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Diabetes Education for Children With Type 1 Diabetes Mellitus and Their Families

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

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We are grateful to Karalee Ratzlaff for collecting potentially relevant studies, Dr. Nina Buscemi for providing feedback on the draft of this report, and Ken Bond for editing the report.

Structured Abstract

Objectives: To determine the effectiveness of diabetes education on metabolic control, diabetes-related hospitalizations, complications, and knowledge, quality of life and other psychosocial outcomes for children with type 1 diabetes and their families.

Data Sources: A systematic and comprehensive literature review was conducted in 21 electronic databases of medical and health education literature to identify randomized controlled trials (RCTs) and observational studies evaluating the effectiveness of diabetes education.

Review Methods: Study selection, quality assessment, and data extraction were conducted independently by several investigators in duplicate. A descriptive analysis is presented.

Results: From 12,756 citations, 80 studies were identified and included in the review (53 RCTs or CCTs, 27 observational studies). The methodological quality of studies was generally low.

Most studies (35/52) that examined the effect of educational interventions on HbA1c found no evidence of increased effectiveness of the interventions over the education provided as part of standard care. Successful interventions were heterogeneous and included cognitive behavioral therapy, family therapy, skills training and general diabetes education. Most studies reported a positive effect on health service utilization (i.e., reduced use), although less than half were statistically significant. There was no clear evidence that educational interventions had an effect on short-term complications.

The effect of educational interventions on diabetes knowledge was unclear with 12/30 studies reporting a significant improvement. Interventions which had varying effects on knowledge scores included diabetes camp, general diabetes education, and cognitive behavioral therapy. In the area of self management/regimen adherence, 10/21 studies reported improving this outcome significantly. Successful interventions included general diabetes education and cognitive behavioral therapy. Educational interventions were successful in improving various psychosocial outcomes.

The results of two studies examining refinements to intensive therapy education suggest that educational interventions may enhance the effects of intensive diabetes management in reducing HbA1c.

Conclusions: Due to the heterogeneity of reported diabetes education interventions, outcome measures, and duration of followup, there is insufficient evidence to identify a particular intervention that is more effective than standard care to improve diabetes control or quality of life or to reduce short-term complications.

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Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/diabetesed/diabetesed.pdf

Executive Summary

Introduction

Currently, type 1 diabetes affects 1 in every 400 to 600 children, and more than 13,000 children are newly diagnosed each year.[1,2]

Type 1 diabetes is managed by insulin replacement and balancing of diet and exercise in order to maintain glycemic control and prevent the occurrence of complications. Glycemic control, which is linked directly to complication rates,[1] is monitored by the measurement of glycosylated hemoglobin (HbA1c), which reflects the mean blood glucose level over the previous 2 to 3 months. Lowering HbA1c has been associated with a reduction of microvascular complications of diabetes.[3]

In order to effectively manage diabetes, education about components of management such as blood glucose monitoring, insulin replacement, diet, exercise, and problem solving strategies must be delivered to the patient. Education is important both at diagnosis, where there is usually no knowledge base and patient and family are given the basic skills for controlling the disease,[4] and throughout the patient's lifetime, with ongoing attention to self-management skills, screening and prevention of complications, and to new developments in these areas. Since management of diabetes requires lifestyle changes, it is important that education be delivered to the whole family.

Key Questions

The American Academy of Pediatrics put forth the following five questions:

1. What is the evidence that diabetes education on day-to-day management of diabetes improves metabolic control (as determined by HbA1c, numbers of diabetes-related hospitalizations, frequency of diabetic ketoacidosis [DKA] and numbers of episodes of hypoglycemia)?
2. What is the evidence that medical nutrition therapy education on day-to-day management of diabetes improves HbA1c values and results in less variability in blood glucose levels?
3. What is the evidence that diabetes education results in improved long-term management of diabetes, including better adherence to recommendations made in clinic and decreased hospitalizations and emergency department (ED) visits for diabetes-related complications?
4. What is the evidence that diabetes education programs improve knowledge about diabetes management?
    a. What is the evidence that this knowledge increases the child's self-confidence in his or her ability to handle the disease and has a positive impact on the child's quality of life (QOL) and other psychosocial issues (e.g., school absences, school performance, adherence to a medical regimen)?
    b. What is the evidence that this knowledge improves long-term metabolic control (i.e., decreases or prevents diabetes-related complications), as shown in the Diabetes Control and Complications Trial (DCCT) (as measured by retinal, renal, cardiovascular, and neurological evaluations), in children of families who receive

these diabetes education or medical nutrition therapy program services compared to children of families who do not receive these services?

5. What is the evidence that training in intensive diabetes management (consistent with DCCT, including blood glucose monitoring at least four times a day, three or more daily insulin injections or use of an insulin pump and education on when and how to adjust insulin doses) conducted in the practitioner setting yields:
   a. Improved metabolic control, (as determined by HbA1c values, numbers of diabetes-related hospitalizations, frequency of DKA and numbers of episodes of hypoglycemia)?
   b. A decrease in or prevention of diabetes-related complications (as measured by retinal, renal, cardiovascular, and neurological evaluations), as demonstrated by DCCT?

Methods

Literature Search

Search terms were adapted for the following electronic databases: MEDLINE® Ovid, Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), HealthSTAR, EMBASE, CINAHL®, ERIC, PsycINFO®, CINAHL Plus with Full Text (EBSCO), Science Citation Index Expanded® and Social Sciences Citation Index® (both via ISI Web of Knowledge℠), PubMed®, LILACS (Latin American and Caribbean Health Science Literature), Proquest® Dissertations & Theses, CRISP (Computer Retrieval of Information on Scientific Projects), National Library of Medicine (NLM) Gateway, OCLC ProceedingsFirst and PapersFirst, and trial registries such as The National Research Register, ClinicalTrials.gov, and Current Controlled Trials. We also searched websites of relevant professional associations, and reference lists of relevant reviews and included studies. Only English-language studies were included.

Study Selection

Two reviewers independently screened titles and abstracts to determine if an article met general inclusion criteria. The full text of all articles identified as “include” or “unclear” was retrieved for formal review.

Using a priori inclusion criteria, two reviewers independently assessed each full text article using a standard form. Disagreements were resolved by consensus or third-party adjudication.

Quality Assessment

Two reviewers independently assessed the methodological quality of included studies. The Jadad Scale and Schulz criteria for allocation concealment were used to assess the methodological quality of randomized and nonrandomized controlled clinical trials. In a post hoc assessment, trials were given credit if outcome assessors were blinded to outcomes. The Thomas Quality Assessment Tool for Quantitative Studies was used to assess studies of other designs. In addition, the funding source was recorded.

Data Extraction

Data were extracted by one reviewer using standardized forms and checked for accuracy and completeness by a second reviewer. Extracted data included inclusion/exclusion criteria, and the characteristics of participants, interventions, and outcomes. Disagreements were resolved by consensus or third-party adjudication.

