC Skinner[2]
J Hart[3]
L Storey[1]
H Gage[4]
D Foxcroft[5]
A Kimber[6]
K Shaw[7]
J Walker[8]

[1] Department of Psychology, University of Surrey, UK
[2] Department of Psychology, University of Bath, UK
[3] School of Psychology, University of St Andrews, UK
[4] Department of Economics, University of Surrey, UK
[5] School of Health Care, Oxford Brookes University, UK
[6] Department of Mathematics and Statistics, University of Surrey, UK
[7] Department of Medicine, Queen Alexandra Hospital, UK
[8] Paediatric Department, St Mary's Hospital, UK

[*] Corresponding author

Competing interests: none declared

Published April 2001

This report should be referenced as follows:

Hampson SE, Skinner TC, Hart J, Storey L, Gage H, Foxcroft D, *et al*. Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review. *Health Technol Assess* 2001;**5**(10).

Health Technology Assessment is indexed in *Index Medicus*/MEDLINE and *Excerpta Medica*/EMBASE. Copies of the Executive Summaries are available from the NCCHTA website (see opposite).

NHS R&D HTA Programme

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

The research reported in this monograph was funded as project number 96/45/02.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for any recommendations made by the authors.

Criteria for inclusion in the HTA monograph series
Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The editors and publisher have tried to ensure the accuracy of this report but do not accept liability for damages or losses arising from material published in this report. They would like to thank the referees for their constructive comments on the draft document.

ISSN 1366-5278

Published by Core Research, Alton, on behalf of the NCCHTA.
Printed on acid-free paper in the UK by The Basingstoke Press, Basingstoke.

G

Contents

List of abbreviations

AI	anchored instruction
CG	control group
CI	confidence interval
CRD	Centre for Reviews and Dissemination
CST	coping skills training
DCCT	Diabetes Control and Complications Trial
df	degrees of freedom
DKA	diabetic ketoacidosis
GHb	glycated haemoglobin
GP	general practitioner
HbA_1	the normal form of haemoglobin
HbA_{1c}	haemoglobin that is attached to glucose
HDL	high-density lipoprotein
IDDM	insulin-dependent diabetes mellitus
IG	intervention group
LDL	low-density lipoprotein
MODY	maturity-onset diabetes of the young
NS	not significant
RCT	randomised controlled trial
SD	standard deviation
SMBG	self-monitoring of blood glucose

Executive summary

Background

Insulin-dependent diabetes mellitus, also known as type 1 diabetes, is a life-threatening condition and is the third most common chronic illness among young people. As a result of minimal or non-existent insulin production, people with diabetes must take over the normally automatic task of regulation of blood glucose levels. This is achieved by a complex regimen involving multiple, daily administrations of insulin coordinated with dietary intake and energy expenditure and monitored by blood glucose testing.

Objectives

To examine the effectiveness of educational and psychosocial interventions for adolescents with type 1 diabetes designed to improve their diabetes management. Specifically, it addressed the following research questions:

1. Do educational and psychosocial interventions for adolescents with type 1 diabetes have beneficial effects on biological and psychosocial outcomes?
2. Are there types or features of interventions that have been shown to be more effective than others?
3. What evidence is there of the cost-effectiveness of interventions?

Methods

A search strategy was formulated, piloted and refined. Three journals were handsearched, 11 electronic databases were searched and personal contacts, flyers, conferences and web-sites were used to notify the research community of the review to access further literature. This process generated 10,535 abstracts, which, after screening, resulted in 367 articles identified for retrieval. This number was augmented by hand-searching, personal contact and exploding references, and a final total of 457 articles were scrutinised. Of these, 64 reports describing 62 studies were identified as empirical papers evaluating educational or psychosocial interventions. The relevant data were extracted from the papers and summary tables for each study were prepared. Where possible, effect sizes were computed for outcomes from studies that included a randomised control group (CG) and other relevant information.

Results

A descriptive analysis of the 62 studies was undertaken. Most studies (67.7%) were conducted in the USA and 41% were randomised controlled trials (RCTs), none of which were UK-based. Only 48% of the reports provided an explicit theoretical rationale for the intervention. The mean number of participants was 53.8. The studies took place in various settings, evaluated a variety of interventions, involved various interventionists, addressed various components and assessed the effects by a range of outcomes, including measures of metabolic control and psychological and behavioural outcomes. Follow-up assessments were relatively rare.

The effectiveness of interventions

The 25 RCTs were examined in more detail and three of the most effective were described in depth. Effect sizes could be calculated for 14 studies. The mean (pooled) effect size for psychosocial outcomes was 0.37 and 0.33 for glycated haemoglobin with outliers (0.08 without outliers), indicating that these interventions have small to medium beneficial effects on diabetes management outcomes.

A narrative review of the 21 pre–post studies with no CG was performed, including evaluations of interventions conducted at summer camps, interventions for poorly controlled patients and educational interventions. All studies reported beneficial effects.

Cost-effectiveness

Few studies addressed economic considerations associated with interventions, and the lack of information on costs and the diversity of out-comes included by investigators impeded cost-effectiveness comparisons. Shorter hospitalisation at diagnosis is at least as effective in achieving

control and avoiding complications in adolescence as longer stays. Home care may result in improved outcomes but may not be cheaper than hospital care at diagnosis. Targeting poorly controlled subjects may reduce adverse events and hospitalisations and may be more cost-effective than generic interventions. There is a need for rigorous cost-effectiveness studies of educational and psychosocial interventions for adolescents with type 1 diabetes that include longer-term considerations.

Conclusions

The following conclusions were drawn from this review:

1. Educational and psychosocial interventions have small to medium beneficial effects on various diabetes management outcomes.
2. Well-designed trials of such interventions are needed in the UK (no completed RCTs of educational or psychosocial interventions for adolescents with type 1 diabetes conducted in the UK were found).
3. The evidence, arising primarily from studies in the USA, provides a starting point for the design of interventions in the UK.
4. Quantitative and narrative analysis of the evidence suggested that interventions are more likely to be effective if they demonstrate the inter-relatedness of the various aspects of diabetes management. The effectiveness of interventions should be evaluated by assessing outcomes that the intervention explicitly targets for change, and at the appropriate point in time post-intervention to reflect the impact of the intervention.
5. Interventions need to be evaluated by well-designed studies, such as RCTs, including adequately powered patient-preference trials reporting results in such a way as to enable effect sizes to be calculated.
6. An important gap in the evidence is that there is no systematic understanding of whether interventions should be targeted (e.g. modified for different disease stages, different types of diabetes management problems or the different age groups subsumed by adolescence).
7. To reap economic returns, interventions need to show durable favourable effects on behaviour and metabolic control, but there is a lack of cost-effectiveness studies that fully address the resource implications of educational interventions for adolescents and long-term consequences.

Recommendations for further research

Research to date has proceeded piecemeal instead of cumulatively. Given the absence of high quality UK-based studies, a programme of primary research on adolescent interventions should be developed. This review recommends that a phase of programme development be undertaken involving a consultation process with adolescents with type 1 diabetes, their families, doctors, nurses, health economists and health psychologists. This consultation exercise would enable the establishment of possible interventions that are seen as plausible and potentially effective by patients and their parents, feasible and practical in the context of the NHS diabetes services and understood and accepted by doctors and nurses as key and integral parts of diabetes care. The interventions would also need to have the potential to be cost-effective and be based on sound behavioural principles. Such interventions, if subsequently demonstrated by commissioned research to be effective, would be much more likely to be implemented than ones developed without such a process.

Chapter 1
Background

Research questions

This systematic review examined the effectiveness of educational and psychosocial interventions for adolescents with type 1 diabetes. Specifically, it addressed the following questions:

1. Do educational and psychosocial interventions for adolescents with type 1 diabetes have beneficial effects on biological and psychosocial outcomes?
2. Are there types or features of interventions that have been shown to be more effective than others?
3. What evidence is there of the cost-effectiveness of interventions?

These research questions were examined in the following way:

1. Systematic procedures were adopted to locate the literature
2. The relevant data were extracted from the reports
3. The findings were evaluated using both narrative and quantitative approaches, and effect sizes were calculated where possible and appropriate
4. The results were evaluated from a health–economics perspective.

What is diabetes?

Diabetes mellitus is a relatively common chronic disease for which there is, as yet, no known cure. As a diagnostic category, diabetes includes a number of distinct disorders that all share the common symptom of raised blood glucose levels. The two main forms are insulin-dependent diabetes mellitus (IDDM) or type 1 diabetes and non-insulin-dependent or type 2 diabetes. Although type 1 diabetes can be diagnosed in adulthood, it usually develops in childhood and adolescence, whereas type 2 diabetes is not usually diagnosed before the age of 40 years.

Type 1 diabetes is the result of destruction of the beta cells of the pancreatic islets of Langerhans by the autoimmune system. These cells are progressively destroyed, resulting in a loss of insulin production. Insulin is a hormone that enables glucose that is circulating in the blood to be utilised by muscle and adipose tissue, and is involved in the mobilisation of the glucose stored in the liver. Lack of insulin prevents glucose uptake, which results in high levels of blood glucose (hyperglycaemia). Symptoms of hyperglycaemia include excessive urination (polyuria), thirst (polydipsia), weight loss and a feeling of lassitude.

Insulin deficiency also leads to the excessive breakdown of fats and the production of ketones, which are excreted in urine. This breakdown of adipose tissue also results in weight loss. If hyperglycaemia continues, high ketone levels cause ketoacidosis, manifested by vomiting, dehydration, Kussmaul breathing (air hunger) and finally coma, which can be fatal.

Epidemiology

Type 1 diabetes is the third most common chronic condition in young people after asthma and cerebral palsy.[1] Muntoni and Muntoni[2] showed that there is a wide range in the incidence of diabetes internationally with the lowest rates in Peru at 0.41 per 100,000 per year and the highest at 35.3 per 100,000 per year in Finland, for children aged 0–15. In Great Britain, rates range from a low of 6 in southern England to 19.8 (per 100,000 per year) in Scotland, and other studies report a higher incidence in urban compared to rural populations, particularly where there is a low incidence generally.[3] There is evidence of a rising incidence of type 1 diabetes, particularly in the more developed countries where a doubling of incidence over the past 20 years has been described: in the UK, the incidence of diabetes has doubled in the last two decades from 7.0 to 13.5 per 100,000 per year.[4]

Acute complications of diabetes

There are two acute complications of diabetes: hypoglycaemia and ketoacidosis. The former is a major cause of anxiety and alarm to children, their parents and carers, while the latter may

be life-threatening and is difficult to treat. In hypoglycaemia, blood glucose levels drop to dangerously low levels. Individuals may experience sweating, shaking and palpitations. Left untreated, glucose levels may continue to fall, leading to neuroglycopaenia (confusion, lack of coordination, odd behaviour) with cognitive dysfunction, and, in severe hypoglycaemia, unconsciousness and death can result if blood sugars are not elevated. The true prevalence of hypoglycaemia is not known because minor episodes are not usually reported. Studies looking at the prevalence of severe hypoglycaemia in children and adolescents quote ranges of 4–86 episodes per 100 patient years.[5,6]

Diabetic ketoacidosis (DKA) remains a serious and life-threatening condition. Although most cases of DKA occur at diagnosis (25% of children with diabetes present with DKA, 40% of which are under 4 years of age), readmission rates due to DKA during childhood and adolescence are about 0.2 per 100 patient years.[7] Although there is no agreed definition of DKA, the term, in practice, refers to decompensated diabetes resulting in hyperglycaemia, acidosis and the presence of ketones in urine. Once ketoacidosis is identified, the patient requires hospital admission to correct fluid loss, institute insulin therapy and prevent complications, such as aspiration of gastric contents, hypokalaemia and cerebral oedema.

An isolated admission for DKA can usually be attributed to either a concurrent acute illness, or, in teenage males, to excessive alcohol consumption.[8] However, the single most common cause of ketoacidosis is now widely accepted to be intermittent or non-existent insulin administration.[9,10] Despite this, there is little accepted knowledge as to the reasoning behind young people's repeated and dangerous insulin manipulation behaviour.

Chronic complications of diabetes

Poor glycaemic control is of concern during adolescence because of its effects on height, weight and puberty. The excess morbidity and mortality in patients with diabetes result from the long-term microvascular, neuropathic and macrovascular complications of diabetes. These are of less immediate relevance to adolescents, but it is likely that better diabetes control from an early age will postpone or even prevent some of these complications.[11]

The microvascular complications primarily affect the eyes (retinopathy) and kidneys (nephropathy). Prevalence rates vary widely, but long-term follow-up studies show that retinopathy is virtually inevitable in conventionally managed type 1 diabetes. The prevalence of retinopathy has an almost linear relationship with diabetes duration, such that over the subsequent 20 years, prevalence reaches 90%.[12] Proliferative retinopathy is a post-pubertal event, causing blindness through vitreous haemorrhage, fibrosis and retinal detachment. This is rarely seen before 10 years of duration, but threatens visual impairment in up to 50% of type 1 diabetes sufferers after 20 years duration[13] and can lead to blindness, with prevalence estimates ranging from 1–8.5%.[14]

Diabetic nephropathy is an important cause of morbidity and mortality, with a cumulative incidence of 40–50% after 40 years of type 1 diabetes duration.[13] This condition can degenerate to renal failure, which is 17 times more common in patients with type 1 diabetes than in those without. In the UK, it is estimated that 600 young people with diabetes develop renal failure each year, and these account for 15% of all deaths in people with type 1 diabetes aged less than 50.[15]

Neuropathy (motor nerve conduction) has been shown to be abnormal soon after the onset of type 1 diabetes with prevalence rates of up to 72%.[13] The primary loss of function is sensory, affecting the most distal parts of the longest nerves. This can lead to a range of foot problems, in particular, neuropathic ulcers and Charcot's foot. The prevalence of clinically defined sensorimotor neuropathy is about 28–29% in the UK, and prevalence increases markedly with age, duration of diabetes and poor blood glucose control.[16]

Impaired function of autonomic nerves is also common in type 1 diabetes. As many as 40% of patients with type 1 diabetes have an abnormality in autonomic nerve function when tested. This autonomic neuropathy is a major component of erectile dysfunction, 85% of cases being attributed to vascular and neuropathic problems.[17] This is a relatively common problem, and has been estimated to occur in 5–6% of 20–24 year olds with type 1 diabetes, increasing to 52–53% by 55–59 years of age, with some studies finding a prevalence of as high as 75%.[18] This compares with prevalence rate estimates of 0.01–18% in the population without diabetes.

The predominant macrovascular complication of diabetes is that of atherosclerosis. This results in disorders in three main sites: legs, heart and head. Peripheral artery disease of the lower limb gives rise to a range of disorders that can result in the amputation of all or part of the limb.[19] Although uncommon, premature coronary heart disease may present as young as the mid-twenties, and is certainly detected increasingly during the third and fourth decades of life. Current estimates suggest that, independent of other risk factors, all types of diabetes pose a two- to three-fold increase in the risk of coronary heart disease, and, in pre-menopausal women, this risk may be increased by as much as four- to five-fold.[20] There would appear to be a hyperglycaemic threshold (7 mmol/l) for large vessel disease, with a linearly increasing risk with higher mean blood glucose levels. However, it is unclear to what extent blood glucose levels are a primary factor contributing to susceptibility, or whether it is a marker for other disturbed factors.[19]

The diffuse effect of diabetes in the circulation is also manifested in a greatly increased risk of cerebrovascular disease. Again, independent of other risk factors, all types of diabetes increase the risk of cerebrovascular accidents by two- to three-fold.[20] The most common early manifestation of cerebrovascular problems is that of transient ischaemic attack, with sudden development of weakness or sensory change and temporary disruption to vision. Diabetes may also lead to the more insidious development of dementia, due to progressive reduction in blood flow to the brain. Although there is some evidence that these disorders are associated with higher elevated blood glucose levels, the role of hyperglycaemia in their development remains to be clarified.[19]

The excess in morbidity and mortality due to type 1 diabetes is the topic of a systematic review at the University of Surrey, funded by Diabetes UK under the direction of Iaonnis Vlachonikolis.

The management of type 1 diabetes

Healthcare team

In childhood and adolescence, patients are managed by a diabetes care team and usually have outpatient appointments every 3 months, reducing to every 6 months in adult clinics. In addition to this outpatient service, nurse specialists and, to a lesser extent, dieticians are available for consultation throughout the week, with many centres also running a 24-hour emergency helpline. The diabetes team normally consists of a medical consultant, a diabetes nurse specialist and a dietician, with a few diabetes centres also employing a clinical psychologist, psychotherapist or counsellor. A few patients with type 1 diabetes are managed by primary care teams, but this remains a substantial minority at present.

The aim of diabetes management is to maintain blood glucose levels as near as possible to the normal range. Glycated haemoglobin (GHb) is now used as the gold standard for estimating average blood glucose control. This laboratory assay estimates the percentage of haemoglobin that has glucose bound to it, and, as such, is an estimate of blood glucose levels over about an 8–12-week period. Regular assessments are recommended and results are used to guide modifications to insulin prescriptions and other management advice.

Self-management

Diabetes is a chronic condition and therefore patients and their families are responsible for its day-to-day management. Due to their minimal or non-existent levels of insulin production, a person with diabetes must assume responsibility for the normally automatic regulation of blood glucose levels. This is achieved by a complicated, multi-component treatment regimen. Daily subcutaneous insulin administration is required, either by injection or continuous insulin pump. It is also necessary to coordinate dietary intake (including timing, quantity and content of meals and snacks) and energy expenditure to be compatible with circulating insulin levels. To guide self-regulation, capillary blood glucose tests should be undertaken, which involves pricking the finger to obtain a small amount of blood and testing the level of blood glucose with an automated metering device.

The aim of diabetes management by both the healthcare team and the patient is to prevent, postpone or reduce the severity of the acute and chronic complications of diabetes. The Diabetes Control and Complications Trial (DCCT)[11] has demonstrated that better blood glucose control is associated with improved microvascular outcomes. Irrespective of the patient's age, age of onset, baseline GHb values and gender, intensive management of diabetes resulted in improved blood glucose control. Only a small percentage of the sample were adolescents (< 10%) and they were reported to take up a disproportionate amount of staff time and effort. Intensive management consisted of multiple daily insulin injections,

multiple blood glucose tests by the patient and close monitoring and support from the healthcare team. The improvements in blood glucose control achieved by intensive management were linearly associated with delays in the onset and progression of retinopathy, nephropathy and neuropathy. However, intensive management by the healthcare team is time-consuming and costly and there is considerable interest in investigating whether similar beneficial effects on blood glucose control can be achieved by less intense approaches, including psychosocial and educational approaches to improve self-management.

Adolescence and diabetes

Adolescence is a period of rapid change and development. Physical changes are accompanied by continued cognitive development, enabling young people to think in increasingly abstract ways[21] and be less receptive to authority figures. As they compete for jobs or places in higher education, teenagers are establishing their identity and lifestyle, and are making choices that will shape their futures.[21–24]

As adolescents spend increasing amounts of time away from home, their leisure activities become less structured, with diminishing adult supervision and involvement.[25] Increased experimentation and risk-taking is commonplace during this transitional period.[26] With puberty comes the adjustment to a changing body and interest in sexual relationships, and adolescents are learning how to form and maintain friendships and close intimate and romantic relationships with their peers.[21,23,27] In summary, adolescence is a period of rapid and intense development, and the lifestyles adopted during this time may endure through adulthood.

Diabetes in adolescence

Adolescence is a particularly critical time for young people with diabetes. Whether diagnosed in childhood or adolescence, during this transitional period young people learn to take responsibility for and manage their own diabetes.[28–31] As they integrate self-management of diabetes into their emerging lifestyles, adolescents experience directly the relationship between their actions and their blood glucose levels, which influences their beliefs about diabetes and its treatment. Therefore, these will be formative years in the development of such beliefs. Once fully integrated and accepted, these beliefs will be difficult to change, and are important predictors of self-care and well-being.[32–36]

Adolescence is also frequently seen as the time to change and intensify insulin regimens, and additional pressure to test blood glucose and adjust insulin can mean that the disease may increasingly intrude on other aspects of the young person's life.

Metabolic control during adolescence

Research consistently demonstrates that there is a marked worsening of metabolic control during adolescence[37,38] associated with the onset and progression of complications in this age group.[11,39,40] Although this decline is partly attributable to the physiological changes occurring at this time, the decline in self-care behaviour is of at least equal importance.[29,37,41–43] This deterioration is particularly marked and of concern in the area of insulin administration: self-report data have suggested that missed insulin injections are common and the pharmacy record data from the DARTS database demonstrated that about 28% of adolescents and young adults do not even obtain sufficient insulin to fulfil their prescribed regimen.[9] This decline in self-care is also characterised by young people dropping out of the healthcare system and not attending diabetes services.[35,44,45] Although this decline in metabolic control seen during adolescence is temporary, with adults and children having better control on average, evidence is accumulating that even brief periods of elevated glucose levels are damaging and accelerate the onset of microvascular and macrovascular complications.

Therefore, it is clear that adolescents with type 1 diabetes are in the unique and unenviable position of facing the same developmental tasks and demands as other young people, in addition to learning to manage and live with their diabetes. This poses healthcare professionals with numerous challenges as they seek to improve adolescents' metabolic control without sacrificing quality of life.

Psychosocial and educational interventions

Psychosocial and educational interventions aim to improve adolescents' knowledge, skills and management of all aspects of their diabetes. Educational interventions primarily teach diabetes-related knowledge and skills such as testing blood glucose levels and injecting insulin correctly. Psychosocial interventions are diverse and provide training and support in such areas as social skills, diabetes-related problem-solving and coping skills, communication skills, and individual and family-

based counselling. It is widely recommended that such interventions should be an integral part of diabetes care.[1,46]

No previous review or meta-analysis has been devoted exclusively to evaluating the effects of psychosocial and educational interventions on adolescents. A recently completed survey, commissioned by the charity Diabetes UK, evaluating psychosocial and educational interventions for adults with diabetes concluded that these interventions are beneficial, but that this optimism must be tempered by the methodological weaknesses of many of the studies.[44] This survey included all published meta-analyses on this topic,[47–53] which, together, suggested that effect sizes are larger for self-report psychosocial outcomes than for more objective ones, such as metabolic control. In addition, there may be systematic effects of the setting and approach of the intervention. The effects of the intervention may be more short-lived for outcomes such as weight loss and metabolic control, whereas effects on knowledge and skills may increase over time. Older patients may show smaller changes than younger ones. One meta-analysis of correlation studies of both adults and adolescents suggested that the associations between knowledge, skills and individuals' social environments and their diabetes self-care and metabolic control may be even stronger in adolescents than in adults.[54]

Based on a consideration of the past research and the unique factors affecting adolescents, we initially posed a number of questions to examine in the current systematic review.

Education and care at diagnosis

Increasing numbers of adolescents are diagnosed before reaching a state of DKA. For these individuals, clinical practice, both internationally and nationally, shows wide variation in the delivery of care and education. Some paediatric services require the newly diagnosed adolescent to be admitted into hospital for at least 1–2 nights with education provided in the hospital, whereas others endeavour to keep adolescents out of hospital by providing as much care and education as possible in the community. Even when the two differing approaches teach the same knowledge and skills, the difference in setting (which has significant resource implications) may affect outcomes.

Individual and group education

Whether diagnosed in adolescence and needing educating from scratch or diagnosed in childhood and needing re-educating and/or updating, providing the young person with the knowledge and skills for self-management remains a primary goal of patient care. Traditionally, this is done through one-to-one didactic tuition with dieticians and nurse specialists, either at clinics or in the home. Alternatively, clinicians and researchers have utilised group education as the way forward, as it is thought to be more cost-effective with the additional benefit of adolescents being able to learn from each other. Therefore, the relative effectiveness of individual versus group education needs to be evaluated.

Targeted versus generic approaches

The intervention research for adolescents with diabetes is marked by the diverse range of approaches that have been used, such as crisis intervention,[55] stress management training,[56] family therapy,[57] parental simulation[58] and negotiating skills training for parents.[59] Such diversity raises the questions of which approaches are best used in which situations. Some approaches may be particularly effective at specific times in the diabetes career of young people, such as during the first few months after diagnosis[60] or when the individual starts to take responsibility for insulin adjustment.[61] Interventions may need to be modified for younger versus older adolescents. Every young person's experience of diabetes is unique,[62] and each will face an idiosyncratic set of challenges. There is evidence in the adult literature that interventions that target individual's particular management problems are effective,[63] suggesting that targeting may also be important for adolescents.

Economic considerations

Attempts to estimate the economic burden of diabetes for affected individuals or society are beset with data-related problems.[64] For this reason, most investigators have concentrated on calculating the direct costs of treating the disease and its complications, and have excluded productivity and quality-of-life implications.[65] Between 1 and 2% of the British population is diagnosed with diabetes (all types), but studies suggest that they consume some 4–5% of NHS resources.[66–68] The excess cost of in-hospital treatment for diabetes has been estimated to be over 80%, most of which resulted from vascular complications.[64] When productivity losses associated with type 1 diabetes were calculated, they were found to be at least equal to the direct treatment costs.[69]

Whereas cost-of-illness studies of this nature indicate the extent of potential savings attainable

through primary and secondary prevention, they do not provide guidelines for decision-makers seeking to invest limited resources in those technologies that offer greatest value for money. To this end, the issue of cost-effectiveness, which appraises the economic worth of particular interventions, must be addressed. The delivery of educational and psychosocial interventions will incur additional expenditures in health services, but these may be offset by productivity gains and utilisation savings elsewhere in the system in both the short and longer term. Furthermore, they may confer private benefits on affected individuals over their lifetimes. Unfortunately, few evaluative studies include economic considerations such as these, and research designs that follow adolescents over decades are difficult to orchestrate. However, modelling approaches can be used to project (within confidence intervals (CIs)) the impact of achieving alternative levels of metabolic control on future morbidity and mortality, and hence on costs. Recent studies of this type associated with the DCCT have illustrated the value of healthcare interventions that result in effective control.[70,71]

Aims of this review

This systematic review examined studies evaluating the effects of educational and psychosocial interventions for adolescents with type 1 diabetes on a range of outcomes. Evaluations of educational interventions aimed at improving knowledge, diabetes problem solving and management skills, as well as more psychological interventions targeting self-care and psychological outcomes were considered.