Data Analysis

Due to extreme heterogeneity in study designs, interventions, populations, and outcomes, no meta-analyses were performed. Interventions were grouped into nine broad categories: general diabetes education (21 studies), interventions based on cognitive behavioral therapy (24 studies), family therapy (9 studies), skills training (7 studies), and programs delivered at diabetes camps (17 studies), as well as psychoeducation (2 studies) and a physical activity program (1 study). Results are presented first by outcome (e.g. HbA1c), then by intervention, and then by population subgroup (general population, children with newly diagnosed diabetes, or children with poor metabolic control).

Results

Included Studies

As a result of the search, 12,756 citations were identified. One hundred articles were included in the review, representing 80 unique primary studies.[5-84] The number of enrolled participants in the studies ranged from 11 to 332 (median = 50 [IQR = 30 to 89]). The mean age of study participants ranged from 2.7 to 16 years.

Outcomes

HbA1c. 52 studies assessed the effectiveness of diabetes education programs in controlling HbA1c levels (Table 1). Overall, the methodological quality of studies was low, with three RCTs assessed as high quality and nine studies assessed as moderate quality. Thirty-one studies assessed the general population of children with diabetes. Nine studies reported that HbA1c levels decreased significantly following the interventions. The successful interventions fell into the categories of family therapy (n = 3), cognitive behavioral therapy (n = 4), general diabetes education (n = 1), and skills training (n = 1). The one moderate quality RCT examined the addition of a coping skills intervention to intensive diabetes management. Six studies found that HbA1c levels improved significantly for both the intervention and control groups; however, differences between groups were not statistically significant. The remaining 16 studies reported that diabetes education had no significant effect on improving HbA1c levels, thus in the majority of the studies there was no evidence for increase in effectiveness of the educational interventions over the education provided in standard care.

Eight studies assessed diabetes education delivered to children with newly diagnosed diabetes and their families (Table 1). Three studies assessed general diabetes education or family therapy programs that were delivered in an ambulatory setting vs. education delivered during hospitalization. One study reported that the decrease in HbA1c levels was significantly greater for the home-based group vs. the inpatient group, whereas the other two found no significant differences in HbA1c levels between groups. The results of the remaining studies were inconsistent. Three studies reported that cognitive behavioral therapy and skills training interventions resulted in lower HbA1c levels in the intervention group, one study reported that both groups improved, and one study found no difference between the two groups.

Thirteen studies examined HbA1 in children with poorly controlled diabetes (Table 1). Two large, high quality RCTs examining general diabetes education and family therapy reported that the intervention had no significant impact on HbA1c levels. The results of the remaining studies were inconsistent. Four studies reported that HbA1c levels improved following the intervention. Two studies reported an improvement in HbA1c in both intervention and control groups, but there was no significant difference between groups. The remaining five studies reported that diabetes education had no significant effect on HbA1c levels. Due to the heterogeneity across studies and the general low methodological quality, it is difficult to conclude which interventions may have an effect over and above standard care.

Health service utilization. Eleven studies assessed impact of diabetes education on health service utilization (Table 1). Measures of health service utilization included length of stay and hospital or ED admissions for diabetes- and non-diabetes-related complications. Overall, the methodological quality was moderate with one RCT assessed as high quality, six rated as moderate, and four rated as low quality.

The four studies assessing this outcome in the general patient population provide some evidence that diabetes education has an impact on utilization (Table 1). However, there is considerable heterogeneity across studies making it difficult to generalize the results.

Three of the four studies that examined children with newly diagnosed diabetes reported some reduction in health services utilization following the intervention. The results of the three studies that targeted children with poor metabolic control were inconsistent. The high quality RCT reported increased hospital admission rates for both intervention and control groups (i.e., no improvement), while the two low quality trials reported significantly fewer hospital admissions in the intervention group compared to the control group.

Complications. Fifteen studies examined the effect of diabetes education in controlling complications (Table 1). Most studies reported on the incidence of severe hypoglycemia; six reported on the incidence of DKA. Six of the studies were of moderate quality and the other nine were assessed as low quality.

Of the 10 studies that examined the general population of children with diabetes, six found that the intervention had a significant effect. The effective interventions included general diabetes education (n = 2), cognitive behavioral therapy (n = 2), and skills training (n = 2).The remaining studies either showed that there was no improvement or that there was no significant difference between groups for this outcome.

Of three studies assessing this outcome in children with newly diagnosed diabetes, two reported a significant improvement in the intervention group. The third study comparing inpatient vs. outpatient delivery of education found no difference between groups.

The remaining 2 studies assessed children with poor metabolic control and the results both favored the interventions (general diabetes education and diabetes camp).

Knowledge. Thirty studies assessed the effectiveness of diabetes education in improving knowledge. Most studies (n = 20) were assessed as low quality, however, 10 were evaluated as moderate and one RCT as high quality (Table 1). Twenty-four studies examined the general population of children with diabetes. Interventions included general diabetes education (n = 8), cognitive behavioral therapy (n = 6), diabetes camps (n = 7) and skills training (n = 2). Two before-after studies of moderate quality studies reported gains in knowledge after a cognitive behavioral therapy and general diabetes education intervention; however, three other moderate quality before-after studies did not find a significant change following the intervention. The results of the remaining studies were also inconsistent: five reported statistically significant increases in knowledge; two reported found the interventions to be effective in subgroups of the study population; six reported knowledge gains that were not statistically significant or were not retained over the long-term.

Three moderate quality studies compared inpatient vs. ambulatory education in children with newly diagnosed diabetes. All three studies reported increases in knowledge levels for both groups, but differences between groups were not statistically significant. It should be noted that the interventions and outcome measures among studies were different from one another, so results may not be generalizable.

Three studies assessed knowledge among children with poor metabolic control. One high quality RCT did not find a significant change in knowledge for either group. One before-after study reported significant increases in knowledge following a diabetes camp, and one CCT reported significantly higher knowledge levels over the short-term but these gains were not sustained over the long-term.

Skills. Nine studies assessed the effect of diabetes education on the development of diabetes management skills, including self-monitoring of blood glucose (SMBG), nutrition and diet-related skills, and urine testing (Table 1). In the general population of children with diabetes, four studies (2 cognitive behavioral therapy[48] and 2 camp interventions) found gains in these skills, while four reported no significant change in skills following the intervention.

In the population of children with poor metabolic control, one RCT conducted at diabetes camp found no significant difference between intervention and control groups in SMBG.

Self-management/adherence. Twenty-one studies assessed self management and regimen adherence (Table 1). Of these, fourteen focused on the general population of children with diabetes. One moderate quality and seven low quality studies reported a significant improvement in self-management in the intervention group. Successful interventions included general diabetes education (n = 2), cognitive behavioral therapy (n = 3) and family therapy (n = 2). The remaining studies did not show a significant change.

One study assessed this outcome among children who were newly diagnosed with diabetes and found no significant change. Five studies focused on children with poor metabolic control. One RCT found a significant effect on self-management in blood testing and adherence; the remaining studies found no significant change.