Specifically, this review had two purposes: to establish a database of existing research evaluating the effects of psychosocial and educational interventions for adolescents with type 1 diabetes, and to present a narrative and quantitative appraisal of this research to identify what is known from past research and where future research efforts should be directed. The literature was assessed in the light of the research questions outlined above, and in terms of additional questions that arose during the course of the systematic review.

Chapter 2
Methods

The scope of the review

The steps involved in retrieving the literature are outlined in *Figure 1*. The following sections provide the details of the procedures summarised in the figure.

The search strategy was developed following a preliminary scoping exercise that assessed the extent of the literature on children and adolescents with diabetes. The search was then narrowed to only those studies that had carried out an educational or psychosocial intervention. A broad definition of 'educational and psychosocial intervention' was developed, and included one or more of the following: teaching diabetes-related knowledge and skills, providing psychosocial training and support (such as social skills, problem solving, coping skills, communication skills), and giving individual and family-based counselling. Search terms were designed to encompass all the various descriptions used in many different disciplines for 'adolescents' and the processes and outcomes of interventions for type 1 diabetes. At each stage of the process from abstract screening onwards, a conservative approach was taken to exclusion decisions to ensure that the maximum number and range of papers were available for the systematic review. For example, although the research questions were specific to adolescents, papers reporting innovative psychosocial and educational interventions in non-adolescent populations were retained on the basis that they may have provided useful background information.

Identifying the literature by electronic searching

Search strategy

The search strategy was formulated, piloted and refined based on guidelines from the UK NHS Centre for Reviews and Dissemination (CRD).[72] Foreign language articles were included, and no constraints on date of publication were imposed. The search terms used were synonyms of diabetes, adolescence, types of intervention and varieties of outcomes, and truncated terms were used as appropriate for each database. For example, the synonyms used for adolescence/adolescents were youth, young people/person, child, teen, juvenile or puberty. All terms were used as text-words (i.e. words appearing in the title, abstract or keywords of a database entry). A full list of terms appears in appendix 1.

Electronic databases

All databases were searched from their start date until the end of June 1999. The following databases were chosen because each exemplified a different aspect of the topic (e.g. medical, psychological): Bath Information and Data Services – Science and Social Science, British Nursing Index, CINAHL, Cochrane Library, Dissertation Abstracts International, EMBASE, MEDLINE, National Research Register, PsycLIT, Sociofile and ERIC. The electronic databases provided the vast bulk of the studies: 10,535 references were retrieved from those listed above and entered onto Reference Manager software. Duplicates were identified and removed from the database leaving 4639 remaining references.

Identifying the literature by other search strategies

Handsearches

Three journals (one American and two British) were chosen as representative of the subject area, encompassing a range of audiences and backgrounds: *Diabetes Care, Diabetic Medicine* and *Practical Diabetes International*. It was felt particularly important to handsearch *Practical Diabetes International* because it is not usually referenced on electronic databases. All three were searched from their start date until (and including) June 1999 using the same criteria as for the electronic search, and any relevant articles were dealt with in the same way as those retrieved from the electronic search.

Two additional primary research papers were identified and retrieved through the handsearching process, and a number of background papers were retrieved from *Practical Diabetes International* and *Diabetic Medicine*. The capture–recapture figures for the journals handsearched were 100% for *Diabetes Care*, 67% for *Diabetic Medicine* and 0% *Practical Diabetes International* (which is not on any of the electronic databases searched) indicating the sensitivity levels of the electronic searches.

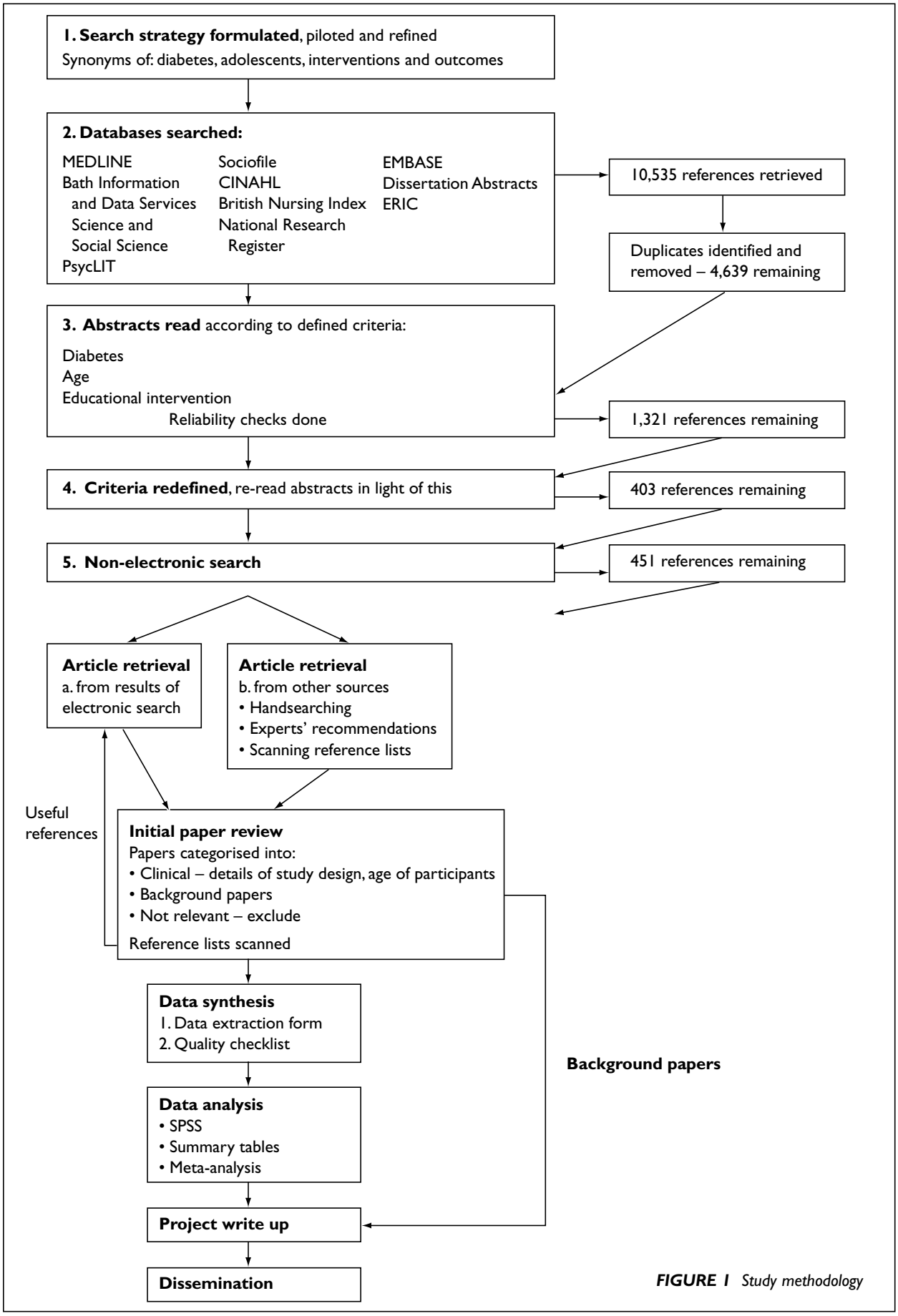


FIGURE 1 *Study methodology*

Personal contacts

Personal contacts were considered particularly important to ensure that the systematic review avoided publication bias. Experts in the area were contacted via a number of methods. A wide variety of relevant email discussion groups were targeted with requests for information, ranging from experts on the age group, such as paediatric-nursing-forum, to physicians in general, such as gp-uk, and those specific to evidence-based medicine, such as evidence-based-health (see appendix 2).

A personal letter was sent to the 72 members of the International Conference for Behavioural Research in Diabetes Mellitus informing them about the project and requesting copies of relevant papers. Individuals were also contacted using information obtained from the National Research Register indicating that they were experts in the subject area. Direct contact was made with colleagues known to be active in the field, the UK Cochrane Centre and HTA programme groups to ensure that no experts had been overlooked.

Reference lists

Reference lists of past reviews that included children and adolescents, and of all retrieved articles, were checked for relevant studies and additional studies not already identified ('exploding' references).

Notices and flyers

Notices calling for information about past and ongoing studies of educational and psychosocial interventions for adolescents with diabetes were published in the American Diabetes Association *Professional Section Quarterly Bulletin* and in the Summer 1998 edition of Diabetes UK's *Diabetes Update*. A flyer was also distributed with the September 1998 issue of *Diabetic Medicine* to 5250 Diabetes UK members.

Conferences

The work for the systematic review was publicised (mainly using flyers) at the following conferences (see appendix 3 for a copy of the flyer used):

- Psychosocial Aspects of Diabetes Study Group Annual Conference, Madrid, Spain, April 1998
- 5th European Association for Research on Adolescence Biennial Conference, Budapest, Hungary, June 1998
- Diabetes Workshop & Diabetes Symposium at the 5th International Congress of Behavioural Medicine, Copenhagen, Denmark, 19–22 August 1998
- 8th National Symposium for Paediatric Diabetes, Loughborough, UK, 3–4 September 1998
- 34th Annual Meeting of the European Association for the Study of Diabetes, Barcelona, Spain, September 1998
- British Diabetic Association Conference, Harrogate, UK, October 1998
- Clinical Audit 98, Harrogate, UK, 12–13 November 1998.

Appendix 4 lists the individuals who responded to any of the contacts made.

Initial screening: abstract check

The abstracts were read by two of the team members (JH and LS) using the following broad inclusion/exclusion criteria:

(1) Was the article primarily about diabetes?
(2) Were the participants adolescents?
(3) Was there any educational or psychosocial intervention?

In some cases, insufficient information was given in the abstract to allow a decision to be made, and the complete article was retrieved. Reliability checks between the two judges were performed for all the abstracts to be excluded. The disagreement rate was 0.32%. All disagreements were discussed and resolved successfully. This process identified 403 articles found by the electronic searches to be retrieved.

Article retrieval

Articles were retrieved from various sources including inter-library loans, making visits to libraries and personal contacts. Articles with abstracts that had previously been categorised as questionable for inclusion were screened again at this stage for their appropriateness.

Detailed screening: initial paper review

The full articles were subjected to a detailed screening to make a final decision about retaining them in the review. This decision was based on the refined inclusion and exclusion criteria summarised below.

Refined inclusion criteria

The key criteria were that the paper referred to type 1 diabetes, the age range was 9–21 years, and that there was an educational or psychosocial intervention or discussion of such an intervention. For this purpose, education was defined broadly to include any intervention aimed at changing diabetes-related behaviour as well as those related more specifically to knowledge.

Exclusion criteria

The main reasons for excluding papers at both the abstract stage and also when doing the initial paper review were that they focused on gestational diabetes, discussion of epidemiology of diabetes in a given geographical area or non-human subjects, or diabetes was not the primary focus of the paper (e.g. it was discussed only in relation to another condition, such as obesity).

The review team developed an initial paper review form that provided a checklist of the inclusion criteria as well as providing some information about the nature of the study (study design, number of subjects, outcomes, etc). The articles were then subjected to an initial review by two team members (JH and LS). The decisions made at this stage were either to include the article as a clinical paper (i.e. a report of an evaluation of an intervention), as a background paper or to exclude it completely. Each paper excluded by one judge was reviewed by the other judge. The disagreement rate was 0.4% and, in the few cases where there was disagreement, the papers were included to ensure maximum inclusiveness.

At the end of the detailed screening, after excluding 209 papers for failing to meet the criteria, there were 248 articles remaining: 64 clinical and 184 background papers. This included all the articles identified from the electronic searches and also articles obtained from other non-electronic sources.

Background papers

The background papers were those that met some but not all of the inclusion criteria and did not include empirical studies. For example, a background paper could be one that described an educational or psychosocial intervention for children but not adolescents as defined for this review. Each background paper was reviewed by at least one member of the review team. The objective was to select papers that would inform the writing of the review. Of those classified as background papers (but not including economic evaluations), 61% fell into four main categories: reviews or meta-analyses, organisation or delivery of medical services, correlation studies and case studies or descriptive articles. The list of background papers is available upon request from the authors. Those papers that discussed cost and economic issues were referred to the team's health economist.

Data extraction and critical appraisal for the primary research papers

A data extraction form was developed using CRD guidelines,[72] which were adapted to the current study. The data extraction form was then piloted with members of the team and the steering group at a 1-day workshop, after which the form was refined. The final form was a six-page document (see appendix 5), and is summarised in *Figure 2*.

There were 64 papers retained for review that described 62 different studies. The findings from the study by Grey and colleagues were reported across three papers.[73–75] These 64 papers were classified as 'clinical' indicating that they met all the inclusion criteria and were evaluations of original empirical research. All these papers were reviewed by one of two members of the review team (SEH or TCS) using the data extraction form, and a data summary table was produced for each paper (see appendix 6).

Critical appraisal followed the principle of a hierarchy of evidence as set out in CRD Report 4.[72] Studies were categorised by type of design, and well-designed randomised controlled trials (RCTs) were regarded as yielding the highest quality of data and have, therefore, been subjected to closer scrutiny in the results section of this review than studies using other types of design. Moreover, the RCTs formed the largest category (41%). The methodological quality of the RCTs was assessed in terms of attrition, randomisation quality and concealment allocation.[76] There was virtually no variation on these variables. Attrition was uniformly low, only one study reported how randomisation was performed, and blinding of patients and interventionists is not possible in this type of study. Blinding of those collecting or analysing the data was not reported. Accordingly, there was no basis for excluding or weighting the RCTs based on their methodological quality. The second largest category of study design was

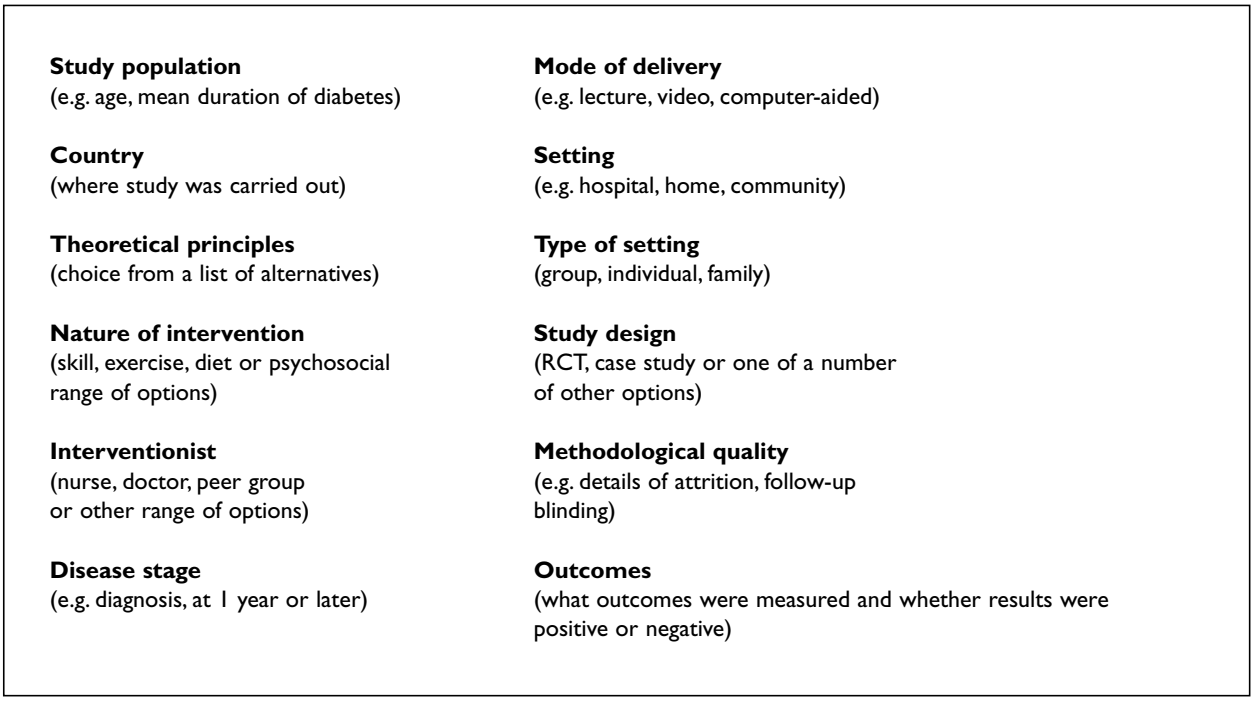


FIGURE 2 *Summary of data extraction form*

pre–post intervention with no control group (CG). This design does not permit effects to be attributed unambiguously to the intervention. However, given the frequency of this type of design in the cohort of studies, they are discussed as a separate group in the results section.

Reliability checks

To assess the reliability of the data extraction process, a third team member (DF) reviewed 10% of the papers selected at random and completed data extraction forms. The mean reliability coefficient for the categorical data such as disease stage, theoretical basis of the intervention and nature of the interventionist, setting and study design was 0.85 (Cohen's Kappa), which shows a high level of agreement given the relatively small sample.

Foreign articles

The articles included 32 foreign language papers in languages ranging from French and German to Polish and Chinese. The abstracts of the foreign language articles were translated and screened for appropriateness. The complete paper was translated for those that were included following initial screening. Four foreign language articles were included as clinical papers and data extraction forms and summary tables were completed for them based on the translations.

Reference and data management

All references retrieved were entered on Reference Manager software. An Excel database was used to keep track of papers being issued for review and also to provide a brief summary of all the background papers. The information from the data extraction forms was entered on to SPSS, and the SPSS file was used to compute descriptive statistics (frequencies and percent of sample for categorical data, and means and standard deviations (SDs) for interval data).

Computation of effect sizes

When integrating findings from several studies, it is sometimes useful to conduct a meta-analysis by computing effect sizes. Effect sizes give a pure number free of the original measurement unit.[77,78] By converting changes in outcomes to effect sizes, it is possible to combine the effects from several studies using different measurement units of the same outcome (e.g. different GHb assays). The mean size of the effect across several studies can then be examined to draw conclusions about trends across the group of studies included in the review.

However, where there are marked differences among the studies to be combined, the findings from meta-analyses must be treated with caution. There is precedence for conducting meta-analyses

of effect sizes derived from a wide variety of interventions. Meta-analyses have been conducted on the effects of a range of interventions for adults with diabetes,[47] and for children and adolescents with a variety of chronic diseases, including diabetes.[79] Therefore, we undertook such analyses here, but it should be noted that this approach has limitations.

Effect sizes were only computed for studies that included a randomised CG because these are the most rigorous design. Within these studies, effect sizes were computed for all outcomes for which the necessary information was provided. In designs involving a randomised CG, the effect of the intervention is assessed by the interaction between group (intervention versus control) and time (baseline versus follow-up). The intervention group (IG) should show a greater improvement, relative to the CG, in outcomes from baseline to follow-up. The formula used to compute the effect size (d) was:

$$\frac{\text{(Difference between group means at follow-up) – (Difference between group means at baseline)}}{\text{Pooled SD at baseline}}$$

The higher the number, the larger the effect. A negative number indicates an effect in the opposite direction to that expected and a positive number indicates an effect in the expected direction. It is possible for effect sizes to exceed +1.0 and –1.0 although the majority tend to fall within this range. It is conventional in the behavioural sciences to interpret effect sizes of about 0.20 to be small in magnitude, those of about 0.50 to be medium, and those greater than 0.80 to be large.[77]

For effect-size analyses, outcomes were categorised as psychosocial, GHb, other metabolic measures, self-management behaviour or knowledge. The psychosocial category included outcomes that were self- or parent reports of changes on psychological or inter-personal constructs (e.g. self-efficacy, diabetes-specific stress). The GHb category included haemoglobin A_1 (HbA_1; the normal form of haemoglobin) and haemoglobin A_{1c} (HbA_{1c}; haemoglobin that is attached to glucose) outcomes, and other metabolic measures were fructosamine, fasting and urinary blood glucose. The self-management category included outcomes that assessed behaviour (e.g. diet choice, frequency of blood glucose testing), and knowledge included measures of diabetes knowledge. The heterogeneity of the outcome categories was assessed with chi-squared tests, and a fixed-effects model was assumed.[80]

Some studies had more than one measure within a particular category, e.g. it was common for several psychosocial measures to be included. In integrating effect sizes for outcomes across studies, each effect size for all the outcomes in a given study could be used. However, this method would give more weight to those studies with more outcomes. To avoid this problem, the mean effect size was calculated across all the measures within a given category for each study so that each study only contributed one effect size per category.[47] Similarly, unless otherwise stated, the mean effect size was calculated across all the assessment points (post-test and follow-up).

There were two exceptions to the 'one effect size per outcome category per study' principle. Two studies[58,60] evaluated more than one intervention by assigning participants to one of two groups receiving one of two possible interventions. For these studies, separate effect sizes were retained for each group.

Chapter 3
Results

The search process identified 62 studies reported across 64 papers.[55,56,58–61,73–75,81–135] The results are organised into six sections: (1) descriptive statistics on the 62 studies, (2) addressing the original questions posed for this review, (3) meta-analyses of a subset of the RCTs, (4) descriptions of selected RCTs, (5) review of the pre–post studies, and (6) economic analyses.

Descriptive results

The key features of each of the 62 studies, including design, details of the intervention and results, are summarised in tables in appendix 6.

Study publication year

The earliest study identified was published in 1978[104] (see *Figure 3*). The cut-off date for published studies was June 1999. Two unpublished studies have subsequently been published.[75,134] The distribution showed that more of the studies identified were published in the 1990s than in the 1980s. This may indicate an increasing interest over time in adolescent interventions or it may simply reflect the general increase in all publications over this period.

Theoretical bases to the intervention

More than half of the studies reviewed (52%) had no theoretical principles that were explicitly stated in the report (see *Figure 4*). For those that did specify theoretical principles, the largest subgroup used family therapy, the second largest subgroup used behavioural principles and the third largest used social learning theory. The final group was the 'other' category, which included any studies with specified theoretical principles that could not be categorised as family therapy, behavioural therapy or social learning theory, such as anchored instruction (AI)[118–121] or social support.[108]

Design characteristics

RCTs accounted for the largest subgroup of studies (41.9%), followed by pre–post designs with no CG (33.9%). There were several studies that used a non-randomised CG (9.1%) and the remainder

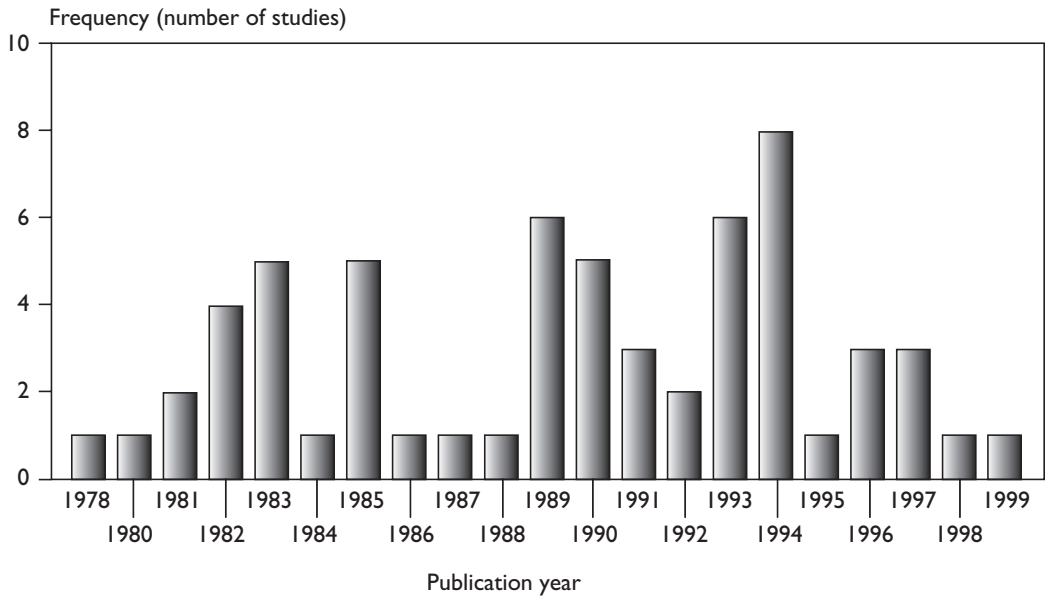


FIGURE 3 *Number of studies published in each publication year*

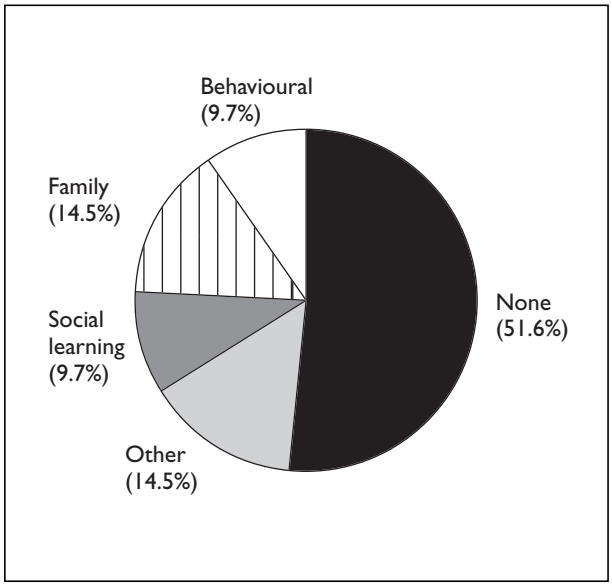


FIGURE 4 *Theoretical principles behind the interventions used in the studies reviewed*

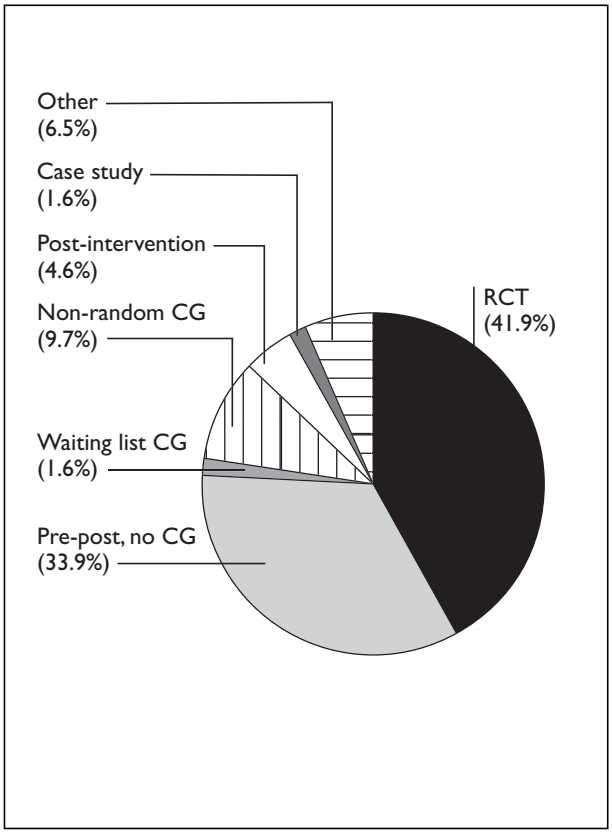


FIGURE 5 *Design of the studies reviewed*

were post-intervention only, waiting list CG, case studies or some other type of design (see *Figure 5*). Studies typically had one IG (see *Figure 6*), either with no CG (38.7%) or one CG (41.9%). A small number had two IGs with one CG (11.3%) or no CG (6.5%).