Psychosocial outcomes. Thirty-nine studies examined one or more psychosocial outcomes, including family or social relationships, family or social support, social skills, coping, self-perception, self-efficacy, stress, depression and anxiety (Table 1). Diabetes education was effective in improving several psychosocial outcomes; however, the

methodological quality of the studies was generally low and there was considerable heterogeneity across interventions, time points, and measures used.

Quality of life. Two studies found that cognitive behavioral therapy and general diabetes training intervention improved quality of life in the intervention group (Table 1). The remaining two studies that examined this outcome reported that the education interventions had no significant effect.

School performance. There was limited evidence relating to this outcome (Table 1). In the two studies assessing this outcome, diabetes education programs did not have a significant effect on school absence or sick days.

Table 1. Summary table for diabetes education for children with type 1 diabetes

Intervention	Quantity of evidence	Quality of evidence	Results			Summary of findings	Strength of evidence
			IG improved vs. CG; significant	IG or both IG & CG changed; NS	No change		
General population of children with diabetes							
HbA1c							
General diabetes education	4 RCT	Low		1	3	In general, interventions were not effective; heterogeneity across interventions precluded direct comparisons; some studies assessed content while others looked at mode of delivery (e.g., video game, group vs. individual training)	Low
	2 B-A	Moderate	1		1		
	1 B-A	Low		1			
	1 Cohort	Low		1			
Cognitive behavioral therapy	1 RCT	Moderate	1			Individual studies demonstrated that some cognitive behavioral therapy interventions may be effective (e.g., coping skills training); heterogeneity across interventions precluded direct comparisons	Low
	8 RCT	Low	2	3	3		
	1 CCT	Low		1			
	1 Cohort	Low	1				
Diabetes camp	1 RCT	Low			1	No effect	Moderate
	2 CCT	Low			2		
	1 B-A	Low			1		
Family therapy	3 RCT	Low	3			Interventions that focus on family teamwork or support may be effective	Moderate
Physical training	1 RCT	Low			1	Insufficient evidence	
Skills training	1 B-A	Low			1	Mixed effects	Low
	1 Cohort	Low	1				
Psychoeducation	1 RCT	Moderate			1	Insufficient evidence	
Health services utilization							
General diabetes education	1 RCT	Moderate	1			Individual studies demonstrated that some interventions may be effective; heterogeneity across interventions precluded direct comparisons	Moderate
	1 RCT	Low	1				
	1 B-A	Moderate	1				
Diabetes camp	1 B-A	Moderate		1		Insufficient evidence	

*Comparing inpatient vs. ambulatory delivery of education intervention; B-A = uncontrolled before-and-after; CCT = controlled clinical trial; CG = control group; IG = intervention group; NS = non significant; RCT = randomized controlled trial

Table 1. Summary table for diabetes education for children with type 1 diabetes (continued)

Intervention	Quantity of evidence	Quality of evidence	Results			Summary of findings	Strength of evidence
			IG improved vs. CG; significant	IG or both IG & CG changed; NS	No change		
General population of children with diabetes (continued)							
Short-term complications							
General diabetes education	1 RCT	Moderate	1			Individual studies demonstrated that some interventions may be effective; heterogeneity across interventions precluded direct comparisons	Low
	2 B-A	Moderate	1		1		
	1 B-A	Low		1			
	1 Cohort	Low	1				
Cognitive behavioral therapy	2 RCT	Moderate	1		1	Mixed effects; 1 RCT reported complication rates decreased; however, rates were still unacceptably high	Low
	1 Cohort	Low	1				
Physical training	1 RCT	Low			1	Insufficient evidence	
Skills training	1 RCT	Low	1			Skills training interventions may be effective	Low
	1 Cohort	Low	1				
Knowledge							
General diabetes education	3 RCT	Low	1	1	1	Specific interventions may be effective; heterogeneity across interventions and outcome measures precluded direct comparisons	Low
	1 CCT	Low	1				
	2 B-A	Moderate	2				
	2 B-A	Low	1	1			
Cognitive behavioral therapy	1 RCT	Moderate		1		Specific interventions may be effective; heterogeneity across interventions precluded direct comparisons	Low
	2 RCT	Low	1		1		
	3 CCT	Low	1	2			
	1 B-A	Moderate	1				
Diabetes camp	1 RCT	Moderate		1		Mixed effects; content of specific interventions varied across studies	Low
	2 RCT	Low	1		1		
	1 CCT	Low			1		
	3 B-A	Low	2		1		
Skills training	1 B-A	Moderate		1		May be effective; knowledge increased but changes were NS	Low
	1 B-A	Low		1			
Skills							
Cognitive behavioral therapy	1 RCT	Low			1	Specific interventions may be effective; heterogeneity across interventions precluded direct comparisons	Low
	1 CCT	Low	1				
	1 B-A	Low	1				

Table 1. Summary table for diabetes education for children with type 1 diabetes (continued)

Intervention	Quantity of evidence	Quality of evidence	Results			Summary of findings	Strength of evidence
			IG improved vs. CG; significant	IG or both IG & CG changed; NS	No change		
General population of children with diabetes (continued)							
Skills (continued)							
Diabetes camp	3 RCT	Low			3	Mixed effects; content of specific interventions varied across studies	Low
	1 B-A	Moderate			1		
	2 B-A	Low	2				
Self-management or regimen adherence							
General diabetes education	3 RCT	Low	2		1	Specific interventions may be effective; heterogeneity across interventions precluded direct comparisons	Low
	1 CCT	Low	1				
	1 B-A	Moderate			1		
Cognitive behavioral therapy	1 RCT	Moderate	1			Specific interventions may be effective; heterogeneity across interventions precluded direct comparisons	Low
	4 RCT	Low	2		2		
Family therapy	2 RCT	Low	2			Specific interventions may be effective	Low
Diabetes camp	2 CCT	Low			2	No effect	Low
Psychosocial outcomes							
General diabetes education	1 RCT	Low	1			Specific interventions may be effective improving family support and coping skills	Low
	1 B-A	Low	1				
Cognitive behavioral therapy	3 RCT	Moderate	2	1		Specific interventions may be effective in improving family relationships, family support, efficacy, self-perception	Low
	2 RCT	Low	2				
	3 CCT	Low	2		1		
	1 Cohort	Low	1				
	1 B-A	Moderate	1				
Family therapy	3 RCT	Low		1	2	No effect	Low
Diabetes camp	2 CCT	Low	2			Mixed effects; content of specific interventions varied across studies	Low
	1 B-A	Moderate			1		
	3 B-A	Low	1		2		
Skills training	1 B-A	Low	1			Insufficient evidence	
Quality of life							
General diabetes education	1 B-A	Moderate	1			Insufficient evidence	
Cognitive behavioral therapy	1 RCT	Moderate	1			Insufficient evidence	

Table 1. Summary table for diabetes education for children with type 1 diabetes (continued)