The total number of participants in these studies is shown in *Figure 7*. The mean number of participants was 53.8, but more than half of the studies involved fewer than 40 participants. Given that most of the studies involved an IG and a CG, subject numbers per condition tended to be small.

Sample characteristics

The mean age of participants across all the studies was 12.7 years and the mean duration of diabetes was 4.9 years. The majority of the studies were conducted on adolescents who had been diagnosed with type 1 diabetes for more than 1 year (67%). There were seven studies (11%) in which the participants were selected because their diabetes was poorly controlled, and there were seven studies (11%) in which participants were a mixture of newly diagnosed or those in the first year after a diagnosis of type 1 diabetes. The time since diagnosis was not provided in the remaining studies (11%).

The majority of studies were conducted in the USA (67.7%), and the UK was the second most likely location (see *Figure 8*). Two evaluation studies were identified that are currently being run in the UK (by Lesley Howells at Ninewells Medical School, Dundee and by Sue Chanon at the University of

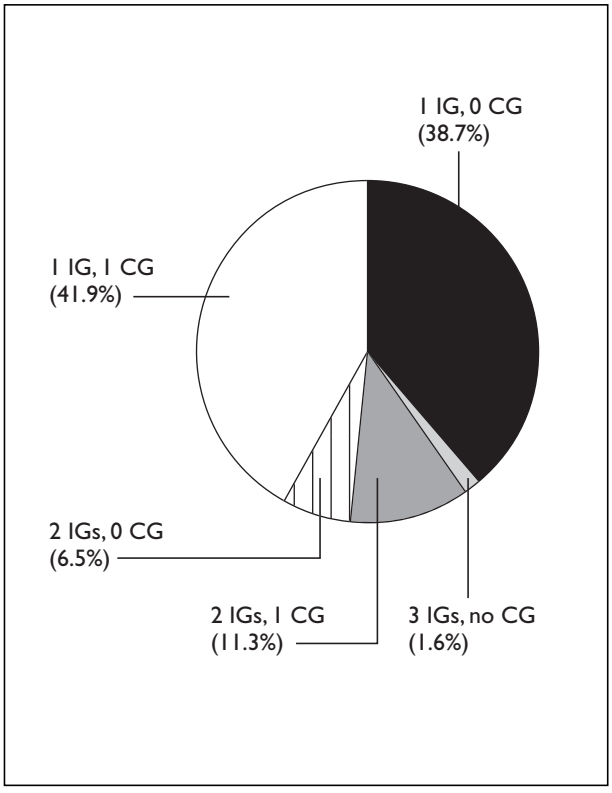


FIGURE 6 *Groups within the studies reviewed*

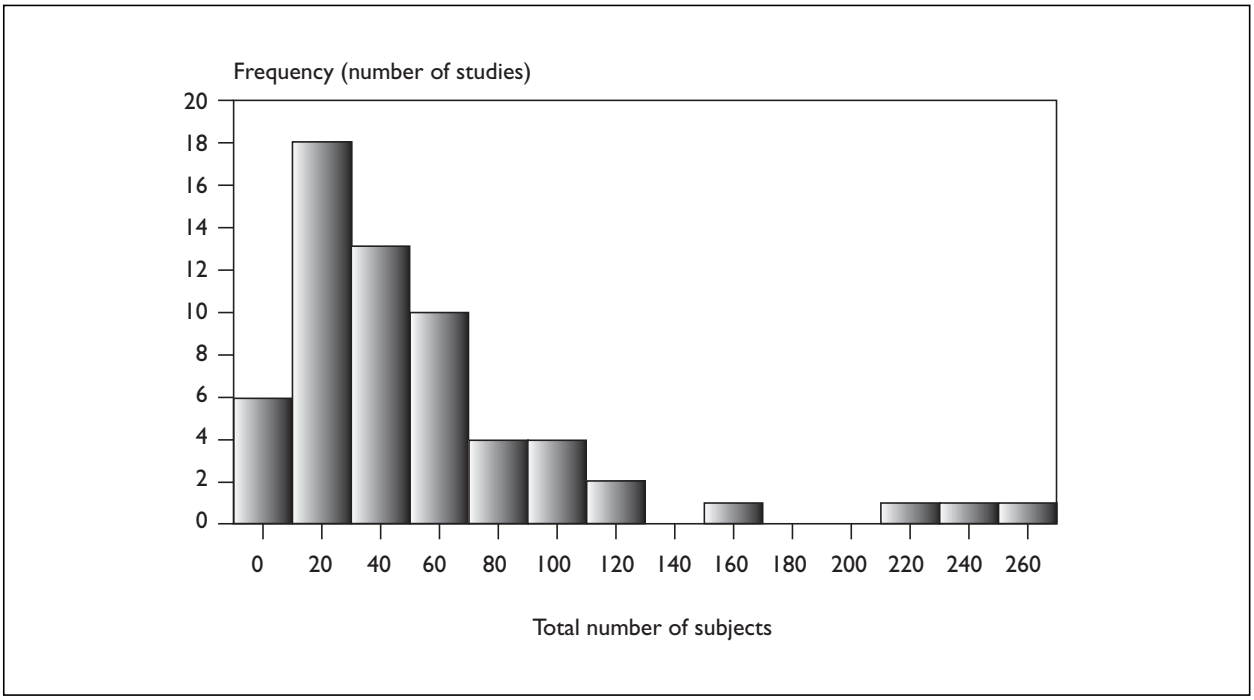


FIGURE 7 *Total number of participants (mean = 54, SD 54.31) in the studies reviewed (n = 61)*

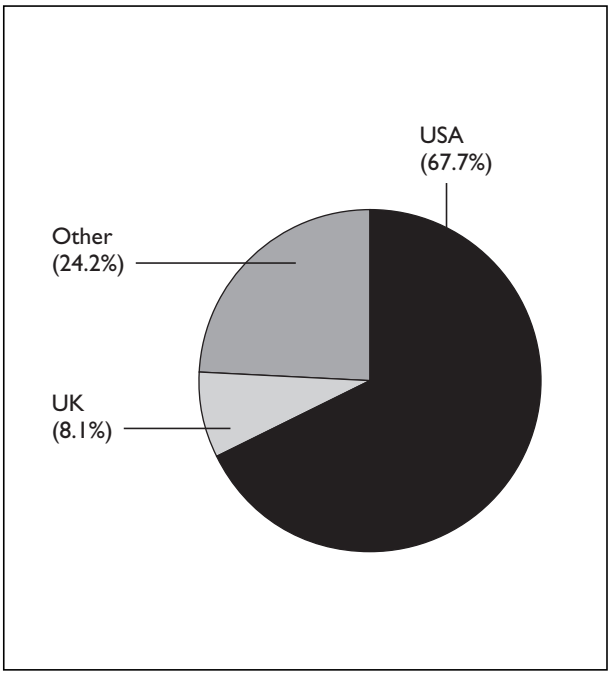


FIGURE 8 *Countries in which the studies were conducted*

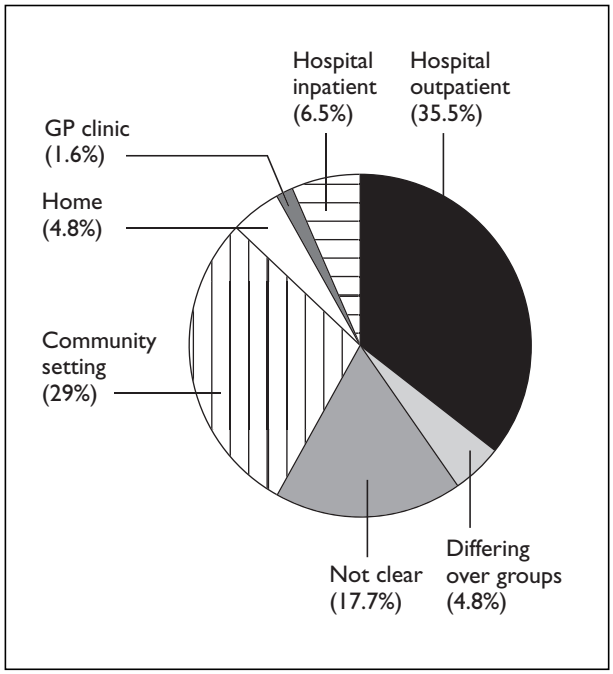


FIGURE 9 *Settings for the participants of the studies reviewed*

Wales College of Medicine, Cardiff), but results are not yet available.

Nature of the intervention

Reports were frequently unclear about where the intervention had been conducted (17.7%). Where this information was provided, hospital outpatients (35.5%) and other community settings (29%) were the most likely settings for interventions, followed by inpatient, home and general practitioner (GP) clinics (see *Figure 9*). In a small number of studies, the setting altered for different aspects of the intervention or for different groups within the study. The most typical community setting was the diabetes summer camp. The studies illustrate a wide variety of interventions (see *Figure 10*), the

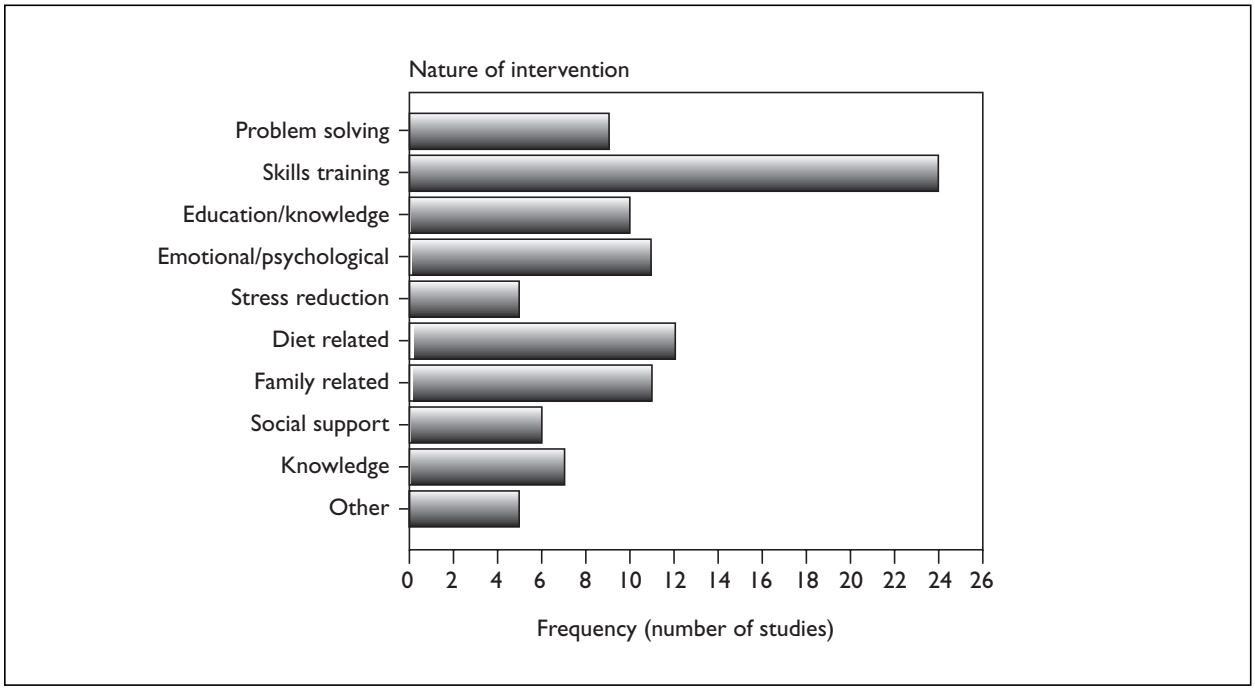


FIGURE 10 *Nature of the interventions in the studies reviewed*

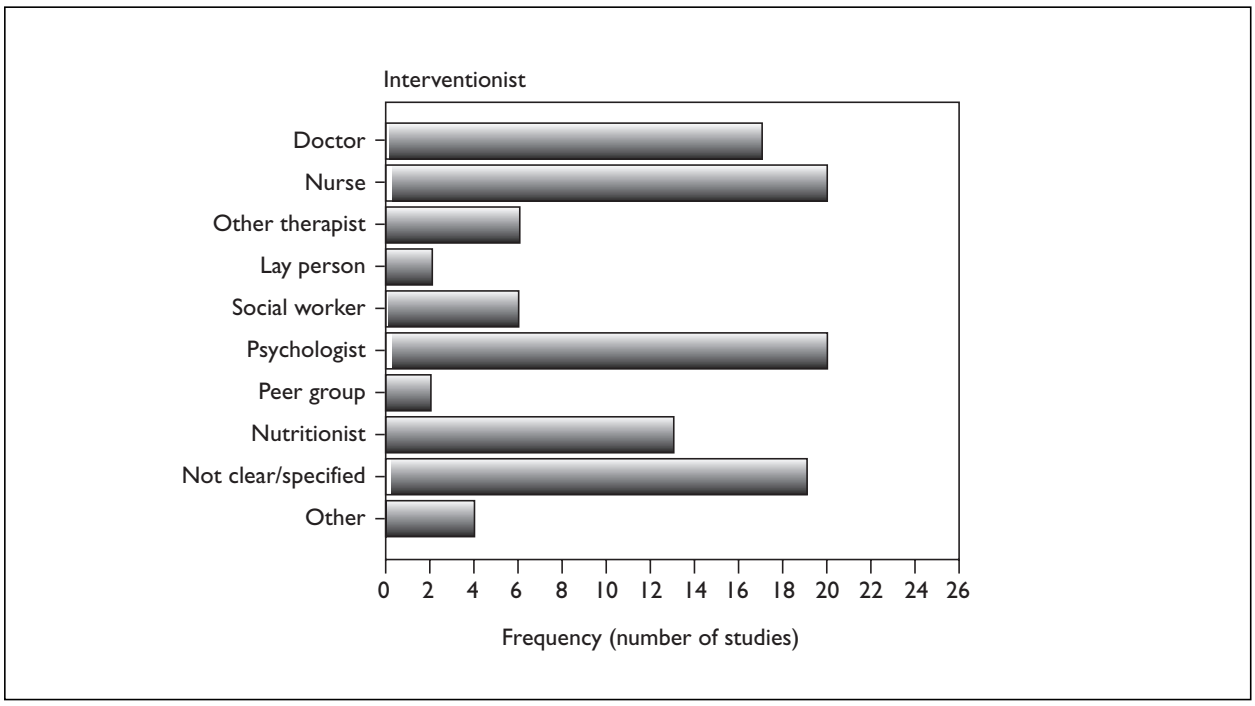


FIGURE 11 *Type of interventionists in the studies reviewed*

most common of which was some form of skills training (38.7%), followed by dietary interventions (19.4%) and emotional/psychological interventions (17.7%). Most commonly, only one interventionist was involved in delivering the intervention (43.5% of studies). The interventionists, when described, were most likely to be nurses (32.3%), psychologists (32.3%) or doctors (27.4%), but the type of interventionist was also frequently unclear from the reports (see *Figure 11*).

Outcomes

A large variety of outcomes were assessed across the 62 studies (see *Figure 12*). The most common was GHb in 62.9% of studies, measured by one of a variety of assays. Psychosocial measures for indi-

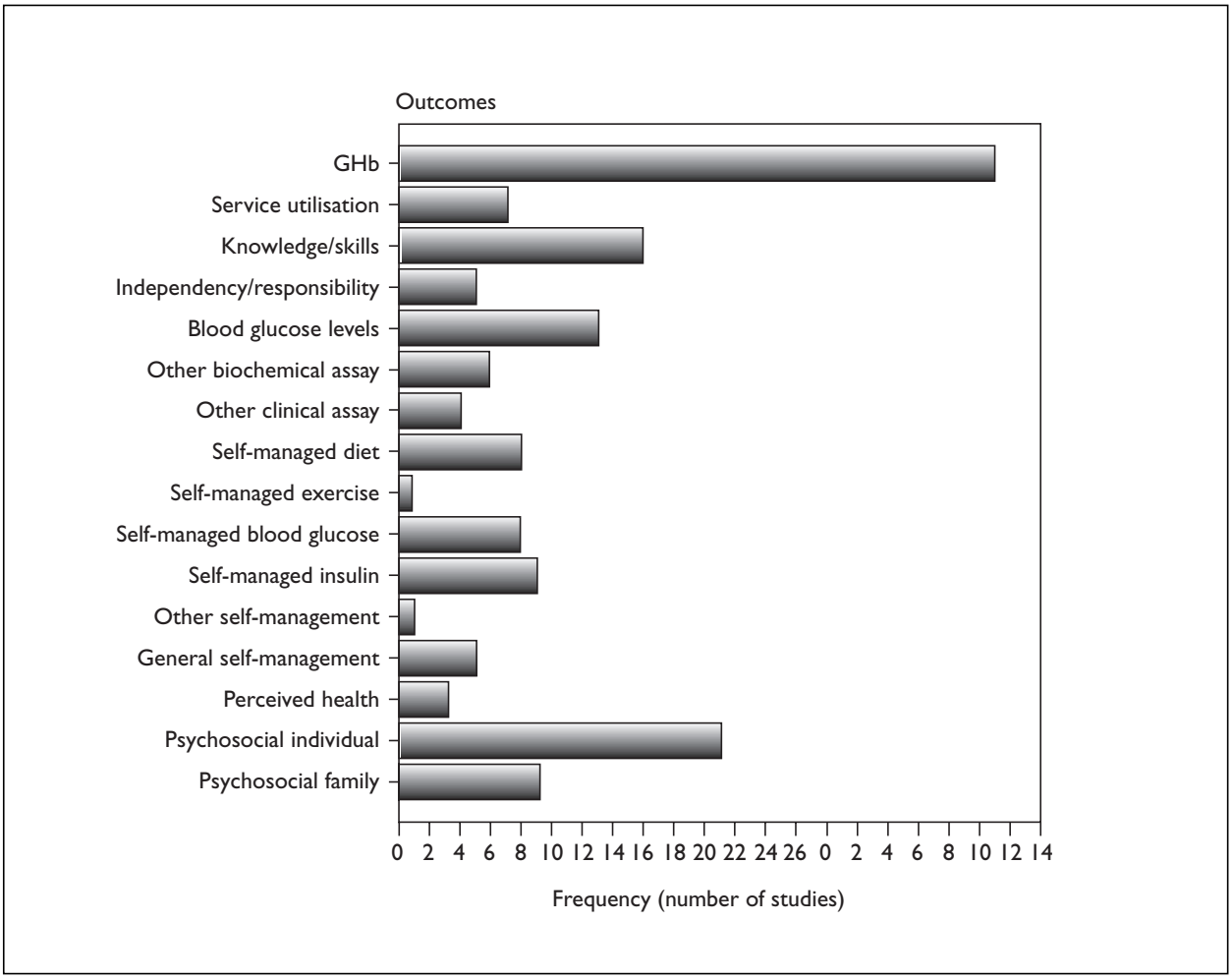


FIGURE 12 *Outcomes assessed in the studies reviewed*

vidual functioning were the next most commonly assessed outcomes (33.3%), which included constructs such as self-efficacy for diabetes management, measures of family functioning, social skills and quality of life. Diabetes self-management behaviours such as adherence to diet (12.9%) and, most markedly, exercise (1.6%) were less commonly assessed.

Follow-ups were defined as assessments that took place some period in time after the post-intervention assessment. As it can be seen from *Figure 13*, most studies did not have a follow-up assessment (59.7%). Of those that did, follow-ups were most likely to occur less than 6 months after the post-intervention assessment (17.7%), although some studies (11.3%) included a follow-up at more than 1 year.

In summary, the descriptive data indicate that evaluations of educational and psychosocial interventions for adolescents have mostly been conducted in the USA. The interventions often had no explicit guiding theoretical principles and there was an enormous variety in the aspects of diabetes management addressed by the interventions. Similarly, there was great variety in the outcomes used to evaluate the effectiveness of the interventions, although GHb was measured in over half of the studies. Although there was a high proportion of RCTs, the typical number of participants per condition was low.

Addressing the questions posed prior to conducting the review

Three issues related to intervention (other than economic aspects) were identified prior to conducting this review: education and care at diagnosis, delivery of interventions to individuals versus groups, and targeted interventions versus generic ones. The studies identified did not permit definitive answers to these questions, however, the relevant evidence is reviewed below.

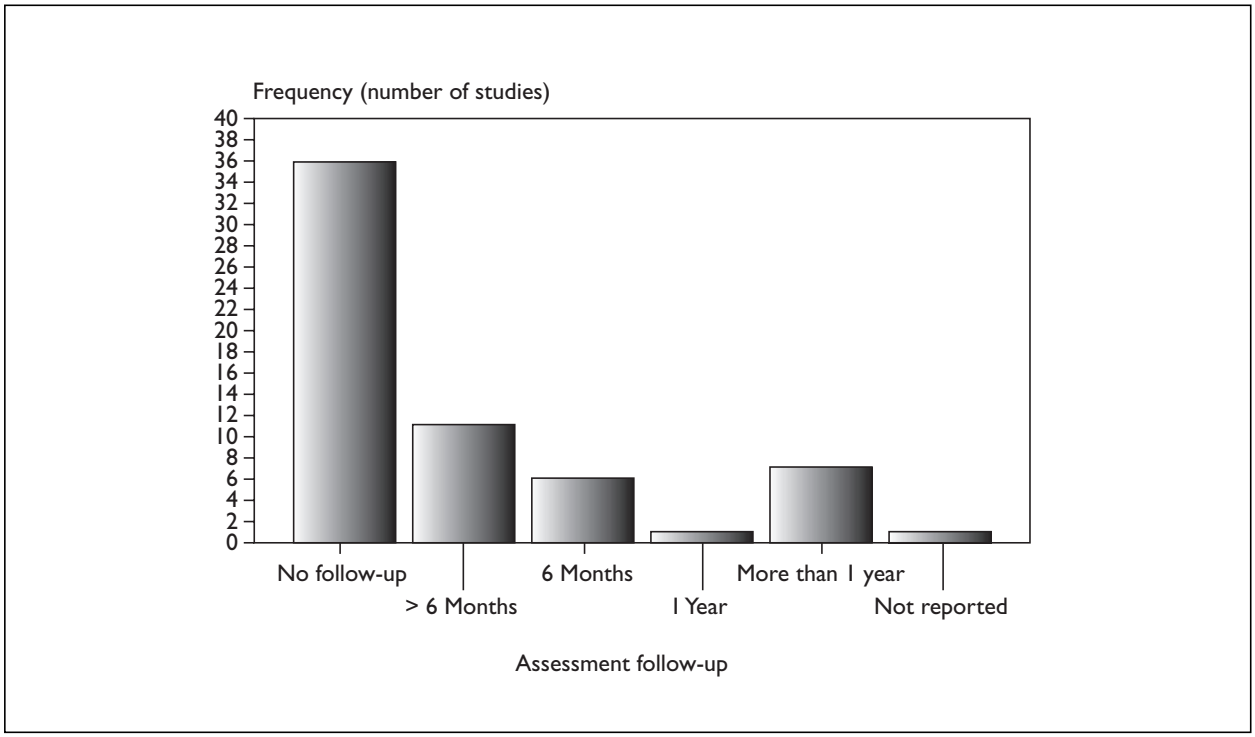


FIGURE 13 *Length of follow-up in the studies reviewed*

Education and care at diagnosis

The majority of studies were conducted on patients who had been diagnosed with diabetes for longer than 3 months. However, in five studies, participants were limited to the newly diagnosed.[55,60,125,129,130] Three of these studies were RCTs,[60,125,129] one used a non-randomised CG,[55] and one was a post-intervention assessment only design in which medical records were examined for those who were hospitalised at diagnosis versus those who were not.[130] The interventions used in these five studies varied, and included one or more of the following: skills training ($n = 3$), social support ($n = 2$), diet ($n = 1$), emotional/psychological ($n = 1$), problem solving ($n = 1$), stress reduction ($n = 1$), family-related ($n = 1$) and other components ($n = 2$).

One RCT evaluated length of hospital stay,[125] one assessed the arrangements for the family to live at the hospital,[129] and one examined a self-management intervention.[60] The length of stay for initial hospitalisation (i.e. 1 week versus 4 weeks) did not affect subsequent metabolic control,[125] where both groups received the same 20-hour education programme. Having the family live in an apartment at the hospital and receive a multi-component intervention did not result in more positive outcomes than usual care that permitted the family to stay at the hospital although not in their own apartment.[129] However, the findings of Delamater and colleagues[60] suggest that the deterioration in control often seen at the end of the so-called 'honeymoon' period (i.e. when residual insulin production ceases), can be avoided by self-management training as outpatients in the early months following diagnosis.

The study of newly diagnosed patients using a non-randomised CG[55] indicated that intensive psychosocial support at diagnosis has long-term (3–15 years of follow-up) beneficial effects, but this study used non-validated measures. Only one study examined the specific question of home care versus hospitalisation at diagnosis,[130] which had a retrospective design using medical records. The findings suggested that home care resulted in fewer subsequent hospitalisations, however, there are many confounds associated with this type of study design.

In summary, these five studies did not provide sufficient evidence to reach conclusions about the choice between education and care at home versus hospitalisation, or the best components of intervention at diagnosis. However, there is evidence that a longer hospital stay at diagnosis confers no advantage over a shorter stay,[125] and that psychosocial and educational intervention in the months immediately following diagnosis can be effective in preventing deterioration of control when residual insulin production ceases.[60]

Individual versus group education

There were 13 studies in which the interventionist primarily worked one-to-one with the adolescent,[55,82,85,86,88,90,99,100,110,122,123,125,132] and 33 studies in which the intervention mostly took place in a group setting.[56,58,59,73,81,83,84,87,92,93,95,96,98,102–109,111–113,117–121,126,127,131,133] Of the remaining studies, the interventions took place in family units,[59,60,97,124,129,134] in a mixture of group and individual settings,[94,114–116,130] in some other arrangement or the details were not provided.[57,89,91,101,128]

Of the 13 individual-based interventions, eight studies included a CG (five were RCTs and three involved a non-randomised CG). Of the 33 group-based interventions, 16 studies included a CG (14 were RCTs and two involved a non-randomised or waiting-list CG). Individual-based interventions showed no emphasis on a particular component with at least one study including one or more of all the various component types. Group-based interventions tended to include components on skills (16 of 33 studies, 48%), such as self-monitoring of blood glucose (SMBG), but otherwise showed no tendency to favour any particular component.

Individual-based interventions may be more costly in terms of staff involvement than group-based interventions, but they permit a more targeted approach that meets the individual's particular needs, which may be more cost-effective in the long term. However, adolescents may benefit from the interactions generated in group-based interventions. Beneficial effects were reported for both types of interventions, but no studies were identified that had compared delivery of comparable interventions to individuals versus groups.

Targeted versus generic approaches

There were no studies that compared targeted (i.e. assessment of each participant's specific diabetes management problems and intervention only on those problems) versus generic (i.e. use of the same intervention in all participants) approaches. Moreover, there were no studies that evaluated a targeted intervention at all. In the adult literature, there is evidence that targeted approaches are effective in improving dietary outcomes,[63] but this type of approach remains to be evaluated in adolescents.

Revision of the review

Given that the original questions posed for this review could not be addressed in depth, a revised approach was developed. In the hierarchy of evidence, the RCT is regarded as the most superior design. RCTs also included the largest number of studies identified, and a quantitative review of these was conducted, computing effect sizes for many of them. The next largest design category was the pre–post studies with no CG, and a narrative review of these findings is given.

RCTs

A review of the 25 RCTs identified yielded 16 interventions for which sufficient detail was provided to enable effect sizes to be calculated, and the representativeness of these studies was evaluated by comparing them with the remaining studies. There were no significant differences in the following variables: study country, theoretical principles, age of participants, duration of diabetes, interventionist, disease stage of participants, no follow-up versus any follow-up, individual versus group interventions, and number of participants. The only significant difference was that the effect-size studies were likely to have been published more recently (mean year 1993) than the non-effect-size studies (mean year 1989). The studies for which effect sizes could be calculated, therefore, appeared to be reasonably representative of the entire corpus of 62 studies.

Effect sizes could be computed for GHb in 12 of 18 interventions. There was considerable diversity in the other outcomes studied. For eight of the interventions, effect sizes could be computed on outcomes coded as psychosocial. The psychosocial category was diverse and included measures such as self-efficacy for diabetes management,[56,85] measures of family climate[97,129] or conflict,[59,61,134,135] diabetes-specific stress[56] and quality of life.[90] For each of the remaining categories of outcomes (self-management, knowledge, and other metabolic outcomes) effect sizes could be computed for fewer than four of the interventions. The effect sizes for GHb and psychosocial outcomes are shown in *Table 1*.

The mean of the 12 effect sizes for GHb was 0.33 (95% CI, –0.04 to 0.70). However, the effect sizes for GHb were significantly heterogenous ($\chi^2 = 28.45$, degrees of freedom (df) = 11, $p < 0.05$). This was due to the two large effects from the interventions evaluated by Satin and colleagues.[58] When these two effect sizes were removed, the category was homogenous ($\chi^2 = 9.9$, df = 9, p = not significant (NS)), and the mean was reduced to 0.08 (95% CI, –0.10 to 0.26).

TABLE 1 *The mean effect size for GHb and psychosocial outcome variables for each intervention. Effect sizes were averaged across different outcomes within each category within each study*

Study	GHb	Psychosocial
Anderson[59]	0.47	
Anderson[61]	–0.48	0.72
Boardway[56]		0.11
Brown[84]	–0.11	0.36
Daley[89]		0.28
Delamater[60]		
Intervention 1	0.18	
Intervention 2	0.18	
Grey[72,74]	0.34	0.48
Hansson[96]		0.62
Marrero[109]	–0.17	
McNabb[111]	0.15	
Satin[58]		
Intervention 1	1.18	
Intervention 2	2.03	
Simell[124]	0.23	
Sundelin[128]		0.00
Wysocki[133]	–0.03	0.37
All studies		
Mean	0.33	0.37
Median	0.18	0.36

The median (0.18) may be a more reliable indicator of the typical effect on GHb in these studies. To give an indication of their clinical relevance, these effect sizes can be converted into change in percentage HbA_{1c} using the mean and SD for HbA_{1c} reported by Mortenson and Hougaard[136] in their study of 2873 children and adolescents from 18 different countries (mean 8.6%, SD 1.7%). Using these data, an effect size of 0.33 is equivalent to a change of just over one half of a percentage point in HbA_{1c} (0.60%), and an effect size of 0.18 is equivalent to a change of just less than one-third of a percentage point (0.31%).

The large effect sizes in the study by Satin and colleagues[58] suggest that there was something unusual about these two interventions, and, therefore, they have been singled out for description in a later section.

The mean of the eight effect sizes for psychosocial outcomes was 0.37 (95% CI, 0.19 to 0.55). Despite being derived from a diversity of measures, this category was not significantly heterogeneous ($\chi^2 = 4.42$, df = 7, p = NS), and the median was similar to the mean (0.36).

There are a number of reasons to predict that the effects of these interventions on psychosocial outcomes will be larger than on GHb. The former are typically assessed by self-report or, much less commonly, by reports from other family members. As such, they are vulnerable to demand effects (to report more beneficial change than actually occurred). Measures of metabolic control, particularly measures of GHb (which assesses control over the preceding 8–12 weeks), are less open to such bias. However, due to the fact that changes in metabolic control are expected to result from changes in intervening variables assessed by psychosocial outcomes, it is to be expected that changes on these intervening variables may be more substantial than changes on GHb measured concurrently. In addition, the effects on GHb may be expected to occur at later follow-ups after the behavioural and psychological changes have, in turn, affected metabolic sequelae.

Psychosocial interventions are usually designed to have direct, short-term impacts on psychosocial variables and indirect, long-term impacts on metabolic control. Accordingly, the effect sizes for psychosocial variables should be larger than those for GHb (as seen in *Table 1*). The mean effect size for the psychosocial outcomes (0.37) was significantly larger than for GHb (0.08) when the outliers were removed ($t = 2.34$, df = 16, $p < 0.05$). For all four studies where both GHb and psychosocial effect sizes were available, the psychosocial effect sizes were larger. This pattern of effect sizes suggests that the interventions may have larger impacts on psychosocial outcomes than on GHb.

Of the 12 effect sizes for GHb, seven were derived from studies with an explicit theoretical basis for the intervention and five were derived from studies without an explicit theoretical basis. The mean effect sizes for the theoretically based (0.09) and non-theoretically based (0.06) interventions were virtually identical when the outliers from the Satin study were not included in the theoretically based group. When these are included, the theoretically based interventions resulted in substantially larger effect sizes (0.52) than the non-theoretically based interventions (0.06). This pattern of results suggests that theoretically based interventions may be more beneficial, but the nature of the interventions evaluated by Satin and colleagues needs to be carefully examined (see below).

In conclusion, the RCTs demonstrated small to medium effects on GHb and psychosocial outcomes, with stronger effects more likely for psychosocial outcomes than for GHb. The meta-analysis must be treated with caution given the variation among studies in terms of the nature of the interventions evaluated. Moreover, the category of psychosocial outcomes was very diverse (although not statistically heterogeneous). With these caveats, the meta-analysis provides confirmation that psychosocial and educational interventions for adolescents with type 1 diabetes are moderately effective.

Descriptions of particular RCTs

Anderson and colleagues[61] conducted the RCT that produced the largest effect size on psychosocial outcomes. The largest effect on GHb was produced by the two interventions in the study by Satin and co-workers.[58] The intervention developed by Grey and colleagues[73–75] produced consistent effects on both psychosocial outcomes and GHb. These RCTs were thus singled out for description in order to suggest the features of the relatively more effective interventions for adolescents.

Anderson and colleagues[61]

This study addressed the issue of declining parental involvement in the management of diabetes, which may be associated with the decline in control observed among adolescents. The participants ($n = 85$) were younger adolescents (mean age 12 years), and the intervention focused on parent–teen responsibility for sharing diabetes tasks and ways to avoid conflicts that would undermine such teamwork. Families met individually with a research assistant for four sessions at the usual time of routine clinic appointments over a 1-year period. An attention CG met with the research assistant for an equivalent amount of time and received traditional didactic education with no emphasis on parental involvement, and a standard care group had no intervention sessions. At the end of the 1-year intervention period, the teamwork group (IG1) showed no major deterioration in parent involvement in insulin administration or blood glucose monitoring compared to either the attention CG or standard care group. The IG1 also reported less family conflict. The effects of teamwork intervention on GHb were marginally significant when compared to the combination of the attention CG and the standard care group and using the measure of number of patients (frequency) in either an 'improved' or a 'not improved' category, rather than using a continuous measure of GHb. However, the results of the effect size calculations reported in the present review do not reflect this beneficial effect on GHb: when the mean GHb of the IG1 is compared with that of the CG, the IG1 appears to have deteriorated compared to the CG. Thus, the beneficial effects of this intervention on GHb are not robust.

Satin and colleagues[58]

The study by Satin and colleagues[58] evaluated a multi-family group intervention in 32 adolescents (mean age 14 years) with or without parental simulation of diabetes and compared this to usual care (CG). The groups were composed of three to five families (limited later in the study to a maximum of four families) that met with professional group leaders who used principles of group therapy once a week for 6 weeks. The first 2 weeks focused on feelings about diabetes and how it affected family members ('grieving'), and subsequent weeks focused more on diabetes management, specifically what the family could do to improve treatment adherence. In the parental simulation arm of the study only, adolescents taught their parents how to manage their 'diabetes' at the third session. This involved administration of two 'insulin' (saline) injections daily, measurement of urinary glucose and ketones four times daily, recording the results, following a meal plan, following an exercise prescription, recording late or missed meals and snacks, and submitting to a blood test for GHb. The simulation lasted 1 week, and parents discussed their experience at subsequent meetings.

At 3-month follow-up, GHb had decreased (improved) for the parental simulation group but increased (deteriorated) for the other two groups, particularly for the CG. The difference between the parental simulation condition and the CG, but not between the two group therapy conditions, was statistically significant. When only participants in the later stages of the study were considered (when the group leaders were more experienced and when group size was restricted to no more than four families), both group interventions produced significant improvements in GHb compared to the CG at both 3- and 6-month follow-ups, and these improvements were of clinically important magnitude (a 2.5–3% change in HbA_{1c}).

The largest effect size (2.03) for GHb in the Satin study was produced by the parental simulation condition. No other intervention in any study included in the present review used parental

simulation, yet it appeared to be dramatically effective in producing beneficial changes in GHb in adolescents.

Grey and colleagues[73–75]

The study by Grey and colleagues was reported across three publications.[73–75] It evaluated the effects of providing coping skills training (CST) as an adjunct to intensive insulin therapy in adolescents of a mean age of 16 years (n = 77). Grey's intervention was designed to address the particular challenges faced by adolescents on intensive therapy. The aim of CST was to increase the teenager's sense of competence and mastery by giving training in positive coping skills for the stresses arising from intensive management. Specifically, CST taught social problem solving, social skills, cognitive behaviour modification, and conflict resolution using scenarios depicting problematic social situations for adolescents. Adolescents role-played the situations with a trainer (master's prepared nurse practitioner), and scenarios included managing food choices with friends, decision-making about drugs and alcohol and independence conflicts. Training occurred in groups of two to three adolescents with the nurse trainer, followed by three to five peer-led sessions. A handbook is available describing the CST protocol in depth.

The results indicated that CST had beneficial effects on both GHb and psychosocial outcomes, with effect sizes of 0.34 and 0.48, respectively. Adolescents receiving CST had better diabetes control, greater self-efficacy, were less upset by their diabetes, found it easier to cope with their diabetes and experienced less negative impact on their quality of life than those receiving intensive management only. These effects were maintained at both 6-[74] and 12-month follow-ups.[75]

Pre–post studies

The second largest group of studies were ones without a CG that assessed participants pre- and post-intervention. This design does not permit results to be attributed unambiguously to the intervention and findings from these studies must, therefore, be interpreted cautiously. Seven studies in this category evaluated the effects of interventions conducted at diabetes summer camps, six studies were conducted on participants in poor control of their diabetes and eight studies evaluated education programmes.

Evaluations of interventions conducted at diabetes camps

Summer camps for children and adolescents with diabetes are more common practice in the USA than Europe, although two of these seven studies were conducted in Italy.[114,117] Diabetes camps provide all the usual recreational activities as well as diabetes support and education. These studies demonstrated the effectiveness of diabetes interventions delivered at camps within the limitations of the pre–post design.[126] One advantage of evaluating interventions at diabetes camp is that all participants undergo similar life experiences.

Camps typically included diabetes education and the four studies that assessed diabetes knowledge all reported that children were significantly more knowledgeable at the end of camp than at the beginning.[103,104,114,117] A wide range of other beneficial outcomes was also reported in these studies. The experience of the Outward Bound course resulted in significantly fewer self-reports of behavioural problems.[98] Skills training produced significant increases in independence in insulin administration and urine testing assessed by parents and camp staff.[104] A life-skills curriculum, which addressed assertive communication, decision-making and stress management, was evaluated in two consecutive camp years by Smith and colleagues.[126,127] They observed an increase both in reports of intentions to use more adaptive stress management techniques[126] and in self-perceptions of assertiveness. Camps can have a beneficial impact on metabolic control that can be maintained after the camp: Misuraca and colleagues[114] reported that camp participants required lower doses of insulin and had reduced GHb and that these benefits were sustained at 3-month follow-up.

These studies suggest that diabetes camps have beneficial effects on objectively measured outcomes, such as metabolic control, knowledge and skills as well as more subjective outcomes (e.g. self-perceived assertiveness). However, it is not possible to attribute these improvements specifically to the interventions described in these studies or to the experience of attending diabetes camps since the two are confounded in these studies.

Approaches to poor control

There were six pre–post studies that were conducted with adolescents selected specifically because their blood glucose was poorly controlled. A variety of interventions for these young people

are represented in these studies, but all were intended to improve blood glucose control. Arguably, these adolescents are the ones most in need of intervention, and the ones who should show the most improvement in GHb.

Ratner and co-workers[122] used self-hypnosis as a means to increase adherence to the diabetes regimen and thus achieve better control. All participants (n = 7) showed improved GHb during the self-hypnosis phase (6–12 months) compared with the previous 6 months. Rose and co-workers[123] reported the effects of an anxiety management programme applied to five poorly controlled girls. During the 5-month intervention, participants showed improvements in their urinary glucose values over baseline. Carney and colleagues[86] reported the effects of training parents to use contingent praise to increase their children's SMBG (n = 3). All three children monitored themselves more during the intervention and at 4-month follow-up, and all had better GHb at follow-up. Chase and colleagues[88] used as many as necessary of a sequence of eight interventions to improve blood glucose control for 38 children and adolescents, beginning with increasing insulin and ending with parents taking over management for the most challenging cases. Improvement was defined in terms of improved GHb. Of the 21 participants who improved, 10 responded to changes in insulin regimen, six to a family conference, and four to a parent temporarily taking over responsibility. Orr and colleagues[116] described the results of detailed psychosocial assessments of 15 adolescents with poor metabolic control and recurrent hospitalisation. Participants received standard care (diabetes education and a revision of their insulin regimen) plus the necessary psychosocial intervention, depending on the results of the assessment: 10 were referred to counselling, with five attending a support group. There were no further hospitalisations for participants over the 12–18-month follow-up period, but there were no improvements in GHb. A beneficial effect on hospitalisations, but not on GHb, was also found in a study of 52 youngsters in residential treatment by Geffken and co-workers.[94] While in the residential programme, each young person received a variety of interventions, and at discharge, after a mean of 138 days, participants had gained weight and were more knowledgeable about diabetes.

A common feature of all these studies of adolescents with poorly controlled diabetes is the small sample size and lack of specificity of the intervention. It is not possible to conclude from these studies what interventions are effective for poor diabetes control, although all of the approaches produced beneficial effects.

Education programmes

Diabetes education is commonly evaluated using pre–post designs, possibly because it is considered essential for children and adolescents and, therefore, unethical to deprive some individuals of education in an RCT. Eight studies were identified in this review that used a pre–post design to evaluate the effects of various education programmes.

General education sessions were evaluated in four studies,[84,106,107,131] and although the length (12 hours to 5 days) and the duration (2 weeks to 18 months) of these programmes varied substantially, they all showed benefits. Lucey and co-workers[106] and Brandt and colleagues[84] reported gains in knowledge and problem-solving skills that were sustained at 3-month follow-up. Both Magrath[107] and Warren-Boulten and colleagues[131] reported beneficial effects of group education on metabolic control, and Warren-Boulten and co-workers[131] also showed improvements in cholesterol. However, the intervention for these latter two studies did not only involve diabetes education but also included various psychosocial elements.

Two studies focused on providing dietary education.[93,105] Both interventions resulted in significant beneficial effects on total caloric intake and fat intake, and Lorini and co-workers[105] also reported reductions in low-density lipoprotein (LDL) and increases in high-density lipoprotein (HDL).

The effects of instruction in aerobic exercise were evaluated by Marrero and colleagues.[109] Adolescents (n = 10) attended three group sessions and were also given a take-home video. After 12 weeks, participants showed significant improvements in objective measures of fitness and in GHb.

Challener and co-workers[87] described the effects of provision of memory blood glucose meters on 16 adolescents. They reported increased frequency of testing and modest improvements in GHb, although no tests of significance were conducted.

In summary, these various education programmes were all described as having beneficial effects on various outcomes including knowledge.

Conclusions from pre–post studies

These studies illustrate the variety of interventions that have been used for adolescents, and the range of outcomes that have been examined. The studies all reported some beneficial effects. However, the quality of these pre–post studies was, by definition, lower than that of the RCTs and, in addition, tended to be conducted on small sample sizes. Accordingly, the findings should be viewed as provisional until evaluated in more rigorous designs.

Economic analysis

Objective

The aim of the economic analysis was to establish, if possible, the incremental cost per unit of outcome for individual interventions and for groupings of similar interventions, so that value-for-money relativities could be investigated. To this end, all included papers were reviewed and details of the resource use and consequences of interventions recorded.

Economic evidence

The search process resulted in the identification of a wide variety of interventions, ranging from multi-faceted education and self-management programmes to initiatives that focused on specific issues such as diet, exercise, sick days and family relations. There was equal diversity in study populations, settings, interventionists, outcomes, research designs and methodological quality. It was consequently impossible to make pure groupings of interventions from which meaningful comparisons could be made, and studies were appraised on an individual basis.

Across the studies as a whole there was scanty treatment of economic considerations. Just one study[131] included costings of professional time involved in the intervention. Some more recent American studies acknowledged economic constraints by designing their interventions to be 'low cost' or 'office-based'.[59–61] No cost-effectiveness ratios were calculated by any of the investigators. Although many papers included descriptions of the human resource implications of the interventions, this could not be adequately ascertained from other accounts, and the magnitude of the full economic costs could rarely be estimated due to non-existent reporting of capital equipment and overhead costs.

Utilisation outcomes

Eight studies reported the effect of interventions on subsequent service utilisation or adverse events.[60,73,85,88,94,110,116,130] Two studies targeting poorly controlled individuals recorded significantly reduced hospitalisation following in-depth psychosocial counselling[116] and a lengthy period of residential treatment.[94] Due to the short follow-up periods, it is not possible to determine whether the discounted benefits would exceed the costs of the interventions in these two studies. It is more difficult to show significant short-term utilisation effects due to interventions in already moderately or well-controlled subjects because of the infrequency of adverse events amongst such adolescents. Weak positive effects were, however, shown by three such studies.[60,73,110] Another study demonstrated that the distribution of a diabetes-related video game was associated with a reduced number of urgent doctor visits.[85] Two studies that investigated the 10-year impact of not hospitalising patients at diagnosis showed very different results. One showed that this had no effect on complications and hospitalisation,[88] whilst the other found that it reduced subsequent hospital admissions.[130]

Hospitalisation at diagnosis

The effect of length of hospital stay at diagnosis on subsequent metabolic control has also been investigated, and no additional benefits have been revealed from a longer hospital stay[125,129] suggesting that hospital savings might be effected by quicker discharge, although an economic evaluation in Canada found no overall cost-savings associated with home care at diagnosis. Despite significantly better health outcomes after 2 years for the home care group compared with those that received routine hospital care at diagnosis, the healthcare delivery costs were higher at home and exceeded the savings in familial expenses.[137] However, significant savings in hospital costs at diagnosis have already been achieved in the UK through home management by paediatric diabetes nurse specialists.[138]

Poorly controlled adolescents

Since many of the costs associated with diabetes arise from complications induced by poor metabolic control, the potential benefits of assisting poorly controlled individuals are above average. Therefore, interventions that target hard-to-manage adolescents are of special interest. Effective initiatives could have higher cost-savings but may be more difficult to achieve with this patient group and thus require a higher commitment of resources.

Twelve studies focused on poorly controlled subjects and mostly used interventions

involving family therapy and individual or group counselling. Although seven studies reported improved metabolic control,[57,88,94,122–124,131] and the other five recorded improvements in a variety of behavioural or psychosocial outcomes,[56,86,97,116,134] only two of these studies showed significantly reduced hospitalisations following intervention.[94,116] Collectively, these studies illustrate that poorly controlled subjects can be assisted by tailored interventions, but they do not provide robust evidence of the cost-effectiveness of such approaches.

Conclusion

Studies lacked the information required to undertake a detailed economic analysis and the diversity of the interventions and outcomes further impeded cost-effectiveness comparisons. In line with the conclusions of a review of educational interventions for adults with diabetes,[139] no evidence was found to show that similar interventions for adolescents saved money. Furthermore, the small to medium-sized beneficial effects recorded across such a range of interventions and outcomes for adolescents with diabetes as in this review is consistent with the findings of reviews of similar interventions for childhood asthma.[140,141] Future appraisals of educational or psychosocial interventions for adolescents with diabetes need to include a full economic evaluation of the costs and benefits. This should take into account the potential future social and private cost-savings associated with achieving better metabolic control, which could be substantial.[11,142]

Chapter 4

Discussion and conclusions

Obstacles to evaluating educational and psychosocial interventions for diabetes

In discussing the findings of this review, it is important to consider the obstacles to the conduction of appropriate controlled clinical trials of educational and psychosocial interventions for diabetes.[143] As type 1 diabetes is a life-threatening disease, basic education and skills training at diagnosis are essential for survival. Therefore, all adolescents with diabetes (and/or their parents) will have received some basic education. For obvious ethical reasons, education at diagnosis cannot be evaluated against no education. Subsequent interventions must, therefore, show an effect over and above the effects of the intervention administered at diagnosis. Consequently, such effects may be relatively modest.