Intervention	Quantity of evidence	Quality of evidence	Results			Summary of findings	Strength of evidence
			IG improved vs. CG; significant	IG or both IG & CG changed; NS	No change		
General population of children with diabetes (continued)							
Quality of life (continued)							
Family therapy	1 RCT	Low		1		Insufficient evidence	
Skills training	1 B-A	Low		1		Insufficient evidence	
School performance							
Diabetes camp	1 RCT	Moderate		1		Insufficient evidence	
Children with newly diagnosed diabetes							
HbA1c							
General diabetes education	1 RCT	Moderate	1*			Compared inpatient vs. ambulatory delivery of education; mixed effects; interventions were dissimilar	Low
	1 Cohort	Moderate			1*		
Cognitive behavioral therapy	1 RCT	Moderate	1			Specific interventions may be effective (e.g., family-based skills training); the comparison group for one study was 'no education'	Low
	1 CCT	Low	1				
Family therapy	2 RCT	Low		1*	1	Insufficient evidence; 1 study found no difference between inpatient vs. ambulatory delivery of education	
Skills training	1 RCT	Low		1		Mixed effects	Low
	1 Cohort	Moderate	1				
Health service utilization							
General diabetes education	2 Cohort	Moderate	1		1*	Insufficient evidence; 1 study compared inpatient vs. ambulatory setting; 1 assessed skill level of educator	
Cognitive behavioral therapy	1 CCT	Low	1			Insufficient evidence	
Skills training	1 Cohort	Moderate	1			Insufficient evidence	
Short-term complications							
General diabetes education	1 RCT	Moderate		1*		Insufficient evidence	
Cognitive behavioral therapy	1 CCT	Low	1			Insufficient evidence	
Skills training	1 Cohort	Moderate	1			Insufficient evidence	

Table 1. Summary table for diabetes education for children with type 1 diabetes (continued)

Intervention	Quantity of evidence	Quality of evidence	Results			Summary of findings	Strength of evidence
			IG improved vs. CG; significant	IG or both IG & CG changed; NS	No change		
Children with newly diagnosed diabetes (continued)							
Knowledge							
General diabetes education	1 RCT	Moderate		1*		Compared inpatient vs. ambulatory delivery of education; knowledge increased in both groups; interventions were dissimilar	Low
	2 Cohort	Moderate		2*			
Self-management and regimen adherence							
General diabetes education	1 RCT	Moderate	1*			Compared inpatient vs. ambulatory delivery of education; mixed effects	Low
	1 Cohort	Moderate			1*		
Psychosocial outcomes							
General diabetes education	1 RCT	High	1			No effect	Low
	1 RCT	Low			1		
	2 Cohort	Moderate			2		
Cognitive behavioral therapy	1 RCT	Low			1	Insufficient evidence	
Family therapy	3 RCT	Low			3	No effect	Moderate
Skills training	1 RCT	Low	1			Insufficient evidence	
School performance							
General diabetes education	1 RCT	Moderate		1		Insufficient evidence	
Children with poor metabolic control							
HbA1c							
General diabetes education	1 RCT	High			1	No effect	Low
	1 RCT	Low		1			
Cognitive behavioral therapy	4 RCT	Low		1	3	In general, interventions were not effective; heterogeneity across interventions precluded direct comparisons	Low
	2 CCT	Low	2				
Diabetes camp	1 B-A	Low	1			Insufficient evidence	
Family therapy	1 RCT	High			1	No effect	Low
	1 B-A	Low			1		
Skills training	1 RCT	High		1		No effect	Low
	1 RCT	Low			1		
Psychoeducation	1 CCT	Low	1			Insufficient evidence	

Table 1. Summary table for diabetes education for children with type 1 diabetes (continued)

Intervention	Quantity of evidence	Quality of evidence	Results			Summary of findings	Strength of evidence
			IG improved vs. CG; significant	IG or both IG & CG changed; NS	No change		
Children with poor metabolic control (continued)							
Health service utilization							
General diabetes education	1 RCT	High			1	Insufficient evidence	
Skills training	1 RCT	Low	1			Insufficient evidence	
Psychoeducation	1 CCT	Low	1			Insufficient evidence	
Short-term complications							
Diabetes camp	1 B-A	Low	1			Insufficient evidence	
Knowledge							
General diabetes education	1 RCT	High			1	Insufficient evidence	
Cognitive behavioral therapy	1 CCT	Low		1		Insufficient evidence	
Diabetes camp	1 B-A	Low	1			Insufficient evidence	
Self-management and regimen adherence							
General diabetes education	1 RCT	Low	1			Insufficient evidence	
Cognitive behavioral therapy	2 RCT	Low		1	1	No effect	Low
Family therapy	1 RCT	High		1		No effect	Low
	1 B-A	Low			1		
Skills							
Diabetes camp	1 RCT	Low			1	Insufficient evidence	
Psychosocial outcomes							
General diabetes education	1 RCT	High			1	No effect	Low
	1 RCT	Low			1		
Cognitive behavioral therapy	4 RCT	Low			4	No effect	Low
	1 CCT	Low	1				
Family therapy	1 RCT	High	1			Mixed effects	Low
	1 B-A	Low			1		

Discussion

Key Question 1. The results of this review do not indicate that any specific educational intervention improves day-to-day management of metabolic control as determined by HbA1c. More intensive interventions such as cognitive behavioral therapy and family therapy appear to have a small benefit. Studies set in diabetes camps do not show any clear improvement in diabetes control. Diabetes education appears to be effective in decreasing health care utilization, and this effect appears to be associated with education that is intense, provided by specialists, and multidisciplinary teams, and involves some form of psychotherapy or psychosocial focus.

Results were unclear in the area of diabetes-related short-term complications. Most studies did not have high enough rates of DKA to show significant differences. Studies reporting on hypoglycemia covered the spectrum of possible outcomes. A possible explanation for this may be that hypoglycemia has so many potential causes. For example, an intervention may target nocturnal hypoglycemia, but not physical activity-related hypoglycemia. It is also possible that both standard care and standard diabetes education effectively reduce the incidence of hypoglycemia, making it difficult to demonstrate differences among types of educational interventions.

It has been hypothesized that changes in HbA1c may be mediated by changes in knowledge, skills, attitudes and/or behavior. In the 16 studies that examined the association between knowledge and short-term metabolic control the results were inconsistent. It appears that an increase in knowledge is not sufficient to bring about behavior change that improves metabolic control. Likewise, in the 24 studies that measured both psychosocial outcomes and HbA1c, the four studies that measured quality of life and HbA1c, the two studies that measured skills and HbA1c, and the 18 studies that measured adherence and HbA1c, there was little coherence across these outcomes.

Key Question 2. There is no clear evidence on whether medical nutrition therapy education does or does not improve diabetes control. We identified only one uncontrolled before-and-after study that specifically assessed medical nutrition therapy education as the intervention for children attending a diabetes camp. There were several studies that described a nutritional component or module as part of their intervention and reported improved nutritional knowledge or behavior after the intervention; however, this did not correlate with a lowering of HbA1c. Several other studies showed no significant changes in HbA1c or regimen adherence. Further research is needed to answer this question.

Key Question 3. There were no data to answer the question about what, if any, educational interventions improve long-term control and reduce long-term diabetes-related complications. Long-term followup in diabetes is considered 5 to 10 years. Only three studies followed participants for more than 2 years.