Theoretical models relating educational and psychosocial interventions to outcomes through mediating variables remain to be fully developed.[144] As a result, there is debate over the appropriate outcomes to assess when evaluating the impact of interventions.[145] Although metabolic control has been viewed by many as the primary outcome, educational and psychosocial interventions are concerned with changing self-management behaviours, attitudes and beliefs, which are viewed as mediating improved health status. Therefore, assessing changes in these behavioural and psychological outcomes is a fairer evaluation of the intervention than assessing changes in metabolic control.[146]

Moreover, changes in metabolic control are the result of numerous factors beyond the interventionist's control.[42] Typically, educational and psychosocial interventions are conducted as a supplement to standard medical care. In a drug trial, it can be required that participants are not taking other medications, and that they do not start another medication during the course of the trial. In a trial of educational or psychosocial interventions for diabetes, it is not considered ethical for such restrictions to be placed upon participants. Therefore, their medical treatment may be changed during the intervention or follow-up period, with resulting consequences for metabolic control that may obscure intervention effects. Ideally, medical care and education should be integrated, as in the DCCT.[6,11] However, under these circumstances, it is not possible to isolate the effects of the non-medical aspects of care.

The ultimate goal of diabetes care is to increase patients' quality of life by reducing the morbidity and mortality associated with the disease. Therefore, evaluating the effectiveness of interventions is a long-term enterprise in which patients should be followed-up sufficiently for any impact on chronic complications to be observed. However, follow-up over several years is problematic, because numerous other uncontrolled factors intervene making it impossible to attribute changes in disease status to an educational or psychosocial intervention some years earlier.

Despite these obstacles, there is a considerable body of research on interventions for adolescents. This review identified 62 studies evaluating 64 different educational and psychosocial interventions for adolescents with type 1 diabetes. A meta-analyses of 16 of these interventions indicated that small to medium beneficial effects were observed in psychosocial outcomes and GHb.

Shortcomings of past research

Although the largest proportion of studies (41%) were RCTs, 59% of the studies were of a less powerful design that prevented evaluation of the intervention with potential bias minimised as much as possible. Sample sizes were not based on power calculations and the power of the study was rarely discussed. It is unlikely, however, that studies in which fewer than 40 participants (i.e. the majority of studies in this review) were allocated to one of two groups would yield significant results when only small to medium effect sizes can be anticipated. Specifically, to achieve a significant effect size of 0.20 with power of 0.90, a total of 270 participants is required, and to achieve a significant effect size of 0.35 with power of 0.90, 90 participants are required. Most studies (67%) have been conducted in the USA, and the generalisablity of these finding to

the UK setting is undetermined. Interventions developed in the USA require modification and re-evaluation for application in the UK.[147]

This review exposed the enormous variety of interventions that have been developed for adolescents with type 1 diabetes. These interventions have taken place in a variety of settings (e.g. from medical offices to summer camps), focused on various combinations of aspects of diabetes management, involved a range of interventionists and been evaluated by assessing widely differing outcomes (e.g. from 'romantic appeal' to fructosamine). Even where different studies have assessed comparable outcomes, they have not necessarily used the same measure or even ones of known reliability and validity. Given this heterogeneity, the existing research is piecemeal rather than cumulative, which makes it difficult to identify what progress has been made.

More than half the studies reviewed (55%) had no explicit theoretical basis underlying the intervention. A theoretical basis determines not only the contents of the intervention but the most appropriate outcomes to measure and when to measure them. A theoretical basis also permits predictions to be made for outcomes that are not expected to change versus ones that are expected to change, which provides a powerful test of the intervention's effects.

This review found that outcomes were not likely to be assessed at follow-up; only 40% of studies had a post-test assessment and the majority of these took place within less than 6 months. However, outcomes range along a continuum from proximal to distal. An intervention designed to change proximal outcomes (e.g. skill at injecting insulin) should produce larger effects on proximal outcomes (e.g. observed injecting skill) than on more distal ones (e.g. GHb), which is probably partially mediated by injecting skill but might also be subject to other influences. The length of appropriate follow-up should be based on the theoretical model underlying the assumed intervention effects on different outcomes. Long-term effects are unlikely for interventions that do not address long-term maintenance issues.

Findings from the 25 RCTs

None of the RCTs identified in this review were conducted in the UK, thus the generalisability of any of the findings to the UK setting remains unknown. However, the work conducted in the USA provides valuable information about likely effective components of interventions and is, therefore, a good starting point for designing a UK intervention.

The importance of integrating medical care and educational and psychosocial interventions was underscored by at least three of the RCTs. The interventions evaluated by Anderson and colleagues,[59] Delamater and colleagues[60] and Marrero and colleagues[108] focused on SMBG and related it to other aspects of diabetes management (e.g. insulin adjustment, lifestyle aspects). By demonstrating how this information can be used to guide other management behaviours, SMBG becomes meaningful and more likely to be performed. The results from integrating medical and non-medical aspects of diabetes management suggest that multicomponent interventions may be more successful for adolescents than ones that just focus on one aspect. These interventions, such as those used by Grey and co-workers,[73–75] address all aspects of diabetes management and the complex interrelationships between management activities are considered. Grey's intervention was also integrated with medical care because all participants were on intensive insulin therapy.

One important issue for adolescents is the question of parental involvement. In the studies identified here that addressed the issue of parental involvement, the evidence supports the widely held clinical view that developmentally appropriate, negotiated responsibility has beneficial outcomes. Anderson and colleagues[59,61] hypothesised that the increasing decline in control observed in adolescents is the result of declining parental involvement during this period. In one intervention,[59] they maintained parental involvement by intervening with both adolescents and their parents, although this was through separate groups. This intervention had significant positive effects on GHb. In their more recent study,[61] the intervention was designed explicitly to maintain parental involvement through family counselling sessions and although the effects on psychosocial outcomes were positive, the effects on GHb were not. (However, when a different analytic approach was used, the report indicated a marginal beneficial effect on GHb.) In one of the interventions used by Satin and colleagues,[58] parents became intensely involved by simulating the experience of having diabetes for 1 week under the tutorship of their child. This intervention presumably resulted in the parents having a better understanding of their child's experience of diabetes,

which may have helped them negotiate the responsibility issues. Finally, the intervention used by McNabb and colleagues[112] aimed to increase developmentally appropriate responsibility for management tasks by younger adolescents. All of these interventions had beneficial effects on diabetes management, and the parental simulation used by Satin and colleagues[58] resulted in a large beneficial effect on GHb.

An unresolved issue is the extent to which targeted interventions are more effective than generic ones. There are a number of ways in which interventions can be targeted. A particular stage in the disease can be selected, e.g. results from intervention in the first few months after diagnosis suggested that this is effective.[55,60] Interventions for adolescents who have had diabetes for several years or who are in poor control may need to focus on different issues. The period of adolescence, as defined for this review, includes a wide age-range and different approaches need to be considered for younger versus older adolescents. Each adolescent experiences diabetes in a unique way and faces idiosyncratic challenges, suggesting that interventions might need to address specific concerns of the individual adolescent patient in addition to those issues common to most, if not all, patients. However, no studies have examined the effects of this type of targeting.

The meta-analysis only included a subset of findings from the RCTs, nevertheless it generated some suggestions for future interventions. Although effects of educational and psychosocial interventions at diagnosis cannot be fully evaluated, given ethical constraints, it appears that length of hospital stay is not a critical factor in subsequent diabetes management. However, the provision of such an intervention[60] in the early months after diagnosis was found to be effective in slowing the subsequent decline in GHb, suggesting that this may be an optimal time to intervene. There was no strong evidence to favour individual, group or family-based interventions, suggesting that the choice of unit of intervention can be governed by other factors such as cost and convenience. There was no evidence to support targeted approaches over more generic ones because this issue had not been explicitly addressed.

Psychosocial and educational interventions are expected to have a larger impact on corresponding psychosocial and educational outcomes than on metabolic control. In line with this expectation, the meta-analysis indicated that these interventions had larger effects on psychosocial outcomes than on metabolic control. A significant difference in mean effect sizes (0.37 for psychosocial outcomes versus 0.08 for GHb) was observed when the two large effect sizes in the GHb group were removed to achieve homogeneity.

In summary, the RCTs demonstrated that these interventions have beneficial impacts on a range of outcomes, and the effect sizes are typically in the small to medium range.

Pre–post studies

There were 21 studies in which a pre–post design with no CG had been used. This design does not permit results to be attributed unambiguously to the intervention, so the findings from these studies should be treated with caution. A narrative review of these studies revealed that they all reported beneficial effects of the various interventions examined, but there is a danger here of publication bias. Studies with this type of weak design are possibly less likely to be published if they report the absence of beneficial effects.

Limitations of this review

Extensive electronic searching and soliciting of reports was undertaken and many abstracts were screened. The eventual corpus of clinical studies consisted exclusively of journal articles or reports destined for journals, suggesting that the 'grey' literature may not have been accessed successfully.

Not all the RCTs were included in the meta-analysis and effect sizes could not be calculated for all the outcomes reported in those studies that were included, thus the effect sizes used in the meta-analysis may have been unrepresentative. Given the limited number of effect sizes in this review, it was decided not to weight them differentially. Only one type of effect size was used based on means and SDs because the large majority of outcomes were continuous variables. However, this decision meant that no effect sizes for categorical variables were included and it remains a possibility that the findings of a meta-analysis including this type of outcome would be different.

However, these limitations of the meta-analytic component should be considered in the light of its strengths. The studies for which effect sizes were available were not unrepresentative of the whole set of studies, except in so far as they

included studies with a CG and ones published more recently. They were, therefore, higher quality studies to which more weight should be given. The quantitative integration of findings across several studies can be a more rigorous approach than a qualitative, narrative review. On balance, the effect size analyses generated useful indicators of the impact of these interventions, but should be viewed with caution.

Conclusions

Based on the process of location, analysis and discussion of the research identified by this review, the following conclusions may be drawn.

1. Educational and psychosocial interventions have small to medium-sized beneficial effects on a variety of diabetes management outcomes.
2. There is a need for well-designed clinical trials of these interventions in the UK. (No completed RCTs of educational or psychosocial interventions for adolescents with type 1 diabetes conducted in the UK were located although two studies are currently underway).
3. The evidence-base, arising primarily from studies in the USA, provides a starting point for the design of interventions for the UK.
4. Quantitative and narrative analysis of the evidence-base suggests that interventions are more likely to be effective if they demonstrate the inter-relatedness of the various aspects of diabetes management, assess outcomes that the intervention explicitly targets for change, and assess outcomes at the appropriate point in time post-intervention to reflect the impact of the intervention.
5. The evaluation of interventions needs to be by well-designed studies such as RCTs including patient-preference arms[148] with adequate power and which report results in such a way that effect sizes can be calculated.
6. An important gap in the evidence is that there is no systematic understanding of whether interventions should be targeted (e.g. modified for the different age groups subsumed by adolescence, for the different disease stages, or for adolescents with different types of diabetes management problems).

This review was based on a systematic literature search up to June 1999. As research has tended to be piecemeal rather than programmatic, it is very unlikely that more recently published papers will substantially change the conclusions arrived at here. Moreover, our contacts with active researchers in the field have not identified any major new studies underway in the USA, and only two in the UK (see chapter 3).

Recommendations for future research

Research to date has proceeded piecemeal instead of cumulatively and this limits the extent to which firm conclusions can be drawn about what is already known of the effectiveness of education and psychosocial intervention for adolescents with type 1 diabetes. In order for more cumulative research to be conducted, studies need to be based on explicit theoretical principles in which the design of the intervention and the selection of the outcomes are theoretically guided. Outcomes need to be assessed using reliable and valid measures, preferably ones that are widely used so that evidence across studies can be combined. However, even if these principles are followed, there will still be an enormous number of possible interventions that could be developed and evaluated. There is a tendency, perhaps a preference, for researchers to develop their own interventions independently, which adds to the non-cumulative nature of this field.

The lack of UK-based studies highlights a gap in the evidence. To fill this gap, this review recommends that a programme of primary research on adolescent interventions be developed. Past research conducted elsewhere will assist to some extent in the development of what are expected to be effective interventions. However, there is insufficient evidence to narrow the possibilities significantly. Instead of further encouraging the piecemeal development of research in this area, this review recommends that a phase of programme development is undertaken involving a consultation process with stakeholders (i.e. adolescents with diabetes, their families, doctors, nurses, health economists and health psychologists). The aim of such a consultation exercise would be to arrive at the outline of interventions that are seen as plausible and potentially effective by patients and their parents, feasible and practical in the context of NHS diabetes services and understood and accepted by doctors and nurses as key and integral parts of diabetes care. The interventions should also have the potential to be cost-effective and be based on sound behavioural principles. Such interventions, if demonstrated to be effective, would be much more likely to be implemented than ones established outside of such a developmental phase.

The types of issues to address during such a consultation process could include, but not be limited to, the following.

1. Establishing the intervention topics viewed by each stakeholder group as most important for inclusion.
2. Individual- versus group- versus family-based interventions.
3. Targeting by disease stage and age of adolescent.
4. The use of information technology (e.g. videos, video games, glucometers, palm-top computers) both for delivering interventions and as aids to self-management.
5. The location of the intervention (e.g. hospital outpatients, GP clinics, some other community setting) to facilitate maximum attendance.
6. Parental involvement.
7. Integration of the intervention with medical care.
8. The practicalities of running RCTs of these interventions in NHS settings.
9. The views of adolescents and their parents about participating in RCTs and patient-preference trials.
10. What constitutes an acceptable CG from both the researchers' and participants' perspectives.

At the conclusion of this developmental phase, the information obtained would be documented and used to shape the interventions to be developed and evaluated by commissioned research. In this way, UK-based research on education and psychosocial interventions for adolescents with type 1 diabetes would proceed in a cumulative and consensual manner with implementation in mind from the outset.

Acknowledgements

The authors thank Sue Cradock, RGN, MSc, DipN, FETC and E Adele McEvilly, RGN, RSCN, FETC for assisting the review team at their two workshops by commenting on the approach and results of the review, and by providing expertise on aspects of care and management of diabetes in adolescents. In addition, they thank them and Professor Rosemary Crow for commenting on the draft report.

The authors are indebted to the referees for their attention to the report and the quality of their comments. The views expressed are those of the authors, who are also responsible for any errors.

References

1. Betts P, Buckley M, Davies R, McEvilly E, Swift P. The care of young people with diabetes. *Diabet Med* 1996;**13**(Suppl 4):S54–9.

2. Muntoni S, Muntoni SI. New insights into the epidemiology of type 1 diabetes in Mediterranean countries. *Diabetes Metab Res Rev* 1999;**15**:133–40.

3. Lamb WH. Aetiology, epidemiology, immunology, environmental factors, genetics and prevention. In: Court S, Lamb B, editors. Childhood and adolescent diabetes. Chichester: John Wiley & Sons; 1997. p. 1–16.

4. Metcalfe MA, Baum JD. Incidence of insulin dependent diabetes in children aged under 15 years in the British Isles during 1988. *BMJ* 1991;**302**:443–7.

5. Goldstein D, England J, Hess R, Rawlings S, Walker B. A prospective study of symptomatic hypoglycaemia in young diabetic patients. *Diabetes Care* 1981;**4**:601–5.

6. Diabetes Control and Complications Research Group. Diabetes Control and Complications Trial (DCCT): update. *Diabetes Care* 1994;**13**:427–33.

7. Edge JA, Matyka K. Acute complications of diabetes. In: Court S, Lamb B, editors. Childhood and adolescents diabetes. Chichester: John Wiley & Sons; 1997. p. 201–24.

8. Thompson CJ, Greene SA. Diabetes in the older teenager and young adult. In: Court S Lamb B, editors. Childhood and adolescent diabetes. Chichester: John Wiley & Sons; 1997. p. 67–86.

9. Morris AD, Boyle DIR, McMahon AD, Greene SA, MacDonald TM, Newton RW. Adherence to insulin treatment, glycemic control and ketoacidosis in insulin-dependent diabetes mellitus. *Lancet* 1997;**350**:1505–10.

10. Thompson CJ, Cummings F, Chalmers J, Newton RW. Abnormal insulin treatment behaviour: a major cause of ketoacidosis in the young adult. *Diabet Med* 1995;**12**:429–32.

11. Diabetes Control and Complications Research Group. Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes mellitus. *J Pediatr* 1994;**125**:177–88.

12. MacGuish AC. Early detection and screening for diabetic retinopathy. *Eye* 1993;**7**:254–9.

13. Court S. Long-term complications – prevalence and management. In: Court S, Lamb B, editors. Childhood and Adolescent Diabetes. Chichester: John Wiley & Sons; 1997. p. 225–38.

14. Kohner EM. Diabetic retinopathy. *BMJ* 1993;**207**:1195–9.

15. Watts GF. Diabetic renal disease. In: Shaw K, editor. Diabetic complications. Chichester: John Wiley & Sons; 1996.

16. MacLeod A, Sonksen P. Diabetic neuropathy. In: Shaw K, editor. Diabetic complications. Chichester: John Wiley & Sons; 1996.

17. Ryder REJ, Facey P, Hayward MWJ, Evans WD, Bowser WG, Peterr JR, *et al.* Detailed investigation of the case of impotence in 20 diabetic men. *Practical Diabetes* 1991;**9**:7–11.

18. Alexander WD, Cummings M. Erectile dysfunction and its treatment. In: Shaw K, editor. Diabetic complications. Chichester: John Wiley & Sons; 1996.

19. Shaw KM. Macrovascular disease in diabetes mellitus. In: Shaw K, editor. Diabetic complications. Chichester: John Wiley & Sons; 1996

20. Yudkin JS, Blauth C, Drury P, Fuller J, Henley J, Lancaster T, *et al.* Prevention and management of cardiovascular disease in patients with diabetes mellitus: an evidence base. *Diabet Med* 1996;**13**:S101–21.

21. Coleman JC, Hendry L. The nature of adolescence. 2nd ed. London: Routledge; 1990.

22. Jackson S, Rodriguez-Tome H. Adolescence: expanding social worlds. In: Jackson S, Rodriguez-Tome H, editors. Adolescence and its social worlds. Hove: Lawrence Erlbaum Associates; 1993. p. 1–14.

23. Nielsen L. Adolescence: a contemporary view. 3rd ed. Orlando: Harcourt Brace; 1996.

24. Silbereisen RK, Kracke B. Variation in maturational timing and adjustment in adolescence. In: Jackson S, Rodriguez-Tome H, editors. Adolescence and its social worlds. Hove: Lawrence Erlbaum Associates; 1993. p. 67–94.

25. Hendry L, Shucksmith J, Love JG, Glendinning A. Young people's leisure and lifestyles. London: Routledge; 1992.

26. Plant M, Plant M. Risk takers: alcohol, drugs, sex and youth. London: Routledge; 1992.

27. Montemayor R. The study of personal relationships during adolescence. In: Montemayor R, Adams GR, Gullotta TP, editors. Personal relationships during adolescence. London: Sage; 1994. p.1–6.

28. Allen DA, Tennen H, McGrade BJ, Affleck G, Ratzan S. Parent and child perceptions of the management of juvenile diabetes. *J Pediatr Psychol* 1983;**8**:129–41.

29. Anderson BJ, Auslander WF, Jung KC, Miller JP, Santiago JV, Abraham C, et al. Assessing family sharing of diabetes responsibilities. *J Pediatr Psychol* 1990;**15**:477–92.

30. Ingersoll GM, Orr DP, Herrold AJ, Golden MP. Cognitive maturity and self-management among adolescents with insulin-dependent diabetes mellitus. *J Pediatr* 1986;**108**:620–3.

31. Wysocki T, Clarke WL, Meinhold PA, Bellando BJ, Abrams EC, Bourgeois MJ, *et al.* Parental and professional estimates of self-care independence of children and adolescents with IDDM. *Diabetes Care* 1992;**15**:43–52.

32. Glasgow RE, Strycker LA, Hampson SE, Ruggiero L. Personal-model beliefs and social environmental barriers related to diabetes self-management. *Diabetes Care* 1997;**20**:556–61.

33. Hampson SE, Glasgow RE, Toobert DJ. Personal models of diabetes and their relations to self-care activities. *Health Psychol* 1990;**9**:632–46.

34. Hampson SE, Glasgow RE, Foster LS. Personal models of diabetes among older adults: relationship to self-management and other variables. *Diabetes Educ* 1995;**21**:300–7.

35. Skinner TC, Hampson SE. Social support and personal models of diabetes in relation to self-care and well-being in adolescents with type 1 diabetes mellitus. *J Adolesc* 1998;703–15.

36. Skinner TC, John M, Hampson SE. Social support and personal models of diabetes as predictors of self-care and well-being: a longitudinal study of adolescents with diabetes. *J Pediatr Psychol* 2000;**25**:257–67.

37. Allen C, Zaccaro DJ, Palta M, Klein R, Duck SC, D'Alessio DJ. Glycemic control in early IDDM. The Wisconsin Diabetes Registry. *Diabetes Care* 1992;**15**:980–7.

38. Amiel SA, Sherwin RS, Simonson DC, Lauritano AA, Tamborland WV. Impaired insulin action in puberty: A contributing factor to poor glycemic control in adolescents with diabetes. *N Engl J Med* 1986; **315**:215–19.

39. Flack A, Kaar ML, Laatikainen L. A prospective study examining the development of retinopathy in children with diabetes. *Acta Paediatr* 1996;**5**:313–19.

40. Kovacs M, Charron-Prochownik D, Obrosky DS. A longitudinal study of biomedical and psychosocial predictors of multiple hospitalizations among young people with insulin-dependent diabetes mellitus. *Diabet Med* 1995;**12**:142–8.

41. Johnson SB, Silverstein J, Rosenbloom A, Carter R, Cunningham W. Assessing daily management of childhood diabetes. *Health Psychol* 1986;**5**:545–64.

42. Johnson SB, Freund A, Silverstein J, Hansen CA, Malone J. Adherence-health status relationships in childhood diabetes. *Health Psychol* 1990;**9**:606–31.

43. La Greca AM, Follansbee D, Skyler JS. Developmental and behavioral aspects of diabetes management in youngsters. *Children's Health Care* 1990;**19**:132–9.

44. Griffin S. Lost to follow-up: the problem of defaulters from diabetes clinics. *Diabet Med* 1998; **15**(Suppl 3):S14–24.

45. Olsen R, Sutton J. More hassle, more alone: adolescents with diabetes and the role of formal and informal support. *Child Care Health Dev* 1998;**24**:31–9.

46. St Vincent Joint Task Force for Diabetes. European Diabetes Policy Group. A desktop guide to type 1 (insulin dependent) diabetes mellitus. *Diabet Med* 1999;**16**:253–67.

47. Brown SA. Effects of educational interventions in diabetes care: a meta-analysis of findings. *Nurs Res* 1988;**37**:223–9.

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

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

50. Posovac EJ. Evaluations of patient education programs. *Eval Health Prof* 1980;**3**:47–62.

51. Mazzuca SA. Does patient education in chronic disease have therapeutic value? *J Chronic Dis* 1982;**35**:521–9.

52. Mullen PD, Green LW, Persinger MS. Clinical trials of patient education for chronic conditions: a comparative meta-analysis of intervention types. *Prev Med* 1985;**14**:753–81.

53. Padgett DK, 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.

54. Nagasawa M, Smith MC, Barnes JH, Fincham JE. Meta-analysis of correlates of diabetes patients' compliance with prescribed medications. *Diabetes Educ* 1990;**16**:192–200.

55. Galatzer A, Amir S, Gil R, Karp M, Laron Z. Crisis intervention program in newly diagnosed diabetic children. *Diabetes Care* 1982;**5**:414–19.

56. Boardway RH, Delamater AM, Tomakowsky J, Gutai JP. Stress management training for adolescents with diabetes. *J Pediatr Psychol* 1993;**18**:29–45.

57. Ryden O, Nevander L, Johnsson P, Hansson K, Kronvall P, Sjoblad S, *et al.* Family therapy in poorly controlled juvenile IDDM: effects on diabetic control, self-evaluation and behavioural symptoms. *Acta Paediatr* 1994;**83**:285–91.

58. Satin W, La Greca AM, Zigo MA, Skyler JS. Diabetes in adolescence: effects of multifamily group intervention and parent simulation of diabetes. *J Pediatr Psychol* 1989;**14**:259–75.

59. Anderson BJ, Wolf FM, Bukhart MT, Cornell RG, Bacon GE. Effects of peer-group intervention on metabolic control of adolescents with IDDM: randomized outpatient study. *Diabetes Care* 1989;**12**:179–83.

60. Delamater A, Bubb J, Davis S, Smith J, Schmidt L, White N, *et al.* Randomized prospective study of self-management training with newly diagnosed diabetic children. *Diabetes Care* 1990;**13**:492–8.

61. Anderson BJ, Brackett J, Ho J, Laffel L. An office-based intervention to maintain parent–adolescent teamwork in diabetes management. *Diabetes Care* 1999;**22**:713–21.

62. Schur H, Gamsu D, Barley V. The young person's perspective on living and coping with diabetes. *J Health Psychol* 1999;**42**:223–36.

63. Glasgow RE, La Chance P, Toobert DJ, Brown J, Hampson SE, Riddle MC. Long term effects and costs of brief behavioral dietary intervention for patients with diabetes delivered from the medical office. *Patient Educ Couns* 1997;**32**:175–84.

64. Currie C, Peters J. The demand and financial cost of hospital care for diabetes mellitus and its related complications. *Diabet Med* 1998;**15**:449–51.

65. Leese B. The costs of diabetes and its complications. *Soc Sci Med* 1992;**35**:1303–10.

66. Alexander WD, South East Thames Diabetes Physicians Group. Diabetes care in a UK health region: activities, facilities and costs. *Diabet Med* 1988;**5**:577–81.

67. Gerard K, Donaldson C, Maynard AK. The cost of diabetes. *Diabet Med* 1989;**6**:164–70.

68. Laing W, Williams R. Diabetes. London: Office of Health Economics; 1989.

69. Gray A, Fenn P, McGuire A. The cost of insulin dependent mellitus (IDDM) in England and Wales. *Diabet Med* 1995;**12**:1068–76.

70. Eastman R, Javitt J, Herman W, Dasbach E, Copley-Merriman C, Maier W, *et al.* Models of complications of NIDDM: analysis of the health benefits and cost-effectiveness of treating NIDDM with the goal of normoglycemia. *Diabetes Care* 1997;**20**:735–44.

71. Herman W, Eastman R. The effects of treatment on the direct costs of diabetes. *Diabetes Care* 1998;**21**:C19–24.

72. Deeks J, Glanville J, Sheldon T. Undertaking systematic reviews of research on effectiveness. York: NHS Centre for Reviews and Dissemination; 1996. Report no.: CRD Report No. 4.

73. Grey M, Boland E, Davidson M, Yu C, Sullivan-Bolyai S, Tamborlane W. Short-term effects of coping skills training as adjunct to intensive therapy in adolescents. *Diabetes Care* 1998;**21**:902–8.

74. Grey M, Boland E, Davidson M, Yu C, Tamborlane W. Coping skills training for youths with diabetes on intensive therapy. *Appl Nurs Res* 1999;**12**:3–12.

75. Grey M, Boland E, Davidson M, Li J, Tamborlane W. Coping skills training for youth on intensive therapy has long-lasting effects on metabolic control and quality of life. *J Pediatr* 2000;**137**:107–13.

76. Moher D, Cook DJ, Jadad AR, Tugwell P, Moher M, Jones A, *et al.* Assessing the quality of reports of randomised trials: implications for the conduct of meta-analyses. *Health Technol Assess* 1999;**3**(12).

77. Cohen J. Statistical power for the behavioral sciences. Hillsdale, NJ: Erlbaum; 1988.

78. Wolf FM. Meta-analysis: quantitative methods for research synthesis. Newbury Park: Sage; 1986.

79. Kibby MY, Tyc V, Mulhern RK. Effectiveness of psychological intevention for children and adolescents with chronic medical illness: a meta-analysis. *Clin Psychol Rev* 1998;**18**:103–17.

80. Sutton AJ, Abrams KR, Jones DR, Sheldon TA, Song F. Systematic reviews of trials and other studies. *Health Technol Assess* 1998;**2**(19).

81. Ayarra N, Trave T, Benavent M. The organization and development of summer camps for young diabetics. *Enfermeria Clinica* 1994;**4**:15–21.

82. Barglow P, Edidin DV, Budlong-Springer AS, Berndt D, Phillips R, Dubow E. Diabetic control in children and adolescents: psychosocial factors and therapeutic efficacy. *J Youth Adolesc* 1983;**12**:77–94.

83. Bloomfield S, Calder J, Chisholm V, Kelnar C, Steel J, Farquhar J, *et al.* A project in diabetes education for children. *Diabet Med* 1990;**7**:137–42.

84. Brandt P, Magyary D. The impact of a diabetes education program on children and mothers. *J Pediatr Nurs* 1993;**8**:31–40.

85. Brown S, Lieberman D, Gemeny B, Fan Y, Wilson D, Pasta D. Educational video game for juvenile diabetes: results of a controlled trial. *Med Inform* 1997;**22**:77–89.

86. Carney R, Schechter K, Davis T. Improving adherence to blood glucose testing in insulin-dependent diabetic children. *Behav Therapy* 1983;**14**:247–54.

87. Challener J, Ozen S, Barnes N. The memory blood glucose reflectance meter: a useful educational tool for the diabetic adolescent? *Practical Diabetes* 1989;**6**:219–22.

88. Chase HP, Rose B, Hoops S, Archer PG, Cribari JM. Techniques for improving glucose control in type 1 diabetes. *Pediatrician* 1983;**12**:229–35.

89. Kluczowe M, Dziatkowiak H, Boduch G, Adamczyk A, Wislocka E. Evaluation of the results of providing a full or partial education programme in the treatment of children suffering from insulin-dependent diabetes. *Pol Tyg Lek* 1992;**47**:8–11.

90. Daley B. Sponsorship for adolescents with diabetes. *Health Soc Work* 1992;**17**:173–82.

91. Elamin A, Eltayeb B, Hasan M, Hofvander Y, Tuvemo T. Effects of dietary education on metabolic control in children and adolescents with type 1 diabetes mellitus. *Diabetes, Nutrition Metab* 1993;**6**:223–9.

92. Epstein LH, Beck S, Figueroa J, Farkas G, Kazdin D, Daneman D, *et al.* The effects of targeting improvements in urine glucose on metabolic control in children with insulin dependent diabetes. *J Appl Behav Anal* 1981;**14**:365–75.

93. Esquivel-Herrera S, Villalpando-Hernandez S, Barron-Uribe C, Perez-Pasten E. Effects of nutritional education on food consumption in a group of children with insulin-dependent diabetes mellitus. *Bol Med Hosp Infant Mex* 1984;**41**:525–7.

94. Geffken G, Lewis C, Johnson S, Silverstein J, Rosenbloom A, Monaco L. Residential treatment for youngsters with difficult-to-manage insulin dependent diabetes mellitus. *J Pediatr Endocrinol Metab* 1997;**10**:517–27.

95. Gross AM, Heimann L, Shapiro R, Schultz RM. Children with diabetes: social skills training with hemoglobin A1c levels. *Behav Modif* 1983;**7**:151–64.

96. Gross AM, Magalnick LJ, Richardson P. Self-management training with families of insulin-dependent diabetic children: a controlled long-term investigation. *Child Family Behav Therapy* 1985;**7**:35–50.

97. Hansson K, Ryden O, Johnsson P. Parent-related family climate: a concomitant to metabolic control in juvenile IDDM. *Family Systems Med* 1994; **12**:405–13.

98. Herskowitz RD. Outward bound, diabetes and motivation: experiential education in a wilderness setting. *Diabet Med* 1990;**7**:633–8.

99. Heston J, Lazar S. Evaluating a learning device for juvenile diabetic children. *Diabetes Care* 1980;**3**:668–71.

100. Horan PP, Yarborough MC, Besigel G, Carlson DR. Computer-assisted self-control of diabetes by adolescents. *Diabetes Educ* 1990;**16**:205–11.

101. Huttunen N-P, Lankela S-L, Knip M, Lautala P, Kaar M-L, Laasonen K, *et al.* Effects of once-a-week training program on physical fitness and metabolic control in children with IDDM. *Diabetes Care* 1989;**12**:737–40.

102. Kaplan RM, Chadwick MW, Schimmel LE. Social learning intervention to promote metabolic control in type 1 diabetes mellitus: pilot experiment results. *Diabetes Care* 1985;**8**:152–5.

103. Kemp S, Canfield M, Kearns F, Elders M. The effect of short-term intervention on long-term diabetes management. *J Ark Med Soc* 1986;**83**:241–4.

104. Lebovitz F, Ellis G, Skyler JS. Performance of technical skills of diabetes management: increased independence after a camp experience. *Diabetes Care* 1978;**1**:23–6.

105. Lorini R, Ciriaco O, Salvatoni A, Livieri C, Larizza D, D'Annunzio G. The influence of dietary education in diabetic children. *Diabetes Res Clin Pract* 1990;**9**:279–85.

106. Lucey D, Wing E. A clinic based educational programme for children with diabetes. *Diabet Med* 1985;**2**:292–5.

107. Magrath G. Adolescent diet – fact or fantasy? *Practical Diabetes* 1985;**2**:22–5.

108. Marrero DG, Myers G, Golden MP, West D, Kershnar A, Lau N. Adjustment to misfortune: the use of a social support group for adolescent diabetics. *Pediatr Adolesc Endocrinol* 1982;**10**:213–18.

109. Marrero DG, Fremion A, Golden MP. Improving compliance with exercise in adolescents with insulin-dependent diabetes mellitus: results of a self-motivated home exercise program. *Pediatrics* 1988;**81**:519–25.

110. Marrero DG, Vandagriff JL, Kronz K, Fineberg NS, Golden MP, Gray D, *et al.* Using telecommunication technology to manage children with diabetes: the computer-linked outpatient clinic (CLOC) study. *Diabetes Educ* 1995;**21**:313–19.

111. Massouh S, Steele T, Alseth E, Diekmann J. The effect of social learning intervention on metabolic control of insulin-dependent diabetes mellitus in adolescents. *Diabetes Educ* 1989;**15**:518.

112. McNabb W, Quinn M, Murphy D, Thorp F, Cook S. Increasing children's responsibility for diabetes self-care: the In Control study. *Diabetes Educ* 1994;**20**:121–4.

113. Mendez F, Belendez M. Effects of a behavioral intervention on treatment adherence and stress management in adolescents with IDDM. *Diabetes Care* 1997;**20**:1370–5.

114. Misuraca A, Di Gennaro M, Lioniello M, Duval M, Aloi G. Summer camps for diabetic children: an experience in Campania, Italy. *Diabetes Res Clin Pract* 1996;**32**:91–6.

115. Nurick M, Johnson S. Enhancing blood glucose awareness in adolescents and young adults with IDDM. *Diabetes Care* 1991;**14**:1–7.

116. Orr DP, Golden MP, Myers G, Marrero DG. Characteristics of adolescents with poorly controlled diabetes referred to a tertiary care center. *Diabetes Care* 1983;**6**:170–5.

117. Petrolini N, Vanelli M, Chiari G, De Fanti A, Boselli E, Cantoni S. Some clinical, psycho-emotional and cognitive aspects in insulin-dependent diabetic young patients at end of camps. *Minerva Pediatr* 1994;**46**:239–43.

118. Pichert J, Murkin S, Snyder G, Boswell E, Kinzer C. Problem-based diabetes education using a video anchor. *Diabetes Spectrum* 1993;**6**:160–4.

119. Pichert J, Smeltzer C, Snyder G, Gregory R, Smeltzer R, Kinzer C. Traditional vs anchored instruction for diabetes-related nutritional knowledge, skills, and behavior. *Diabetes Educ* 1994;**20**:45–8.

120. Pichert J, Snyder G, Kinzer C, Boswell E. Problem solving anchored instruction about sick days for adolescents with diabetes. *Patient Educ Couns* 1994;**23**:115–24.

121. Pichert J, Meek J, Schlundt D, Flannery M, Kline S, Hodge M, *et al.* Impact of anchored instruction on problem-solving strategies of adolescents with diabetes. *J Am Diet Assoc* 1994;**94**:1036–9.

122. Ratner H, Gross L, Casas J, Castells S. A hypno-therapeutic approach to the improvement of compliance in adolescent diabetes. *Am J Clin Hypn* 1990;**32**:154–9.

123. Rose M, Firestone P, Heick H, Faught A. The effects of an anxiety management training on the control of juvenile diabetes mellitus. *J Behav Med* 1983;**6**:381–95.

124. Schafer L, Glasgow RE, McCaul K. Increasing the adherence of diabetic adolescents. *J Behav Med* 1982;**5**:353–62.

125. Simell T, Kaprio E, Maenpaa J, Tuominen J, Simell O. Randomised prospective study of short-term and long-term initial stay in hospital by children with diabetes mellitus. *Lancet* 1991;**337**:656–60.

126. Smith K, Schreiner B, Brouhard B, Travis L. Impact of a camp experience on choice of coping strategies by adolescents with insulin-dependent diabetes mellitus. *Diabetes Educ* 1991;**17**:49–53.

127. Smith K, Schreiner B, Jackson C, Travis L. Teaching assertive communication skills to adolescents with diabetes: evaluation of a camp curriculum. *Diabetes Educ* 1993;**19**:136–41.

128. Stratton R, Wilson DP, Endres RK, Goldstein DE. Improved glycemic control after supervised 8-wk exercise program in insulin dependent diabetic adolescents. *Diabetes Care* 1987;**10**:589–93.

129. Sundelin J, Forsander G, Mattsson SE. Family-oriented support at the onset of diabetes mellitus: a comparison of two group conditions during 2 years following diagnosis. *Acta Paediatr* 1996;**85**:49–55.

130. Swift P, Hearnshaw J, Botha J, Wright G, Raymond N, Jamieson K. A decade of diabetes: keeping children out of hospital. *BMJ* 1993;**307**:96–8.

131. Warren-Boulton E, Anderson BJ, Schwatz N, Drexler A. A group approach to the management of diabetes in adolescents and young adults. *Diabetes Care* 1981;**4**:620–3.

132. Warzak W, Ayllon T, Delcher H. Peer instruction of home glucose monitoring. *Diabetes Care* 1982;**5**:44–6.

133. Wolanski R, Sigman T, Polychronakos C. Assessment of blood glucose self-monitoring skills in a camp for diabetic children: the effects of individualized feedback counselling. *Patient Educ Couns* 1996;**29**:5–11.

134. Wysocki T, Harris MA, Greco P, Bubb J, Danda CE, Harvey LM, *et al.* Randomized controlled trial of behavior therapy for families of adolescents with IDDM. *J Pediatr Psychol* 2000;**25**:22–33.

135. Wysocki T, Harris MA, Greco P, Harvey LM, McDonell K, Danda CLE, *et al.* Social validity of support group and behavior therapy interventions for families of adolescents with insulin-dependent diabetes mellitus. *J Pediatr Psychol* 1997;**22**:635–50.

136. Mortensen HB, Hougaard P for the Hvidore Study Group. Comparison of metabolic control in a cross-sectional study of 2,873 children and adolescents with IDDM from 18 countries. *Diabetes Care* 1997;**20**:714–20.

137. Dougherty G, Soderstrom L, Schiffrin A. An economic evaluation of home care for children with newly diagnosed diabetes. *Med Care* 1998;**36**:586–98.

138. Lowes L. Evaluation of a paediatric diabetes specialist nurse post. *Br J Nurs* 1997;**6**:625–33.

139. Kaplan RM, Davis WK. Evaluating the costs and benefits of outpatient diabetes education and nutrition counseling. *Diabetes Care* 1986;**9**:81–6.

140. Bauchner C, Howland J, Adair R. The impact of pediatric asthma education on morbidity – assessing the evidence. *Am J Dis Child* 1988;**142**:398–9.

141. Panton J, White EA. Family therapy for childhood asthma. Airways module of the Cochrane database of systematic reviews. London: BMJ Publishing Group; 1996.

142. Siddons H. The cost of education. *Diabet Med* 1994;**11**:239–40.

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

144. Glasgow RE, Fisher EB, Anderson BJ, LaGreca A, Marrero D, Johnson SB, *et al.* Behavioral science in diabetes – contributions and opportunities. *Diabetes Care* 1999;**22**:832–43.

145. Glasgow RE, Osteen V. Evaluating diabetes education. *Diabetes Care* 1992;**15**:1423–32.

146. Johnson SB. Methodological issues in diabetes research: measuring adherence. *Diabetes Care* 1992;**15**(Suppl 4):1658–67.

147. Clark M, Hampson SE. Implementing a psychological intervention to improve lifestyle self-management in patients with type 2 diabetes. *Patient Educ Couns.* In press.

148. Bradley C. Designing medical and educational intervention studies – a review of some alternatives to conventional randomized controlled trials. *Diabetes Care* 1993;**16**:509–18.

Appendix 1

Search terms

Section 1 (age)

adolescen*
youth*
young people
young person*
child*
adult [and type 1 and/, ages 16, 17, 18]
teen*
juvenile
pube*

Section 2 (condition)

diabet*

Section 3 (intervention/process)

program*
educat*
interven*
inform*
teach*
train*
skill*
learn*
famil*
parent*

Section 4 (outcomes)

adher*
manage*
control*
empower*
knowledge*
diet*
skill*
exerci*
nutrition
eating and * [f, behaviour/dis,der/pattern]
weight control
regime
insulin sensitivity
behavi*
outcome*

diabet* and (adolescen* or youth* or young people or young person* or child* or teen* or juvenile or pube*) and (program* or educat* or interven* or inform* or teach* or train* or skill* or learn* or famil* or parent*) and (adher* or manage* or control* or empower* or knowledge* or diet* or skill* or exerci* or nutrition or eating or weight control or regime or insulin sensitivity or behavi* or outcome*)

diabet* + (adolescen* , youth* , young people , young person* , child* , teen* , juvenile , pube*) + (program* , educat* , interven* , inform* , teach* , train* , skill* , learn* , famil* , parent*) + (adher* , manage* , control* , empower* , knowledge* , diet* , skill* , exerci* , nutrition , eating , weight control , regime , insulin sensitivity , behavi* , outcome*)

Appendix 2

List of Mailbase discussion groups contacted

podiatry
info-allied health
evidence-based-health
focus
gp-uk
acd-ae-med
beepg
bionet-tltp
comp-med-trials
adol-npra
biomedical-sciences-education
medical-education
paediatric-nursing-forum
psych-clinical
psych-postgrads
public-health
wisdom

Appendix 3

Example of a flyer used to publicise the work of the review

A review of educational interventions for adolescents with diabetes

We are currently carrying out a systematic review of the

"Effectiveness of diabetes education interventions for adolescents"

If you have any relevant information (e.g. knowledge of / involvement with recent or ongoing projects, in any country) then we would be very pleased to hear from you.

Please could you contact Jo Hart or Lesley Storey at the address below, with details.

Jo Hart / Lesley Storey
Department of Psychology
University of Surrey
Guildford
GU2 5XH
UK

Tel: +44 (0)1483 876927
Fax: +44 (0)1483 259553
Email: Jo.Hart@surrey.ac.uk or L.Storey@surrey.ac.uk

Appendix 4

List of those who responded to any request for information

Ralf Ackerman
B J Anderson
Sue Baughan
Mary Boyle
C Bradley
Julie-Anne Burgess
B Carter
Sandy Cook
Jennifer Couper
Sally Croft
Ian Crook
Mark Duman
Trisha Dunning
Deborah Eeidin
Kathryn Ehrich
P Fonagy
Hilary Gray
T Greenhalgh
Margaret Grey
Brian Haynes
Ronald Hillson
R G Hiss
Pat Hughes
Ray Jones
Fran Kaufman
Celia Keenaghan
Z Laron
Rod Lorenz
Johnny Ludvigsson
P J Lustman
A Macklin
Terry Maguire
Ian Moody
Andrea Nelson
Ray Newton
Arie Nouwen
Maryanne Quinn
Dan Remley
Rajna Rimac
L Ruggiero
C M Ryan
K E Smith
E de Sousa
R Surwit
Tim Wysocki
M Zwi

Appendix 5

Data extraction proforma

ID reference number_____ Reviewer_____

1. Bibliographic details

Author (1st only) _____
Publication year _____
References to same study? Y/N ID number _____

2. Details of study

General details

Total number of subjects _____
Number of groups _____
Number in each group _____
Country _____

Study population – intervention group 1 (IG1)

☐ IDDM ☐ MODY (maturity-onset diabetes of the young)
Age range ___ to ___ years Mean age ____ SD ____
Mean time with diabetes _____ SD _____
Gender ____ M ____ F
Socio-economic status reported? Y/N
Racial/ethnic group membership? Y/N % of total?

Study population – intervention group 2 (IG2)

☐ IDDM ☐ MODY
Age range ___ to ___ years Mean age ____ SD ____
Mean time with diabetes _____ SD _____
Gender ____ M ____ F
Socio-economic status reported? Y/N
Racial/ethnic group membership? Y/N % of total?

Study population – control group (CG)

☐ IDDM ☐ MODY
Age range ___ to ___ years Mean age ____ SD ____
Mean time with diabetes _____ SD _____
Gender ____ M ____ F
Socio-economic status reported? Y/N
Racial/ethnic group membership? Y/N % of total?

3. Intervention

Theoretical principles – must be overtly stated (tick as many as apply and please specify author)

☐ None
☐ Cognitive behavioural therapy _____
☐ Family-therapy _____
☐ Other (please specify) _____
☐ Social learning theory _____
☐ Behavioural _____

Nature of intervention (tick as many as apply)

☐ Skills-training (e.g. insulin pump)
☐ Exercise-related
☐ Emotional/psychological
☐ Stress reduction
☐ Other (please specify) _____
☐ Diet-related
☐ Family-related
☐ Social support
☐ Not clear

Brief overview of intervention:

Interventionist (please tick as many as apply)

☐ Doctor
☐ Psychologist
☐ Peer group
☐ Other (please specify) _____
☐ Nurse
☐ Nutritionist/dietician
☐ Not clear/not specified

Disease stage

☐ Onset
☐ First year
☐ Not stated
☐ Poorly controlled
☐ Subsequent years

Mode of delivery – IG1 (please tick as many as apply)

☐ Lecture
☐ Video
☐ Computer
☐ Not clear
☐ Other (please specify) _____
☐ Interactive discussion
☐ Printed information/leaflet
☐ Motivational/patient empowerment

Mode of delivery – IG2 (please tick as many as apply)

☐ Lecture
☐ Video
☐ Computer
☐ Not clear
☐ Other (please specify) _____
☐ Interactive discussion
☐ Printed information/leaflet
☐ Motivational/patient empowerment

Mode of delivery – CG (please tick as many as apply)

☐ Lecture
☐ Video
☐ Computer
☐ Not clear
☐ Other (please specify) _____
☐ Interactive discussion
☐ Printed information/leaflet
☐ Motivational/patient empowerment

Setting (please indicate only one unless different settings for different groups – if so, please specify)

☐ Hospital clinic (outpatient)
☐ GP clinic
☐ Other community setting (e.g. camp) _____
☐ Not clear
☐ Hospital (inpatient)
☐ Home

Type of setting (please tick only one)

☐ Group
☐ Mixture
☐ Individual
☐ Not clear
☐ Family unit

Timing (upper limit)

Total time spent on intervention _____ hours
Number of sessions _____
Over what time period did the intervention take place? _____

4. Study design

Type of study – please tick as appropriate

☐ RCT
☐ Pre–post (no CG*)
☐ Waiting list CG*
☐ Meta-analysis – quantitative
☐ Other (please specify) _____
☐ Case study
☐ Post-intervention only
☐ Non-randomised CG
☐ Meta-analysis – qualitative

(* CG includes any group used for comparative purposes)

5. Assessments

☐ Baseline
☐ No follow-up, post-intervention
☐ 6 months
☐ More than 1 year (please state how long) _____
☐ Post-test
☐ Less than 6 months
☐ 1 year

Measurement of C-peptides (residual insulin production) Y/N?

OUTCOME (please specify outcome in each case)	Please state specific outcome and source of report	Baseline (mean and SD)	Post-intervention (mean and SD)	Follow-up (mean and SD)	Significant results
Outcome 1					
Outcome 2					
Outcome 3					
Outcome 4					

Please use key: IG1, IG2, IG3 and CG for groups
Please give details of other relevant findings including interaction effects

6. Methodological quality

Power of study _____
Participation rate (% of those contacted recruited) _____
Attrition rate (% of those recruited completing study) _____
Randomisation quality, scale 0–5 (please tick grade that applies)

0 = not mentioned
1 = very poor (no randomisation)
2 = poor (e.g. cluster randomisation at some sites but not others, allocation by alternate weeks of attendance)
3 = adequate (individual patients randomised but method not described)
4 = good (individual patients randomised using random number tables)
5 = excellent (patients randomised using independent randomisation system determined by person independent of intervention team)

0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

Concealment of allocation? Y/N

☐ 0 – Not stated
☐ 1 – Single-blind (patient only)
☐ 2 – Double-blind (patient and care team)
☐ 3 – Treble-blind (patient, care team and analyst)

Baseline comparability tested for

☐ Yes ☐ No ☐ Not stated

Reliable measures used?

☐ Yes ☐ No ☐ Not stated ☐ Not clear

Do the statistics used seem reasonable?