Key Question 4. A small number of studies reported that cognitive behavioral therapy or general diabetes education had an effect on knowledge scores in favor of the intervention. However, in the majority of studies that assessed this outcome, there was no difference in knowledge scores between those who received the intervention vs. those who received education that was part of their standard diabetes care. Therefore, no clear recommendation can be made on types of education, beyond standard care, that may improve knowledge. There was also no particular intervention that showed a consistent positive effect of diabetes

education on psychosocial outcomes, including quality of life and school performance. We were unable to assess whether improved knowledge had an effect on long- term metabolic control because none of the included studies followed participants beyond 2 years.

Key Question 5. Three studies contributed information to the key question on training in intensive diabetes management in the practitioner setting. All three studies reported improved metabolic control after initiation of the intensive treatment which persisted up to 1 year later. The results of the two studies that examined refinements to the education provided suggest that educational interventions may support the effects of intensive diabetes management in reducing HbA1c levels. In terms of short-term acute complications, the studies showed mixed results with one group reporting an unacceptably high level of severe hypoglycemia suggesting that further educational interventions may need to be explored.

Future Research Opportunities

Recommendations for further research include:

- Appropriately powered RCTs are needed to assess cognitive behavioral therapy, family therapy, motivational interviewing and frequency of contact with health care professionals on HbA1c and short-term complications, especially in the population of children with poorly controlled diabetes
- RCTs should specify the components of education that is part of standard care and followup. A survey of standard diabetes education programs so that researchers are aware of the diversity of standard care would be a useful addition to the literature.
- Additional research is needed in the area of medical nutrition therapy education.
- Future studies assessing the effect of educational strategies on quality of life should use a standard, validated outcome measure.
- Five- to ten-year followup will help to assess the effect of education on long-term complications of diabetes.
- RCTs and CCTs should blind outcome assessors to the intervention and should report allocation concealment.
- Additional research is needed to examine the aspects of education that improve outcomes associated with intensive diabetes management.

Conclusions

Due to the heterogeneity of reported diabetes education interventions that are delivered to children with type 1 diabetes and their families, outcome measures, and duration of followup, there is insufficient evidence to recommend a particular education intervention to improve metabolic control, reduce short-term acute complications, or improve quality of life.

Evidence Report

Chapter 1. Introduction

Type 1 diabetes is the third most common chronic condition in children and adolescents in the United States.[4] This condition affects 1 in every 400 to 600 children, and more than 13,000 children are newly diagnosed each year.[1,2] In 1995, more than 140,000 children and adolescents were affected by this disorder,[85] while in 2001, the prevalence was estimated to be 1.54 cases per 1000 youth in 2001.[86] In 2002, the total estimated direct and indirect costs related to diabetes (type 1 and type 2) were $132 billion in the United States.[2]

Type 1 Diabetes Mellitus

Diabetes mellitus is the general name for a group of chronic metabolic diseases characterized by high blood glucose levels that result from defects in insulin secretion and/or action. The two main forms of diabetes are insulin-dependent diabetes mellitus (IDDM) or type 1 diabetes and noninsulin-dependent or type 2 diabetes. Type 2 diabetes is more commonly diagnosed in adulthood and is characterized by the body's inability to use insulin properly. Although type 1 diabetes can be diagnosed in adulthood, it usually develops and is diagnosed in childhood and adolescence.

Type 1 diabetes occurs when the beta cells of the pancreatic islets of Langerhans, which are responsible for insulin production, are progressively destroyed by the immune system. The body's ability to produce insulin becomes progressively impaired until eventually no insulin is produced. The insulin deficiency results in decreased insulin utilization and increased hepatic glucose production leading to hyperglycemia. In addition, there is an increased breakdown of adipose tissue leading to ketonemia and eventual diabetic ketoacidosis (DKA) that, if left untreated, is potentially fatal.[87]

Acute Complications of Type 1 Diabetes

Type 1 diabetes and its treatment has two major acute complications: DKA and hypoglycemia. DKA is a metabolic state resulting from acute hyperglycemia. DKA has a mortality rate of 0.5 percent, mostly due to cerebral edema, the most frequent diabetes-related cause of death. DKA is most common at presentation, occurring in an average of 40 percent (15 to 83 percent in population studies) of children presenting with diabetes. In established diabetes, the rate is 1 to 8 percent per year. Risk factors include infection, insulin omission, and equipment malfunction. DKA is treated with immediate hospitalization, insulin replacement, and rehydration.

Hypoglycemia is a complication of insulin treatment. Symptoms caused by a fall in blood glucose include shakiness and emotional instability. In severe cases, there may be seizures or unconsciousness. There has been concern about possible brain dysfunction due to prolonged or repeated hypoglycemic episodes; however, there is limited evidence of permanent cognitive sequelae and they are considered minor.[88,89] The prevalence rates for this complication vary due to potential under-reporting of minor episodes. Studies looking at the prevalence of severe hypoglycemia in children and adolescents report a range of 4 to 86 episodes per 100 patient years.[3,90] Hypoglycemia is most frequent at

night, is most serious in younger children due to their relatively higher rate of glucose utilization, and is a possible cause of death. It can be avoided with education about symptoms, careful meal planning, and nighttime glucose monitoring.

Chronic Complications

Chronic complications associated with type 1 diabetes include microvascular complications such as retinopathy, nephropathy, and neuropathy, and macrovascular complications. Macrovascular complications include circulatory and cardiovascular events such as stroke and myocardial infarction, which are rare in children and adolescents; however, risk factors such as hypertension, smoking and dislipidemia should be managed. Chronic complications have been linked to poor glycemic control and the duration of the disease.[91] Many chronic complications are rare in childhood, but management of diabetes in childhood has implications for later development of complications. Donaghue et al.[92] found that although the survival-free period of retinopathy and microalbinuria was significantly longer for those diagnosed before 5 years of age compared with those diagnosed later, the risk of clinical retinopathy increased by 28 percent for every prepubertal year of duration and by 36 percent for every post-pubertal year of duration. However, there has been a declining incidence of some of the longterm complications over recent decades,[93,94] likely due to improvements in diabetes management.

Diabetes Management and Education

Type 1 diabetes is managed by a combination of insulin replacement and balancing of diet and exercise in order to maintain glycemic control and prevent the occurrence of complications. Glycemic control, which is directly linked to complication rates,[91] is monitored by the measurement of glycosylated hemoglobin (HbA1c), which reflects the mean blood glucose level over the previous 2 to 3 months. Lowering HbA1c has been associated with a reduction of microvascular and neuropathic complications of diabetes.[3]

It is generally accepted that in order to effectively manage diabetes, education about components of management such as blood glucose monitoring, insulin replacement, diet, exercise, and problem solving strategies must be delivered to the patient and family. Education seems necessary both at diagnosis, where there is usually no knowledge base and patient and family are given the basic skills for controlling the disease,[4] and throughout the patient's lifetime, with ongoing attention to self-management skills, screening and prevention of complications, and new developments in these areas. Since management of diabetes requires lifestyle changes, most clinicians feel it is important for education to be delivered to the whole family. The following report attempts to determine whether there is evidence to support the general belief that diabetes education is necessary and/or beneficial.