☐ Yes ☐ No ☐ Not sure

7. Cost data supplied? Y/N

8. Conclusions and implications

9. References to be chased

Appendix 6

Data summary tables (in reference order)

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Galatzer *et al.*, 1982[55]	*N* = 223 (107 IG1, 116 CG) Mean age = 15; 52% males Intervention at diagnosis Israel	IG1 – intensive psychosocial support for first month after diagnosis CG – usual care	Non-randomised CG with 3–15 years follow-up	IG1 had significantly better compliance ($p < 0.001$), family relations ($p < 0.02$) and sociability ($p < 0.025$), but the difference in school/work was not significant. Effects were specific to higher socio-economic groups	Very intensive psychosocial support at diagnosis had benefits at extended follow-up, but assessment not validated
Boardway *et al.*, 1993[56]	Poorly controlled adolescents (*N* = 19) **IG1 (*n* = 9)** Mean age = 15.44 ± 1.19; mean duration = 6.92 ± 5.79 years; 22% males **CG (*n* = 10)** Mean age = 14.32 ± 1.71; mean duration = 6.34 ± 2.61 years USA	IG1 – 13 group-based behavioural intervention sessions over 6 months for SMBG, stress management and adherence training using learning, discussion, role-play, modelling and behavioural contracting CG – usual care	RCT Assessments at baseline and 3, 6 and 9 months	IG1 improved relative to CG on diabetes-specific stress levels ($p < 0.05$) No significant differences in metabolic measures (GHb and fructosamine), maladaptive coping, diabetes self-efficacy, adherence measured by 24-hour recall interview or number of life events	Intervention did reduce reported stress but had no other effects, including metabolic control. Relaxation training was not included and this may be necessary to affect metabolic control
Ryden *et al.*, 1994[57]	Patients with type 1 diabetes for at least 1 year in poor metabolic control (*N* = 25) **IG1 (*n* = 9)** Mean age = 12.8 (four > 12 years); 33% males **IG2 (*n* = 6)** Mean age = 14.0 (four > 12 years); 33% males **CG (*n* = 10)** Mean age = 12.6; 30% males Sweden	IG1 – family therapy (Minuchin) with child psychiatrist (seven 1–2-hour sessions over 6 months) IG2 – practical instruction with paediatrician (only two families attended all seven 1–2-hour sessions over 6 months) CG – usual care	Families from one hospital randomised to IG1 or IG2, those from another hospital served as CG 12-, 22- and 32-month follow-ups depending on measure	Diabetic control (combination of HbA_{1c} and doctor ratings): eight of nine IG1 and two of nine CG patients improved ($p < 0.05$) at 12 months No effect on behavioural symptoms and self-evaluation Self-evaluation in relation to behavioural symptoms: five of nine IG1 compared to two of 10 CG patients showed healthier pattern	IG1 retained more participants than IG2, and had 'integrated and enduring positive effects', i.e. effects on self-evaluation, control and symptoms) Small sample sizes and unknown reliability of diabetes control measure limit interpretation

continued

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Satin *et al.*, 1989[58]	*N* = 32 Mean age = 14.6 ± 2.6; mean duration = 5.9 ± 4.3 years **IG1** Mean age = 15 ± 2.4; mean duration = 6.3 ± 5.1 years; 36% males **IG2** Mean age = 14.9 ± 2.8; mean duration = 5.2 ± 3.8 years; 25% males **CG** Mean age = 13.7 ± 2.7; mean duration = 6.3 ± 4.3 years; 55% males USA	IG1 and IG2 – multi-family group therapy of adolescents and parents to discuss diabetes management for six sessions over 6 weeks Parents in IG2 simulated having diabetes CG – no intervention	RCT HbA_{1c} assessed at baseline and 3 and 6 months after enrolment Parents' and teen-agers' perceptions of diabetes assessed at pre- and post-intervention Parents' ratings of child's self-care on carefulness scale assessed at pre- and post-intervention	IG2 showed significant decrease in HbA_{1c} at 3 months compared with CG ($p < 0.05$), but no difference between IG1 and CG The families that met in smaller groups in both IG1 and IG2 differed significantly from CG at 3 and 6 months Adolescents' attitudes toward 'a teenager with diabetes' in both IG1 and IG2 improved relative to CG ($p < 0.01$), but there were no other significant differences Mothers in smaller groups rated that self-care increased in both IG1 and IG2 ($p < 0.07$) but reduced in CG ($p < 0.05$)	Multifamily group therapy with parental simulation (IG2) shows some improved control Subgroup analyses should be interpreted with caution due to the small number of participants
Anderson *et al.*, 1989[59]	*N* = 70 Age range 11–14 **IG1** Mean age = 12.9; 47% males **CG** Mean age = 12.5; 47% males USA	IG1 – adolescents (taught SMBG and adjustment skills) and parents (taught skills for negotiating management responsibility) had separate concurrent 3-hour meetings every 3–4 months for 18 months at usual outpatient appointments CG – usual care	RCT Pre- and post-intervention assessments	IG1 made more use of blood glucose results to make adjustments CG showed a significantly greater decline in metabolic control over the 18 months ($p < 0.04$)	Intervention had a significant impact on GHb, and was clear and replicable, and may be used in usual outpatient clinics
Delamater *et al.*, 1990[60]	*N* = 36 newly diagnosed Age range 3–16, plus parents **IG1** Mean age = 9.3 ± 3.9; 58% males; 92% white **IG2** Mean age = 8.6 ± 4.1; 50% males; 75% white **CG** Age = 9.8 ± 2.6; 50% males; 92% white USA	IG1 – within first 4 months of diagnosis, seven sessions of SMBG training given to ajdust diet, exercise and insulin IG2 – attention placebo control CG – usual care	RCT Follow-up assessments over 2 years	IG1 had a lower HbA_1 at 1 year ($p < 0.01$) and at 2 years ($p < 0.05$) than CG after controlling for C-peptides, but not lower than IG2 No effects for SMBG Fewer dietary deviations for IG1 than for CG ($p < 0.05$)	Interventions in the first few months after diagnosis may be beneficial for diabetes control over the next 2 years

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Grey *et al.*, 1998[73]	*N* = 65 Age range 12–20 **IG1 (*n* = 34)** Mean age = 15.8 ± 2.1; 44% males **CG (*n* = 31)** Mean age = 15.0 ± 3.6; 42% males USA	IG1 – coping skills training plus intensive diabetes management CG – intensive management only Social skills training, cognitive behaviour modification and conflict resolution taught in small groups using scenarios and role play in four–eight 1–1.5-hour sessions over 4–6 weeks	RCT Baseline and 3-month assessment for all variables except HbA_{1c} which was assessed monthly	HbA_{1c} improved over time in both groups ($p < 0.001$) but more so for IG1 ($p < 0.04$) Incidence of hypos, ketoacidosis and being overweight at 3 months was similar in both groups Diabetes self-efficacy improved more in IG1 ($p < 0.05$), and IG1 patients were less upset with coping ($p < 0.001$), found coping less hard ($p < 0.01$) and diabetes had less impact on their quality of life ($p < 0.04$)	CST plus intensive diabetes management was better than intensive management only Excellent high-quality study so these results are likely to be generalisable, although not necessarily to non-white youths of a lower socio-economic status However, long-term follow-up needed
Ayarra, 1994[81]	*N* = 106 Age range 6.7–16.75; mean duration = 4.5 ± 3.0 years; 62% males Three cohorts studied Spain	Knowledge and skills training at summer camp	Pre–post camp Knowledge test of self-injection and SMBG techniques	Knowledge increased, particularly for first-timers ($p < 0.05$), and injecting and SMBG skills were improved for all	Camp was effective at increasing knowledge and skills
Barglow *et al.*, 1983[82]	*N* = 42 **IG1 (*n* = 21)** Mean age = 13.4 ± 3.3; mean duration = 59 ± 45.4 months; 43% males; 62% black **CG (*n* = 21)** Mean age = 12.2 ± 2.50; mean duration = 38.6 ± 35.4 months; 24% males; 43% black USA	IG1 – intensive, multi-component treatment given by nurse or doctor over 4 months consisting of an initial visit and assessment, clinic visits every 2 weeks, daily telephone calls providing medical care, teaching, clarification and support for self-management plus one group session CG – standard medical care	Non-randomised CG Assessed psychological characteristics at baseline and HbA_1 at baseline, 6–8 and 14–16 weeks	HbA_1 comparable in both IG1 and CG at baseline and the Coddington Social Readjustment Scale was the only measure to enable prediction of initial HbA_1 ($p < 0.01$) HbA_1 improved over time for both groups ($p < 0.01$), but more so for IG1 ($p < 0.05$). Regression analysis showed the Washington University Sentence Completion Test ego control to be the only measure to enable prediction of change in HbA_1 ($p < 0.05$)	Intensive treatment had a significant effect on HbA_1. Those with greater ego control showed more improvement and those with more life events were in poorer control at the start of study

continued

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Bloomfield *et al.*, 1990[83]	*N* = 92 **IG1 (*n* = 24)** Mean age = 9.1 ± 3.1; mean duration = 2.8 ± 2.4 years; 50% males **IG2 (*n* = 24)** Mean age = 8.9 ± 2.9; mean duration = 2.7 ± 1.9 years; 38% males **CG (*n* = 44)** Mean age = 10.4 ± 2.4; mean duration = 4.5 ± 3.2 years; 41% males UK	Diabetes club (informal meetings held in house (part of medical school) where meals prepared and semi-structured discussion groups held) replaced routine clinic on 10 afternoons over 1 year	Crossover RCT with two IGs and non-participants also acting as CG Baseline, post-intervention and 1-year follow-up	Some improvement in knowledge ($p < 0.01$), dietary intake ($p < 0.05$ for fat intake), social contacts ($p < 0.001$) and metabolic control ($p < 0.01$) whilst attending diabetes club, but effects did not last through follow-up	Novel alternative to traditional diabetes clinics, which seemed to have some benefits but the effects did not last when traditional methods of treatment were resumed
Brandt *et al.*, 1993[84]	*N* = 17 Age range 8–13, median = 11.5; mean duration = 2.25; 53% males USA	11 Group education sessions for young person and mother held over 5 days with the primary goal of improving knowledge and management skills of parents and children and the secondary goal of improving the child's feeling of competence and mother's social support	Baseline, post-intervention and follow-up assessment with no CG	Significant improvements in diabetes knowledge ($p < 0.003$), problem solving ($p < 0.002$) and management skills (insulin injection) ($p < 0.02$), which were maintained a follow-up	Knowledge and skills were gained following intervention, but this had no impact on secondary goals
Brown *et al.*, 1997[85]	*N* = 59 (31 IG1, 28 CG) Age range 8–16; duration = at least 3 months USA	Packy & Marlon video game in which characters have diabetes and engage in self-care CG given another game to play with no health connections Both groups had games for 6 months	RCT Baseline, 3- and 6-month assessments	Enjoyment of and amount of time spent playing games was same in both groups Parent reports of child's communication about diabetes ($p = 0.025$) and levels of self-care ($p = 0.003$) both increased significantly, but self-efficacy, knowledge, urgent medical visits and HbA_{1c} showed no significant differences	Video game provided a new approach to teaching diabetes self-management skills that is acceptable to this age group, but these results only showed some effectiveness on parental ratings only
Carney *et al.*, 1983[86]	*N* = 3 poorly controlled Age range 10–14, mean = 11.6; mean duration = 6.6 years; 60% males; 100% white USA	Family taught to use praise and a point reinforcement system to increase SMBG	Pre–post	All three patients had lower GHb and increased frequency of SMBG at 4-month follow-up, but no significance tests or *p*-values reported	Families reported using reinforcement strategies 70% of time, thus behavioural modification techniques can be used to improve specific outcomes; however, effects may have been due to increased parental involvement, as there was no CG to compare with

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Challener *et al.*, 1989[87]	**IG1 (*n* = 16)** Age range 13–17, mean = 14.8; mean duration = 5.8 years UK	Two brief education sessions on SMBG, followed by the use of a meter with a memory facility for 6 weeks	Pre–post and 12- and 24-week follow-ups No CG, although IG1 split into two with crossover design for 6-week memory period	Improvement in glycaemic control and frequency of SMBG seen over study period, but no significance tests or *p*-values reported despite collection of detailed data	Apparent evidence of change in a positive direction
Chase *et al.*, 1985[88]	*N* = 38 Age range 10–19 **IG1** 40% males; 21% black Participants in poor control HbA_1 > 16% USA	Eight stages of increasing intervention: 1. increase insulin dosage > 10% therapy 2. change in injection regimen 3. emphasis on SMBG 4. frequent telephone contact 5. frequent clinic visits 6. psychological help 7. family conference 8. parents take responsibility	Pre–post	At follow-up (mean = 3 years), 40% showed consistently improved HbA_1, 47% showed inconsistent improvement and rest showed no improvement, thus the uptake of different methods and their success varied No *p*-values reported	Most success resulted from change in insulin dosage, change in injection regimen, family conference and parental responsibility Little impact seen from other elements
Kluczowe, 1992[89]	*N* = 162 **IG1 (*n* = 114)** Age range 3.5–19, mean = 13, mean duration = 4.2 years, range 0.2–17.9 **CG (*n* = 48)** Age range 5.3–19.9, mean = 13.6 Poland	IG1 – 2-week knowledge and skills training programme, including diet CG – usual care, with no training programme	No random assignment to groups Post-test only at unspecified time	HbA_{1c} was better in IG1 than CG ($p < 0.001$) No gender differences Older children had poorer HbA_{1c} than younger children	Cannot attribute improved control to intervention because of other confounding differences between IG1 and CG in diabetes care and composition of the groups
Elamin *et al.*, 1993[91]	*N* = 67 Age range 9–18 **IG1 (*n* = 34)** Median age = 14; mean duration 4.4 ± 1.6 years; 50% males **CG (*n* = 33)** Median age = 14; mean duration = 4.2 ± 1.4 years; 52% males Sudan	Patients and mothers were given eight sessions over 3 months and a booklet on diet. Emphasis was placed on the effect of diet on control and prevention of complications and encouragement of parent and patient communication	RCT Baseline and post-test	Significant improvements in reported calories ($p < 0.01$), fasting glucose insulin dose ($p < 0.01$), cholesterol ($p < 0.01$) and GHb ($p < 0.01$)	In-depth dietary education improved diet and biomedical outcomes

continued

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Epstein *et al.*, 1981[92]	*N* = 19 **IG1 (*n* = 6)** Mean age = 10.1, range 9–11; 16% males; mean duration = 2.68 years **IG2 (*n* = 7)** Mean age = 10.2, range 8–12; 28% males; mean duration = 3.80 years **IG3 (*n* = 6)** Mean age = 9.8, range 6–11; 33% males; mean duration = 4.33 years USA	Eight 1–1.5-hour separate parent and child group sessions over 12 weeks, with behavioural intervention for urine testing skills, insulin adjustment, diet and exercise using a contracting and point rewards system	Multiple baseline with three waves of subjects No CG Assessments at pre- and post-intervention and 2 months	The proportion of negative (improved) urine tests increased ($p < 0.01$) from pre- to post-intervention and maintained at follow-up, and triglicerides improved from pre- to post-intervention ($p < 0.05$) Other biological outcomes either showed no change or got worse	This behavioural approach achieved the goal of increasing negative urine tests, but only a pre–post design with no CG
Esquivel-Herrera *et al.*, 1984[93]	*N* = 22 Age range 9–16; duration range 0.5–13 years; 50% males Mexico	Workshop-style nutritional education	Pre–post with no CG Baseline, post-intervention and 6-month and > 1-year follow-up	Significantly improved knowledge ($p < 0.02$) and reductions in self-reported calories ($p < 0.005$), fat ($p < 0.005$), protein ($p < 0.005$) and carbohydrate intake ($p < 0.005$)	Intervention improved knowledge and reduced food consumption over extended follow-up Changes in knowledge not associated with change in diet
Gefken *et al.*, 1997[93]	*N* = 52 poorly controlled Age range 9–18; 40% males; 27% minority USA	Residential unit using highly structured combination of individual, group and family therapy	Pre–post 1-year follow-up	Lower GHb on discharge (p = NS), and significant reduction in hospitalisations at follow-up ($p < 0.0009$) compared to pre-admission year	Improved control seen whilst in residential unit and reduced hospitalisations at follow-up, but this was a very intensive intervention, and may not be necessary to achieve the level of results achieved
Gross *et al.*, 1983[95]	*N* = 11 (6 IG1, 5 CG) Age range 9–12 USA	IG1 – social skills training to enable more appropriate verbal and non-verbal responses to difficult diabetes-related situations CG – no training	Multiple baseline with randomisation to IG1 or CG Baseline, post-training, and 1- and 6-week follow-up	Increase in eye contact and appropriate verbalisation during training in IG1, which was maintained at follow-up (no statistics reported), but no change seen in CG No changes in HbA_{1c} ($t = 0.5$, $p > 0.05$)	Social skills training seemed to be effective for specific behaviours, but changing these behaviours may have no impact on metabolic control

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Gross, 1985[96]	*N* = 14 Age range 9–13; mean duration = 4.8 years **IG1** Mean age = 11.4 **CG** Mean age = 11.5 USA	Parents and children met concurrently but separately for discussion and role playing (both IG1 and CG) IG1 also had behaviour modification training and a written lesson prior to this	RCT Baseline, post-intervention and 6-month follow-up	Children learnt principles of behaviour modification Both groups had significant improvements in HbA_1 ($p < 0.01$) but there was no significant difference between groups A number of other non-validated measures were reported but without significance tests	This study was based on previous work in a sound theoretical way, however, both groups improved Much of the evaluation data was unvalidated, unreliable and not tested for significance, but there was an excellent CG, which points to possible key components
Hansson *et al.*, 1994[97]	*N* = 25 Age range 8–18 **IG1 (*n* = 15)** Mean age = 13.3; all poorly controlled **CG (*n* = 10)** All in optimal control Sweden	IG1 – two subgroups: one traditional family therapy group led by a psychiatrist, one paediatric support group, but there was no difference in outcomes between them so results amalgamated in the report	Non-randomised CG Baseline and 1-year follow-up assessments	Interventions had positive effect on measures of family climate ($p = 0.15$) and closeness ($p = 0.004$) Differences in other measures, e.g. expressiveness were not significant	Study amalgamated results of IG1 subgroups, but these two groups were very different so effects can only be attributed to provision of support
Herskowitz, 1990[98]	*N* = 8 on Outward Bound course Age range 15–19; duration range 2–10 years USA	Involved challenging physical activities (e.g. sailing, rock climbing), insulin self-adjustment, meal planning and preparation With medically trained instructors	Informal evaluation of the course in general before and 7–11 months after Psychological measures available for six participants, with three adolescent case histories	Observation suggested that the course improved self-confidence, inner strength, determination to take charge and management skills (illustrated by three case histories) Improvement between baseline and follow-up on Achenbach Youth Self-Report for IG1 ($p < 0.05$), compared with no change in random selection of comparable adolescents No changes in other measures: Diabetes Adjustment Scale, Locus of Control and Coopersmith Self-Esteem	Evaluation primarily impressionistic with little supporting data, so no conclusions can be drawn
Heston, 1980[99]	*N* = 37 Age range 7–12 **IG1** Mean age = 10.3; 46% males **IG2** Mean age = 10; 40% males **CG** Mean age = 10; 50% males USA	IG1 – read *OK Insulin* and completed assessment game three times G2 – read *OK Insulin* and completed assessment game once CG – only completed pre- and post-test	Non-randomised assignment to groups Pre- and post-intervention knowledge tests for all groups	No differences between groups on knowledge at baseline, but average gain in knowledge higher for IG1 than IG2 and CG (no statistics provided), and there was a significant increase in knowledge for IG1 from pre- to post-intervention ($p < 0.001$) Older children had a 27% increase in knowledge from pre- to post-intervention, and higher knowledge scores than younger children ($p < 0.05$)	Older children (11–12) in early adolescence were more knowledgeable about diabetes than younger children, but still acquired further knowledge by this intervention

continued

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Horan *et al.*, 1990[100]	*N* = 20 Duration = at least 1 year **IG1 (*n* = 10)** Age range 12–19; 30% males; 30% black **CG (*n* = 10)** Age range 12–19; 30% males; 10% black USA	IG1 – computer-assisted learning of Diabetes in Self-Control, including data management and review, factual and applied diabetes education, problem solving and goal setting CG – equivalent written materials Phase 1 = baseline assessments of both IG1 and CG Phase 2 = diabetes education of both IG1 and CG Phase 3 = goal setting and problem solving for IG1 only	Subjects formed matched pairs and were then randomised to IG1 or CG Baseline and post-intervention	No change in HbA_1 or applied knowledge: 60% of IG1 and 50% of CG improved on factual knowledge (no statistical test) Compared to CG, IG1 had improved pre-lunch ($p < 0.02$) and pre-dinner ($p < 0.025$) blood glucose levels, and performed more tests ($p < 0.089$), particularly in phases 2 and 3	Some indication of modest benefits of Diabetes in Self-Control, but sample size was too small for definitive results
Huttunen *et al.*, 1989[101]	*N* = 32 Mean age = 11.9, range 8–17 **IG1** Mean duration = 4.7 years; 59% males **CG** Mean duration = 5.6 years; 59% males Finland	IG1 – 13 weekly 1-hour exercise sessions CG – usual care	RCT Baseline and post-intervention	Significant improvements in aerobic fitness ($p < 0.01$), but significant deterioration in GHb ($p < 0.01$)	Not clear why aerobic fitness improved but metabolic control deteriorated Approach was resource intensive as required the provision of a facility for exercise and a person to lead sessions
Kaplan, 1985[102]	*N* = 21 Age range 13–18; all middle class and white **IG1** Mean age = 14.9 ± 1.6; 54% males **CG** Mean age = 14 ± 1.4; 47% males USA	IG1 – social skills training based on social learning theory (Bandura): role play and discussions of difficult social situations involving peers, and made a video of enacted solutions CG – discussed medical information about diabetes, watched videos and made a video about diabetes	RCT Baseline and post-test	No differences between groups at baseline in HbA_1, diabetes knowledge, attitudes, self-care behaviour, social support satisfaction, means–ends problem solving and lie scale HbA_1 improved for IG1 compared with CG at post-test ($p < 0.05$), but no other pre–post comparisons Attitudes, behaviour, problem solving and lie scale significantly correlated with HbA_1 at follow-up	Described as a pilot study, the small patient number precludes strong conclusions, but suggested that social skills with peers play a role in self-management and better glycaemic control Knowledge did not correlate with control, but improved self-management, attitudes, problem solving and more desirable responses associated with better control
Kemp *et al.*, 1986[103]	*N* = 42 Mean age = 10, range 8–16 USA	Summer camp for 2 weeks in 1983 and 1984 with intensive management of diabetes plus 8 hours of education	Subjects studied over two annual camps, no CG HbA_{1c} assessed at start of each camp, glycated albumin (measure of control over 2–4 weeks) assessed at start and end of each camp	HbA_{1c} declined over the year from 8.1 (0.3) to 10.1 (0.3), glycated albumin improved over the 2 weeks of camp in both years (no statistics reported)	The camp seemed to be effective in improving diabetes control in the short but not the long term

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Lebovitz *et al.*, 1978[104]	*N* = 111 Mean age = 11.7 ± 2.4, range 7–17; 47% males USA	Summer camp for 2 weeks that included skills training to increase independence in diabetes management	Pre–post 6–8-month follow-up	Increased independence in insulin administration at camp ($p < 0.001$) and follow-up ($p < 0.05$) (previous campers were more independent prior to camp and maintained this), increased knowledge at camp that was maintained at follow-up ($p < 0.001$) and increased independence of performing urine tests at camp ($p < 0.001$) that was maintained at follow-up ($p < 0.001$) No improvements in dietary adherence	Educational experience of camp contributed to skills/behaviour changes that were maintained, although at lower level, at follow-up This demonstrates the importance of combining knowledge with skills training
Lorini, 1990[105]	*N* = 36 **IG1** Mean age = 14.2, range 9–21; 47% males Italy	Weekly meetings on dietary education held by doctor and dietitian, followed by further fortnightly meetings for 2 months	Pre–post No CG	Significant improvements in self-reported diet diaries, e.g. reduction in total calorie intake ($p < 0.001$), and some changes in HDL, LDL, serum nitric acid and nitrogen; but no effect on blood glucose control, triglycerides, apolipoproteins and creatinine	Simple dietary education improved patients' self-reported food diaries, with concurrent changes in some biochemical parameters
Lucey, 1985[106]	*N* = 18 Mean age = 11.67, range 8–15; duration range 0.5–9 years UK	Two 6-hour small group educational sessions using videoing and dramatisations leading to problem-solving discussions	Pre–post	Significant improvement in diabetes knowledge ($p \leq 0.025$) and problem solving ($p \leq 0.005$)	Improved knowledge and problem solving in children > 12 years of age Study highlighted knowledge deficits in adolescents
Magrath, 1985[107]	*N* = not specified Age range 11–13 UK	Four monthly small-group study days to improve group HbA_1 emphasis on diet and SMBG	Pre–post No CG Baseline, post-intervention and 6-month follow-up	Improvement in HbA_1, but significance tests not reported	Little detail of intervention, sample characteristics and no inferential statistics
Marrero *et al.*, 1982[108]	*N* = 23 **IG1 (*n* = 10)** Mean age = 15.2; mean duration = 4.9 years; 40% males **CG (*n* = 13)** Mean age = 14.7; 46% males USA	Bi-monthly social support group meetings over 8 months focusing on coping strategies for stressful events developed and rehearsed CG – usual care	RCT with waiting list CG Pre- and post-test	Trend of positive change from pre- to post-test on all outcomes for IG1, including being significantly less depressed than CG at post-test ($p < 0.02$) Differences in self-esteem were non-significant	This small pilot study suggested beneficial effects of increasing social support through a group

continued

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Marrero *et al.*, 1988[109]	*N* = 10 Mean age = 13.3, range 12–14; mean duration = 3.6 years; 60% males USA	Two sessions: one on managing exercise and one group exercise Participants sent home with exercise video to be used three times a week for 12 weeks	Pre–post Assessments at baseline and post-intervention	Significant improvement in aerobic fitness ($p = 0.045$) and GHb post-intervention ($p = 0.03$)	Brief and simple intervention that improved fitness and control If exercise maintained, this could be a useful tool
Marrero *et al.*, 1995[110]	*N* = 106 **IG1 (*n* = 52)** Mean age = 13.4 ± 4.5; 60% males; 2% minority **CG (*n* = 54)** Mean age = 13.3 ± 4.9; 59% males; 6% minority USA	Fortnightly transmission of blood glucose meter data to clinic, which was interpreted by management system and then nurses used algorithm to adjust insulin dosage	RCT Baseline and post-test (intervention lasted over 1 year)	There were no significant differences between groups in HbA_1 ($p = 0.544$), although it declined in both groups, hospitalisations ($p = 0.787$), emergency room visits ($p = 0.614$) and self-image (no *p*-value reported), but IG1 less negative on necessity of keeping blood glucose diaries and sticking finger ($p < 0.001$)	Intervention had no impact on diabetes control, however negative perceptions of testing reduced, presumably because these records were put to use
Massouh *et al.*, 1989[111]	*N* = 33 Age range 12–15 **IG1** Mean age = 12.6 ± 0.7; mean duration = 3.9 ± 3.2; 41% males **CG** Mean age = 13.1 ± 1; mean duration = 4.7 ± 3.5; 50% males USA	IG1 – 8-day diabetes camp with social learning for managing peer pressure CG – reviewed educational programme by writing questions and answers for a game show	RCT Baseline and follow-up assessments	No significant difference between CG and IG1, and both groups had a decline in metabolic control: pre–post change in HbA_1 level for both groups was in the wrong direction (IG1, $p = 0.008$; CG, $p = 0.141$)	No effect of intervention, if anything, data suggest IG1 had worse outcomes
McNabb *et al.*, 1994[112]	*N* = 24 Age range 8–12; 54% males **IG1 (*n* = 12)** Mean age = 9.7; two drop-outs **CG (*n* = 12)** Mean age = 10 USA	IG1 – parents (taught to promote child's responsibility for self-care) and children (taught skills and to take responsibility) met separately in small groups (six 1-hour sessions over 6 weeks) CG – usual care	RCT Assessments at baseline and at 12 weeks	Children's Diabetes Inventory assessed frequency and degree of child's responsibility for 35 self-care behaviours completed by parents No effects on frequency but mean responsibility increased for IG1 compared with CG at post-test ($p < 0.01$), and no effects on GHb when baseline levels controlled for	Child's responsibility for self-care increased without detrimental effects on metabolic control or frequency of performance, which supports a structured approach to developmentally appropriate transfer of self-care responsibility