Current Standards

The American Diabetes Association (ADA) has published standards regarding diabetes management in children[95] and self-management education.[96] Key points are that management should involve a physician-coordinated team of professionals and should recognize the interaction between parent and family, physician, and other members of the health care team. Individual factors (age, schedule, culture, family dynamics, developmental stage, and physiologic differences related to maturity) should be considered when developing a treatment plan. The goal for glycemic control is to self-monitor and to achieve an HbA1c measure as close to normal as possible in the absence of hypoglycemia. Severe or frequent hypoglycemia indicates the need to modify treatment regimens, including setting higher glycemic goals. Since hypoglycemia is more of a concern in children, the optimum glycemic goals for children are set according to age and are higher in younger children.

Medical nutrition therapy, the nutrition education and counseling that is intended to help people with diabetes achieve optimal blood glucose control, should be individualized. Education can help people to balance and adjust their food choices according to their activity and insulin levels, avoid and treat hyperglycemia and hypoglycemia, and adjust meal patterns when feeling ill.[97] The amounts and types of carbohydrates in food affect blood glucose level and need monitoring; however, a low-carbohydrate diet is not recommended. The recommended diet for diabetics is now closer to the recommended guidelines for all Americans, thereby eliminating the need to use special diabetic foods.[97] In children, medical nutrition therapy should be provided at diagnosis and reviewed annually to ensure normal growth.

Diabetes self-management education (DSME) is considered an integral component of care and is recommended at diagnosis and thereafter. DSME helps people with diabetes initiate effective self-care when first diagnosed and also helps people maintain effective self-management as diabetes presents new challenges and as treatment advances become available. In children, education must take into account that younger children will require adult supervision. As children mature, it is expected that they take on more responsibility for their own monitoring and care. An issue in this transition is adherence to insulin and diet regimens.

DSME helps patients optimize metabolic control, prevent and/or manage complications, and maximize their quality of life in a cost effective manner. It is reimbursed as part of the Medicare program.[96]

Intensive Diabetes Management and DCCT

The Diabetes Control and Complications Trial (DCCT) demonstrated that intensive therapy was highly beneficial in decreasing the incidence of complications in type 1 diabetes.[98] Intensive therapy included the administration of insulin by injection or pump 3 or more times daily. The dosage was adjusted in accordance with the results of self-monitoring of blood glucose at least 4 times per day, dietary intake, and anticipated exercise. Specific blood glucose concentration goals were set and patients visited the

study center each month and were in telephone contact to review and adjust regimens. This was in contrast to conventional treatment, which had one or two daily injections of insulin, daily self-monitoring of urine or blood glucose, education about diet and exercise, and did not usually include daily adjustments in insulin dosage. Goals included absence of symptoms and maintenance of normal growth and development, but not specific blood glucose targets.

Followup demonstrated that the benefit of intensive therapy in decreasing complications was maintained. This trial established a new philosophy of treatment in using a multidisciplinary team approach and using adjustments based on data monitored by the patient. It is of interest to know if families can be educated to use this intensive style of management outside the trial setting.

Educational Interventions

Educational interventions can take many forms. Didactic education, computer games, board games, cognitive behavioral therapy, and telephone calls are some of the possible methods of delivery. The education may be directed at the patient alone, parent alone, the whole family, and even peers. Education delivered at diagnosis is different than the education on self-management that occurs throughout the patient's lifetime. At diagnosis, the skills needed to manage the disease are first introduced. Later, education may be needed to adjust to the ongoing challenges of developmental changes with a chronic disease, and to keep apprised of new treatments. The aim of the educational interventions may be, among other things, to improve metabolic control, reduce complications, gain skills in self-management, or improve quality of life.

Reviews of educational and psychosocial interventions for adults with diabetes have been conducted and have shown beneficial effects.[4] Those reviews that have examined programs targeted to meet the particular needs of children have primarily focused on the adolescent population.[4,99] The systematic review by Grey et al. (2000)[21] appears to be the only one that has assessed diabetes education for both children and adolescents.[21] The review by Gage et al. (2004)[4] found that most interventions could be categorized into programs focusing on knowledge/skills, psychosocial issues, and behavior/self-management. They found that there were modest improvements across outcomes such as behavior and metabolic control but that there was little evidence regarding their long-term effectiveness. They also reported that hospital inpatient education at diagnosis was not significantly more effective than home based education and suggested that education may be most beneficial in patients whose metabolic control is poor. The review on psychological interventions by Winkley et al. (2006)[100] found that psychological treatments such as supportive or counseling therapy, cognitive behavior therapy, psychoanalytically informed therapies, and family systems therapy improved glycemic control in children and adolescents with diabetes but had no effect in adults. The review by Grey et al.,[21] which examined education in children specifically, concluded that educational interventions were useful in improving diabetes knowledge, but they were not consistently useful in improving metabolic control. They also reported that psychosocial interventions such as coping skills training helped adolescents to improve

adjustment and metabolic control, and that family interventions may be helpful in reducing parent-child conflict about diabetes management.

Objective of this Evidence Report

The objective of this review is to synthesize the evidence examining the effectiveness of diabetes education on day-to-day management of diabetes as it relates to metabolic control, health care utilization, complications, knowledge about management, and its effect on psychosocial issues and metabolic control, and intensive diabetes management.

The Key Questions

The key questions for this Task Order are:

1. What is the evidence that diabetes education on day-to-day management of diabetes improves metabolic control (as determined by glycosylated hemoglobin[76] [HbA1c] values, numbers of diabetes-related hospitalizations, frequency of diabetic ketoacidosis [DKA] and numbers of episodes of hypoglycemia)?
2. What is the evidence that medical nutrition therapy education in day-to-day management of diabetes improves HbA1c values and results in less variability in blood glucose levels?
3. What is the evidence that diabetes education results in improved long-term management of diabetes, including better adherence to recommendations made in clinic and decreased hospitalizations and emergency room visits for diabetes-related complications?
4. What is the evidence that diabetes education programs improve knowledge about diabetes management?
    a. What is the evidence that this knowledge increases the child's self-confidence in his or her ability to handle the disease and has a positive impact on the child's quality of life (QOL) and other psychosocial issues (e.g., school absences, school performance, adherence to a medical regimen)?
    b. What is the evidence that this knowledge improves long-term metabolic control (i.e., decreases or prevents diabetes-related complications), as shown in the Diabetes Control and Complications Trial (DCCT) (as measured by retinal, renal, cardiovascular and neurological evaluations), in children of families who receive these diabetes education or medical nutrition therapy program services compared to children of families who do not receive these services?
5. What is the evidence that training in intensive diabetes management (consistent with DCCT, including blood glucose monitoring at least 4 times a day, 3 or more daily insulin injections or use of an insulin pump and education on when and how to adjust insulin doses) conducted in the practitioner setting yields:
    a. Improved metabolic control, (as determined by HbA1c values, numbers of diabetes-related hospitalizations, frequency of DKA and numbers of episodes of hypoglycemia)?

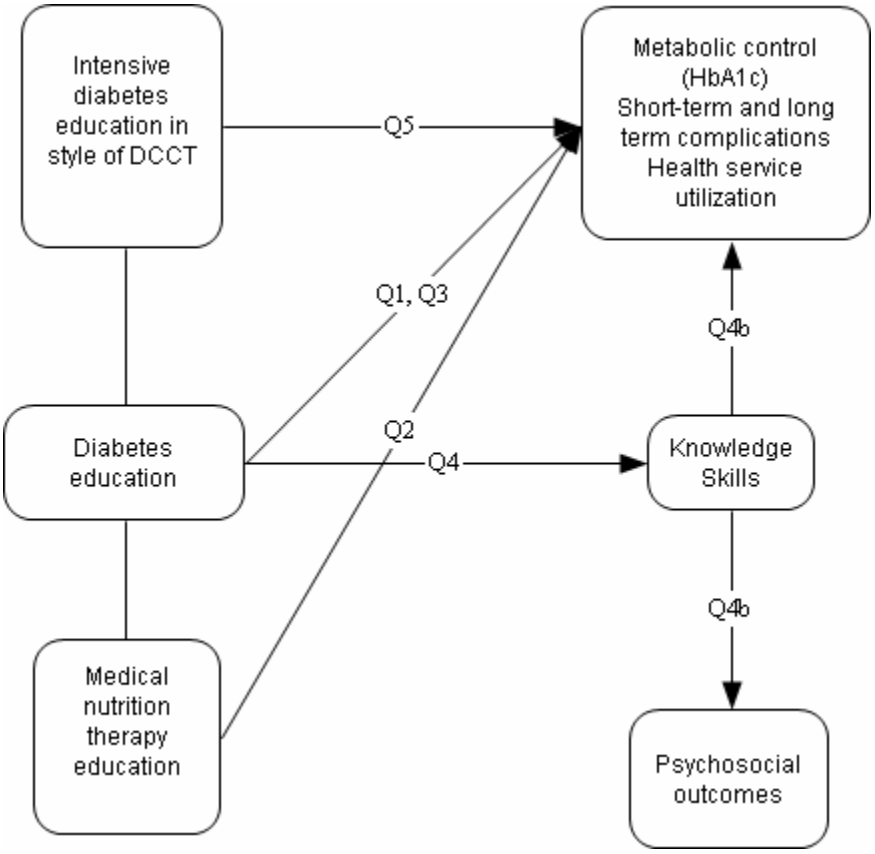
b. A decrease in or prevention of diabetes-related complications (as measured by retinal, renal, cardiovascular and neurological evaluations), as demonstrated by DCCT?

Chapter 2. Methods

In this chapter, we document a prospectively designed protocol that the University of Alberta/Capital Health Evidence-based Practice Center (UA/CH EPC) used to develop this evidence report. To accomplish the tasks as directed, a core research team at the UA/CH EPC was assembled. In consultation with the Agency for Healthcare Research and Quality (AHRQ) Task Order Officer (TOO) and the American Academy of Pediatrics (AAP) representatives, a Technical Expert Panel (TEP) was invited to provide high-level content and methodological expertise in the development of the report (Appendix A).*

In developing a framework for the report, the five key questions were considered parts of a larger question about the effectiveness of diabetes education for children and their families for various short- and long-term physical (metabolic) and psychosocial outcomes (Figure 1).

Figure 1. Analytical framework for evidence report on the effectiveness of diabetes education



*Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabetp.htm

Literature Search and Retrieval

We systematically searched the following electronic resources: MEDLINE® Ovid, Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Cochrane Central Register of Controlled Trials (contains the Cochrane Metabolic and Endocrine Disorders Group, which hand searches journals pertinent to its content area and adds relevant trials to the registry), Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), HealthSTAR, EMBASE, CINAHL®, ERIC, PsycINFO®, CINAHL Plus with Full Text (EBSCO), Science Citation Index Expanded® and Social Sciences Citation Index® (both via ISI Web of Knowledge℠), PubMed®, LILACS (Latin American and Caribbean Health Science Literature), Proquest® Dissertations & Theses, CRISP (Computer Retrieval of Information on Scientific Projects), National Library of Medicine (NLM) Gateway, OCLC ProceedingsFirst and PapersFirst, and trial registries such as The National Research Register, ClinicalTrials.gov, and Current Controlled Trials. We also searched the websites of relevant professional associations and research groups including the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), American Association of Diabetes Educators, European Association for the Study of Diabetes (EASD), and TRIP Database (Turning Research Into Practice) for additional unpublished controlled trials and reports. The reference lists of relevant reviews and included studies were reviewed, and authors of included studies were contacted as required (e.g., to clarify the source of population in cases of multiple publications or to seek additional data). This search was limited to English language studies published after 1982. The search was not limited by study design or publication status. It is considered current up to March 2, 2007.

For the search strategies, a combination of subject headings and keywords were developed for each electronic resource using the following terms: diabetes mellitus, type 1, IDDM, diabetes mellitus, DM, insulin dependent diabetes mellitus, early diabetes mellitus, juvenile diabetes mellitus, labile diabetes mellitus, autoimmune diabetes mellitus, sudden onset diabetes mellitus, diabetic ketoacidosis, DKA, ketoacidosis, patient education, health education, patient care management, self-care, self-regulation, self-monitoring, self-management, home care services, school health services, diabetic diet, diet therapy, nutrition therapy, nutrition education, diabetes education, health behavior, attitude to health, counseling, adolescent psychology, child psychology, behavior therapy, cognitive therapy, family therapy, outcome assessment (health care), attitude to health, program, intervention, inform, teach, train, learn, educate, effect, impact, knowledge, skill, cope, video, game, telephone, self-help groups, treatment program, hypoglycemia, blood glucose, self-monitoring, self-monitoring blood glucose, glycosylated hemoglobin A, hemoglobin A, HbA1c, metabolic control, glycemic control, self-efficacy, program evaluation, treatment outcome, health behavior, problem solving, compliance, improve, quality of life, hospitalization, admission, and service utilization. Appendix B* documents the exact search strategy for each database.

*Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabetp.htm

Study Selection

Our inclusion and exclusion criteria were developed in consultation with the TEP and are documented in Table 2. In consultation with the TEP, we made a post hoc decision to exclude studies that had 10 or fewer study participants.