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Mendez, 1997[113]	*N* = 37 **IG1 (*n* = 18)** Mean age = 13.83 ± 2.0; 50% males; mean duration = 3.73 ± 3.93 years **CG (*n* = 19)** Mean age = 13.36 ± 1.89; 47% males; mean duration = 4.46 ± 3.52 years Spain	IG1 – 10 group sessions for adolescents over 4 months plus two sessions for parents to teach several behavioural procedures (e.g. social skills training, stress management, SMBG) CG – usual care	Quasi-experimental design with non-equivalent CG Pre–post and 13-month follow-up	Significant improvements at post-test on patients' information (p = 0.000), barriers (p = 0.000), daily hassles (p = 0.000), social skills (p = 0.05), SMBG (p = 0.01), and at follow-up on barriers (p = 0.000), daily hassles (p = 0.006) and social skills (p = 0.01) Parents' information social support improved at post-test (p = 0.000) No effect on blood glucose levels, diet or exercise	Multicomponent behavioural intervention had many beneficial effects that were maintained at follow-up, but study design had limitations (e.g. no randomisation) No effects on blood glucose levels, diet or exercise, which could be due to ceiling effects for this well-controlled group
Misuraca *et al.*, 1996[114]	*N* = 256 (87) Mean age = 10, range 8–16; 47% males Italy	Summer camps (mean duration = 10 days) with 3-monthly meetings post-camp	Pre–post	Significant increase in knowledge (p < 0.01) and significant reduction in GHb (p < 0.01)	Data on only 87 presented, no detail of subgroups, some monthly meetings held, but no description of content so cannot draw conclusions
Nurick, 1991[115]	*N* = 15 Age range 11–17 **IG1** Mean age = 14.5; 50% males; 33% black **CG** Mean age = 13.9; 56% males; 11% black All participants were inpatients for poorly controlled diabetes during intervention USA	IG1 – blood glucose awareness training with period of estimating blood sugars and testing, using three 45–60-minute education sessions CG – usual care	Non-RCT Baseline and post-test	Accuracy of blood glucose estimates improved (p < 0.02), but no improvement in mean blood glucose control (NS)	Blood glucose awareness can be improved with brief intervention However, still far from ideal and more intensive training may be required, and does not address the reasons for poor control
Orr *et al.*, 1998[116]	*N* = 15 Mean age = 15.3, range 11–20; 40% males; mean duration = 5.1 years, range 1.5–11.5; lower middle–middle class I Hispanic Poor control USA	Medical, educational and counselling provided based on each patient's needs Counselling was one or more of the following: group therapy, family treatment based on Minuchin, and individual psychotherapy	Pre–post with no CG Assessments at baseline and 12–18 months later HbA_{1c} at baseline and follow-up Other outcomes were subjective judgements of improvement	Nine of 15 patients were judged as having improved on medical, psychological and compliance outcomes (no p-values reported) HbA_{1c} changes were not significant	Cannot attribute improvement to educational or counselling intervention because medical care also changed, and no CG to compare with

continued

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Petrolini *et al.*, 1994[117]	*N* = 53 Mean age = 14.4 ± 2, range 8–15; 58% males; mean duration = 4 ± 2.9 years Italy	8-day summer camp	Pre–post with no CG Baseline and post-intervention assessments	Significant improvement in knowledge ($p < 0.05$), and camps seen as recreational	Unclear description of camp content with poor evaluation that was more about perception of camp
Pichert *et al.*, 1993[118]	*N* = 70 56% males **IG1** Age range 10–15 **CG** Age range 10–15 USA	AI using video to enhance exercise-related diabetes management	RCT Baseline and post-intervention assessments	Significant impact on knowledge ($p < 0.01$), and approaching significance for problem solving ($p = 0.08$)	Sound theory to intervention, but needs longer follow-up, good CG
Pichert *et al.*, 1994[119]	*N* = 69 Age range 9–15 **IG1** Mean age = 11.5; mean duration = 6.1 years **CG** Mean age = 13; mean duration = 6.5 years USA	IG1 – AI using video story to prompt a problem-solving task CG – non-AI education programme	RCT, pre–post	Both IG and CG showed improvements in knowledge and meal choice ($p < 0.01$ for all skills) but no difference between groups	AI did not produce increased benefits over normal education
Pichert *et al.*, 1994[120]	*N* = 84 at diabetes camp Age range 9–15; mean duration = 6.9 years, range 3–14; 36% males 12–15 year olds were compared with 9–11 year olds USA	IG1 – groups of 10–12 campers for two 45-minute sessions for AI on sick day guidelines, which involved watching a videodisk of person facing diabetes-related management problems and discussing solutions CG – watched video on sick day guidelines and discussed	RCT Sick day knowledge test pre- and post-intervention, sick day problem-solving test post-intervention and at 8-months, and assessment of recall, number of explanations, and conditional probability of recalling a guideline and explanation for its use	Older group had higher knowledge scores than younger group, and both IG1 and CG had higher post- than pre-test scores ($p < 0.01$) No effect on recall or explanations post-test, but conditional probability score better for IG1 ($p < 0.01$) At 8 months, older group better than younger on all measures, and explanations ($p < 0.03$) and conditional probability score ($p < 0.02$) better for IG1 than CG. More IG1 than CG parents reported shared responsibility with child for sick day management ($p < 0.05$)	Only mixed support for AI, which did not have different effects for older age group

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Pichert *et al.*, 1994[121]	*N* = 16 Age range 14–15; mean duration = 6.8 years, range 1.5–10; 50% males USA	All received AI in problem-solving strategies for dietary problems using video and discussion in small groups led by dietician for two 50-minute sessions over 1–3 days at summer camp	Half the participants were chosen randomly to be tested a few days before the intervention and half within 24 hours after	In a role-playing/ problem-solving test, more of those tested after AI gave appropriate solutions to a problem particularly less all-or-non and more adjustment ($p < 0.02$)	This pilot study had several limitations, but suggests that AI may result in new knowledge that can be generalised to new situations
Ratner *et al.*, 1990[122]	*N* = 7 long-term non-adherent recruited from poor deprived neighbourhood Mean age = 15.4, range 11–19; mean duration = 7.4 years; 43% males USA	Three initial training sessions on self-hypnosis, taught to practice twice daily. Follow-up sessions for a further 6–12 months	Pre–post	Significant improvements in fasting blood sugar ($p < 0.001$) and GHb over the intervention period ($p < 0.001$)	Intervention seems to have some utility in this lower socio-economic class, low self-care group, but study poorly designed with no follow-up data
Rose *et al.*, 1983[123]	*N* = 6 Age range 15–18; duration > 3 years; 0% males Canada	Psychological testing on personality and intelligence with feedback, followed by anxiety management training over 6 months	Pre–post Baseline and post-test assessments	Significant ($p < 0.01$) reductions in % of glucose in urine (using test strips) and in amount of urine in 24-hour collections. No reduction in measures of anxiety	Although some indices of control improved, these are not accepted as reliable indicators of blood sugar levels, and there was no effect on anxiety with a low participation rate
Schafer *et al.*, 1982[124]	Three case studies: Kathy: age = 18, duration = 7 years Tom: age = 16, duration = 4 years Kim: age = 18, duration = 11 years USA	Social learning theory, involving self-monitoring, goal setting, and behavioural contracting if needed with therapist working with patient and parent	Three case studies using a multiple baseline, across behaviours design Assessments of behaviours daily during baseline and intervention period and at 2-month follow-up Metabolic control assessed by urine and blood glucose tests at pre- and post-intervention and follow-up	Kathy improved on wearing diabetic identification, exercise, frequency of urine testing and metabolic control Tom improved on timing of morning insulin injection (but this was not maintained), frequency of urine testing, exercise and metabolic control Kim's SMBG was unreliable so data not reported No *p*-values reported	Intervention successful with two of three patients across a range of self-management behaviours
Simell *et al.*, 1991[125]	*N* = 61 newly diagnosed Age range 0–14 **IG1 (*n* = 31)** **IG2 (*n* = 30)** Finland	Both groups received diabetes education from a multidisciplinary team over the first month IG1 – short hospital stay (mean = 9 days) so both inpatient and outpatient education IG2 – long hospital stay (mean = 23 days) so all inpatient education	RCT Baseline and regular testing over 1 month and up to 2 years of follow-up	Metabolic control (HbA_1 and HbA_{1c}) improved similarly in both groups over first month ($p = 0.01$) and increased slightly over follow-up ($p = 0.001$). Insulin dose was lower in IG1 than IG2 (p = NS)	Short and long hospital stays seem to be equally effective in managing newly diagnosed diabetes in the first month and for up to 2 years. This has implications for cost-effective treatment at diabetes onset

continued

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Smith *et al.*, 1991[126]	*N* = 108 Mean age = 14.5 ± 1.4; mean duration = 53.7 ± 42.5 months; 44% males; 96% white USA	Stress management intervention delivered in small groups for 1 hour per day during camp	Pre–post, no CG	Ways of coping measured from pre- to post-intervention Increase in problem-focused coping ($p < 0.03$) and decrease in detachment coping from pre- to post-intervention ($p < 0.001$). Girls decreased in wishful thinking whereas boys increased ($p < 0.05$)	Intervention may have led to improvements in intended coping strategies at end of camp compared to those reported to have been used before, but study design weak
Smith *et al.*, 1993[127]	*N* = 86 Mean age = 4.9 ± 3.4, range 13–17; mean duration = 4.1 ± 3.4 years; 57% males USA	Assertiveness training built into summer camp programme through didactic information, sharing of personal experiences and role-playing	Pre–post with no CG Assessments at baseline, post-intervention and 3 months	Assertiveness scores improved at follow-up ($p < 0.001$) and adolescents reported improved communication with father ($p < 0.05$) and mother ($p = 0.06$), but parents did not report any such change following intervention	Significant effect only seen in self-report of behaviour but changes not validated by parents, thus adolescents at least know what assertiveness is and how to do it, but may not be implementing skill
Stratton, 1987[128]	*N* = 16 white **IG1** Mean age = 15.1; 50% males **CG** Mean age = 15.5; 50% males USA	IG1 – 30–45 minutes of exercise training at hospital gym three times a week for 8 weeks CG – exercise recommendations	RCT Baseline and post-test assessments	Improved cardiovascular fitness ($p < 0.05$), and reduced glycosylated serum albumin ($p < 0.01$) and blood glucose values (NS) However, no impact on anthropometric and lipids measures (all NS)	Indicates benefits from making exercise part of diabetes management, but this cannot be used to inform how to achieve increased exercise in adolescents
Sundelin, 1996[129]	*N* = 36 families of those newly diagnosed with diabetes **IG1** Mean age = 8, range 3–13.1 (12 aged 8–15); 37% males **CG** Mean age = 8.8, range 4–14; 37% males Sweden	IG1 – family spent up to 2 weeks in apartment at hospital receiving family therapy from psychotherapist as well as multidisciplinary team support (seven sessions over 6 months) CG – family stayed in hospital and met same amount with pediatrician and received multidisciplinary team support	RCT HbA_{1c} (at baseline, 1 and 2 years), intelligence tests (at baseline and 2 years), self-esteem (at diagnosis, 6, 12 and 24 months), children's behaviour checklist (at 6 and 24 months), family climate (at diagnosis, 1, 6, 12 and 24 months) and family relations (at diagnosis, 6, 12 and 24 months)	HbA_{1c} in the subgroup of children aged 8–15 years appeared to be worse in IG1 ($p < 0.05$) at 2 years, but this was attributed to three extreme scores No other effects for older group reported	There seems to be no clear benefit from the intervention
Swift *et al.*, 1993[130]	*N* = 236 (138 IG1, 98 CG) Age range 0–14 at diagnosis UK	IG1 – cared for at home at diagnosis CG – admitted to hospital at diagnosis	Post-intervention review of medical notes	No significant differences in metabolic control ($p = 0.37$) but fewer hospitalisations in IG1 ($p = 0.001$)	Although fewer hospitalisations in IG1, there are too many confounds to draw conclusions

continued

Reference details	Sample characteristics	Intervention	Study design and assessments	Measures and results	Conclusions and implications
Warren-Boulton *et al.*, 1981[131]	*N* = 5 Age range 17–23; 0% males; 100% black USA	Intensive group setting with multidisciplinary healthcare team Baseline assessments for 5 days in hospital followed by 18 monthly group meetings	Pre–post, no CG	Improved metabolic control during study (fasting glucose, $p < 0.01$; HbA_{1c}, $p < 0.05$; lower cholesterol, $p < 0.05$; and reduced insulin dose, $p < 0.05$) Sample described as having increased personal responsibility for and openness about diabetes, and better school attendance and concentration	Authors concluded that intensive group setting was effective in producing better diabetes control and psychosocial outcomes. Cost of intervention was US$520 per patient
Warzak, 1982[132]	*N* = 20 Age range 9–15 USA	Peer intervention of SMBG during 2-week summer camp	Assessed SMBG frequency by naïve users during the camp	96% practiced SMBG at least once, no *p*-values reported	Peer instruction of SMBG is effective
Wolanski *et al.*, 1996[133]	*N* = 41 (20 IG1, 19 CG, two drop-outs) Age range 8–16; duration range 4 months–12 years; 51% males USA	IG1 – SMBG skills training in a single one-to-one session plus one small group session during camp CG – no SMBG training	RCT, pre–post Baseline and in final week of camp	IG1 improved slightly in the absolute systematic error in blood glucose test, and CG got slightly worse (p = NS) Both groups improved slightly in the random error in blood glucose test (p = NS)	SMBG training not effective, probably because skills were already reasonable. Problem may be more one of attitude to diabetes care than skills deficit
Wysocki *et al.*, 1997[134]	*N* = 119 All had at least moderate levels of general or type 1 diabetes-specific conflict. Age range 12–17 **IG1** Mean age = 14.5 ± 1.2; 44% males; 21% black **IG2** Mean age = 14.1 ± 1.4; 50% males; 20% black USA	IG1 – behaviour family systems therapy: problem solving, communication skills training, and functional and structural family therapy IG2 – family educational support groups CG – usual care	RCT Baseline and post-test	Adolescents (p = 0.004) and mothers (p = 0.002) rated therapy better than education group on treatment evaluation questionnaire Other outcomes reported elsewhere	Well-designed and reported study, but only treatment evaluation questionnaire reported here, which has not been validated as only designed for this study

Health Technology Assessment Programme

Prioritisation Strategy Group

Members

Chair
Professor Kent Woods
Director,
NHS HTA Programme, &
Professor of Therapeutics
University of Leicester

Professor Bruce Campbell
Consultant General Surgeon
Royal Devon & Exeter Hospital

Professor Shah Ebrahim
Professor of Epidemiology
of Ageing
University of Bristol

Dr John Reynolds
Clinical Director
Acute General Medicine SDU
Oxford Radcliffe Hospital

Dr Ron Zimmern
Director, Public Health
Genetics Unit
Strangeways Research
Laboratories, Cambridge

HTA Commissioning Board

Members

Programme Director
Professor Kent Woods
Director, NHS HTA
Programme, &
Professor of Therapeutics
University of Leicester

Chair
Professor Shah Ebrahim
Professor of Epidemiology
of Ageing
University of Bristol

Deputy Chair
Professor Jon Nicholl
Director, Medical Care
Research Unit
University of Sheffield

Professor Douglas Altman
Director, ICRF Medical
Statistics Group
University of Oxford

Professor John Bond
Director, Centre for Health
Services Research
University of Newcastle-
upon-Tyne

Ms Christine Clark
Freelance Medical Writer
Bury, Lancs

Professor Martin Eccles
Professor of
Clinical Effectiveness
University of Newcastle-
upon-Tyne

Dr Andrew Farmer
General Practitioner &
NHS R&D
Clinical Scientist
Institute of Health Sciences
University of Oxford

Professor Adrian Grant
Director, Health Services
Research Unit
University of Aberdeen

Dr Alastair Gray
Director, Health Economics
Research Centre
Institute of Health Sciences
University of Oxford

Professor Mark Haggard
Director, MRC Institute
of Hearing Research
University of Nottingham

Professor Jenny Hewison
Senior Lecturer
School of Psychology
University of Leeds

Professor Alison Kitson
Director, Royal College of
Nursing Institute, London

Dr Donna Lamping
Head, Health Services
Research Unit
London School of Hygiene
& Tropical Medicine

Professor David Neal
Professor of Surgery
University of Newcastle-
upon-Tyne

Professor Gillian Parker
Nuffield Professor of
Community Care
University of Leicester

Dr Tim Peters
Reader in Medical Statistics
University of Bristol

Professor Martin Severs
Professor in Elderly
Health Care
University of Portsmouth

Dr Sarah Stewart-Brown
Director, Health Services
Research Unit
University of Oxford

Professor Ala Szczepura
Director, Centre for Health
Services Studies
University of Warwick

Dr Gillian Vivian
Consultant in Nuclear
Medicine & Radiology
Royal Cornwall Hospitals Trust
Truro

Professor Graham Watt
Department of
General Practice
University of Glasgow

Dr Jeremy Wyatt
Senior Fellow
Health Knowledge
Management Centre
University College London

continued

continued

Diagnostic Technologies & Screening Panel

Members

Chair
Dr Ron Zimmern
Director, Public Health Genetics Unit
Strangeways Research Laboratories
Cambridge

Dr Philip J Ayres
Consultant in Epidemiology & Public Health
The Leeds Teaching Hospitals NHS Trust

Mrs Stella Burnside
Chief Executive, Altnagelvin Hospitals Health & Social Services Trust
Londonderry
Northern Ireland

Dr Paul O Collinson
Consultant Chemical Pathologist & Senior Lecturer
St George's Hospital, London

Dr Barry Cookson
Director, Laboratory of Hospital Infection
Public Health Laboratory Service, London

Professor Howard Cuckle
Professor of Reproductive Epidemiology
University of Leeds

Dr Carol Dezateux
Senior Lecturer in Paediatric Epidemiology
Institute of Child Health
London

Professor Adrian K Dixon
Professor of Radiology
Addenbrooke's Hospital
Cambridge

Mr Steve Ebdon-Jackson
Head, Diagnostic Imaging & Radiation Protection Team
Department of Health, London

Dr Tom Fahey
Senior Lecturer in General Practice
University of Bristol

Dr Andrew Farmer
General Practitioner & NHS Clinical Scientist
Institute of Health Sciences
University of Oxford

Mrs Gillian Fletcher
Antenatal Teacher & Tutor
National Childbirth Trust
Reigate

Professor Jane Franklyn
Professor of Medicine
University of Birmingham

Dr JA Muir Gray
Joint Director, National Screening Committee
NHS Executive, Oxford

Dr Peter Howlett
Executive Director – Development
Portsmouth Hospitals NHS Trust

Professor Alistair McGuire
Professor of Health Economics
City University, London

Mrs Kathlyn Slack
Professional Support
Diagnostic Imaging & Radiation Protection Team
Department of Health
London

Mr Tony Tester
Chief Officer, South Bedfordshire Community Health Council
Luton

Pharmaceuticals Panel

Members

Chair
Dr John Reynolds
Clinical Director – Acute General Medicine SDU
Oxford Radcliffe Hospital

Dr Felicity J Gabbay
Managing Director, Transcrip Ltd
Milford-on-Sea, Hants

Mr Peter Golightly
Director, Trent Drug Information Services
Leicester Royal Infirmary

Dr Alastair Gray
Director, Health Economics Research Centre
Institute of Health Sciences
University of Oxford

Mrs Jeannette Howe
Senior Principal Pharmacist
Department of Health, London

Dr Andrew Mortimore
Consultant in Public Health Medicine
Southampton & South West Hants Health Authority

Mr Nigel Offen
Head of Clinical Quality
NHS Executive – Eastern
Milton Keynes

Professor Robert Peveler
Professor of Liaison Psychiatry
Royal South Hants Hospital
Southampton

Mrs Marianne Rigge
Director, College of Health
London

Dr Frances Rotblat
Manager, Biotechnology Group
Medicines Control Agency
London

Mr Bill Sang
Chief Executive
Salford Royal Hospitals NHS Trust

Dr Eamonn Sheridan
Consultant in Clinical Genetics
St James's University Hospital
Leeds

Mrs Katrina Simister
New Products Manager
National Prescribing Centre
Liverpool

Dr Ross Taylor
Senior Lecturer
Department of General Practice & Primary Care
University of Aberdeen

Dr Richard Tiner
Medical Director
Association of the British Pharmaceutical Industry
London

Professor Jenifer Wilson-Barnett
Head, Florence Nightingale Division of Nursing & Midwifery
King's College, London

Mr David J Wright
Chief Executive
International Glaucoma Association, London

Therapeutic Procedures Panel

Members

Chair
Professor Bruce Campbell
Consultant General Surgeon
Royal Devon & Exeter Hospital

Professor John Bond
Professor of
Health Services Research
University of Newcastle-upon-Tyne

Ms Judith Brodie
Head of Cancer
Support Service
Cancer BACUP, London

Ms Tracy Bury
Head of Research
& Development
Chartered Society of
Physiotherapy, London

Mr Michael Clancy
Consultant in A&E Medicine
Southampton General Hospital

Professor Collette Clifford
Professor of Nursing
University of Birmingham

Dr Katherine Darton
Information Unit
MIND – The Mental Health
Charity, London

Mr John Dunning
Consultant Cardiothoracic
Surgeon
Papworth Hospital NHS Trust
Cambridge

Mr Jonothan Earnshaw
Consultant Vascular Surgeon
Gloucestershire Royal Hospital

Professor David Field
Professor of Neonatal Medicine
The Leicester Royal Infirmary
NHS Trust

Professor FD Richard Hobbs
Professor of Primary Care
& General Practice
University of Birmingham

Mr Richard Johanson
Consultant & Senior Lecturer
North Staffordshire Infirmary
NHS Trust, Stoke-on-Trent

Dr Duncan Keeley
General Practitioner
Thame, Oxon

Dr Phillip Leech
Principal Medical Officer
Department of Health, London

Professor James Lindesay
Professor of Psychiatry for
the Elderly
University of Leicester

Professor Rajan Madhok
Director of Health Policy
& Public Health
East Riding & Hull
Health Authority

Dr Mike McGovern
Branch Head
Department of Health
London

Dr John C Pounsford
Consultant Physician
Frenchay Healthcare Trust
Bristol

Dr Mark Sculpher
Senior Research Fellow in
Health Economics
University of York

Dr Ken Stein
Consultant in Public
Health Medicine
North & East Devon
Health Authority, Exeter

Expert Advisory Network

Members

Professor John Brazier
Director of Health Economics
University of Sheffield

Mr Shaun Brogan
Chief Executive, Ridgeway
Primary Care Group
Aylesbury, Bucks

Mr John A Cairns
Director, Health Economics
Research Unit
University of Aberdeen

Dr Nicky Cullum
Reader in Health Studies
University of York

Professor Pam Enderby
Chair of Community
Rehabilitation
University of Sheffield

Mr Leonard R Fenwick
Chief Executive
Freeman Hospital
Newcastle-upon-Tyne

Ms Grace Gibbs
Deputy Chief Executive
West Middlesex
University Hospital

Dr Neville Goodman
Consultant Anaesthetist
Southmead Hospital, Bristol

Professor Robert E Hawkins
CRC Professor & Director of
Medical Oncology
Christie Hospital NHS Trust
Manchester

Professor Allen Hutchinson
Director of Public Health &
Deputy Dean, ScHARR
University of Sheffield

Professor David Mant
Professor of General Practice
Institute of Health Sciences
University of Oxford

Professor Alexander Markham
Director
Molecular Medicine Unit
St James's University Hospital
Leeds

Dr Chris McCall
General Practitioner
Corfe Mullen, Dorset

Dr Peter Moore
Freelance Science Writer
Ashtead, Surrey

Dr Sue Moss
Associate Director, Cancer
Screening Evaluation Unit
Institute of Cancer Research
Sutton, Surrey

Mrs Julietta Patnick
National Coordinator
NHS Cancer Screening
Programmes, Sheffield

Professor Jennie Popay
Professor of Sociology &
Community Health
University of Salford

Professor Chris Price
Professor of
Clinical Biochemistry
St Bartholomew's & The
Royal London School of
Medicine & Dentistry

Mr Simon Robbins
Chief Executive
Camden & Islington
Health Authority, London

Dr William Rosenberg
Senior Lecturer &
Consultant in Medicine
University of Southampton

Dr Sarah Stewart-Brown
Director, Health Services
Research Unit
University of Oxford

Dr Gillian Vivian
Consultant in Nuclear
Medicine & Radiology
Royal Cornwall Hospitals Trust
Truro

Mrs Joan Webster
Former Chair
Southern Derbyshire
Community Health Council
Nottingham

Feedback

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

The Correspondence Page on the HTA website (http://www.ncchta.org) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

Copies of this report can be obtained from:

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 23 8059 5639 Email: hta@soton.ac.uk
http://www.ncchta.org

ISSN 1366-5278