Table 2. Inclusion and exclusion criteria for studies assessing the effectiveness of diabetes education for children and their families

Study design	*Include:* Any study design *Exclude*: Studies with ≤10 participants
Participants	Children aged 0 to 18 years with type 1 diabetes mellitus or families of children with type 1 diabetes mellitus
Interventions	Diabetes education programs that incorporate at least one of the following content areas: (1) diabetes disease process and treatment options; (2) nutritional management; (3) physical activity; (4) monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control; (5) utilizing medications; (6) preventing, detecting, and treating acute complications; (7) preventing (through risk reduction behavior), detecting, and treating chronic complications; (8) goal setting to promote health and problem solving for daily living; (9) psychosocial adjustment
Outcomes	*Include:* Metabolic control (HbA1c), hospitalization, ED utilization, short-term complications (e.g., diabetic ketoacidosis, episodes of hypoglycemia), long-term complications (retinal, renal, cardiovascular, neurological), quality of life, school attendance and performance, self-confidence in ability to cope with disease, psychosocial outcomes *Exclude:* lifestyle outcomes (e.g., smoking, use of recreational drugs, participation in extracurricular activities)

ED = emergency department

We used a two-step process for article screening. First, two reviewers independently screened the titles and abstracts (when available) to determine if an article met the general inclusion criteria. Each article was rated as "include," "exclude," or "unclear." The full text of all articles classified as "include" or "unclear" was retrieved for formal review. Next, two reviewers independently assessed each study using a standard inclusion/exclusion form (Appendix C).* Disagreements were resolved by consensus or third party adjudication.

Assessment of Methodological Quality

The methodological quality of randomized controlled trials (RCTs) and controlled clinical trials (CCTs) was assessed independently by two reviewers using two quality assessment instruments. They were not blinded to authors, setting, or results. First, a five-point scoring system validated by Jadad[101] (Appendix C)* was used to assess randomization, double blinding, and reporting of withdrawals and dropouts. These components are associated with a risk of bias. Second, allocation concealment, failure of which has been associated with an increase in the potential for selection bias, was assessed as adequate, inadequate, or unclear.[102,103] Decision rules regarding the application of the tools were developed a priori and discrepancies were resolved through discussion between the two reviewers. In addition, the funding source was recorded.[104]

*Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabetp.htm

A post hoc assessment of blinding of outcome assessors was carried out for all RCTs and CCTs. Studies were given credit for this component if they described procedures for blinding outcome assessors to treatment allocation of study participants. Disagreements were resolved through discussion between reviewers.

The methodological quality of all other study designs was assessed independently by two reviewers using the Thomas Quality Assessment Tool for Quantitative Studies[105-107] (Appendix C).* The tool aims to provide assessment criteria applicable to any study design and includes 21 items separated into 8 categories: selection bias, study design, confounders, blinding, data collection methods, withdrawals and dropouts, intervention integrity, and analysis. Following completion of the tool, reviewers provide an overall rating of the study (strong/moderate/weak) for each of the first 6 components. Decision rules for the application of the tool were developed a priori through discussions with the lead investigators. Discrepancies were resolved through discussion between the two reviewers.

Grading the Body of Evidence

To assess the strength of evidence for the key outcomes (HbA1c, short-term complications, knowledge of diabetes, self-management skills, coping with diabetes and quality of life), we used the approach developed by the Grading of Recommendation Assessment, Development, and Evaluation (GRADE) working group.[108-110] This approach assesses the evidence based on five key elements: the strength of the study designs providing the evidence, the quality of the studies, the consistency of the estimates of effect across studies, the precision or degree of certainty surrounding an effect estimate, and the directness of the link between the intervention and outcome measures. We classified the strength of evidence as high, moderate, low, or very low. Decision rules for the application of the GRADE approach were developed a priori, and two reviewers scored each element independently. Differences in assessment were resolved by consensus.

Data Extraction

Data were extracted using standardized forms and entered into a Microsoft Access database (Microsoft Corp., Redmond, WA) (Appendix C).* Data were extracted by one reviewer (AM, CS, ES, or KO) and checked for accuracy and completeness by a second (AM, CS, ES, KO or YL). Extracted data included study characteristics, inclusion/exclusion criteria, and the characteristics of participants, interventions, and outcomes described in Table 2. Reviewers resolved discrepancies in data extraction by consensus or in consultation with a third party.

The following broad categories were used to group studies by outcome: HbA1c, knowledge of diabetes, skills and self-management behaviors, psychosocial outcomes (e.g., coping skills, self-esteem, quality of life), complications (short- and long-term), and health service utilization (e.g., hospitalizations). After reviewing the included studies, we grouped interventions into the following broad categories: general diabetes education (which included education given to both inpatients and outpatients on topics addressing etiology, clinical course, and general management of the disease), skills training (including training in skills

*Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabetp.htm

related to self management, insulin injections, adherence, and nutrition), cognitive behavioral therapy (including techniques such as problem solving, goal setting, behavior modification, stress management, and coping skills), family systems therapy (including techniques that focus on family communication skills and the role of family interaction in adherence to health regimens), medical nutrition therapy, psychoeducation, physical activity, and diabetes camps. Within the parameters of each outcome and intervention, we also extracted and presented the results by population type: the general population of children with diabetes, children that were newly diagnosed with diabetes, and children who have poor metabolic control. For the purposes of this report, we considered an absolute change in HbA1c of 0.5 percent (e.g. from 9.0 percent to 8.5 percent) to be a clinically important difference.

Data Analysis

The following data assumptions were made and imputations performed to transform reported data into the form required for analysis for this review. Graph extraction was performed using CorelDRAW®9.0 (Corel Corp., Ottawa, Canada). If necessary, means were approximated by medians, and 95 percent empirical confidence intervals were used to calculate approximate standard deviations (SD). Change from baseline data at various time points were used whenever possible for continuous data; however, since correlations between baseline data and endpoint data were never reported, a correlation of 0.5 was assumed[111] to calculate the appropriate SD for the change from baseline data. Change from baseline and endpoint data were combined in the same meta-analysis; both figures estimate the difference between treatment groups.[112] For multiarm studies, data from similar treatment groups were combined if appropriate.

Quantitative results were meta-analyzed in Review Manager version 4.2.5 (The Cochrane Collaboration, Copenhagen, Denmark). Dichotomous results (e.g., hospitalizations), are reported as relative risks (RR) for individual studies and a pooled result was calculated for those studies that could be combined. For continuous variables measured on the same scale (e.g., HbA1c), mean differences were calculated for individual studies, and the weighted mean difference (WMD) was calculated for the pooled estimate. For continuous variables measured on different scales (e.g., knowledge of diabetes), mean differences were calculated for separate studies and the standardized mean difference (SMD) was calculated for the pooled estimate. All results are reported with 95 percent confidence intervals (95% CI), when possible.

Due to expected differences among studies, we decided a priori to combine results using random effects models.[113] Statistical heterogeneity was quantified using the I-squared (I^2) statistic.[114] A value greater than 50 percent was considered to be substantial heterogeneity, and grounds for not presenting the combined results.[114]

For our primary outcome, HbA1c, we tested visually for publication bias using the funnel plot and quantitatively using the rank correlation test,[115] the graphical test,[116] and the trim and fill method.[117] Publication bias calculations were performed using STATA 7.0 (STATACorp., College Station, TX).

Peer Review

Eight experts in pediatric endocrinology, diabetes education, or medical nutrition education agreed to act as peer reviewers (Appendix A)* and were sent a copy of the draft report. Reviewers had one month in which to provide critical feedback. All comments and authors' replies were submitted to the AHRQ for assessment and approval. The draft report was amended based on reviewers' comments.

*Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabetp.htm

Chapter 3. Results

Literature Search

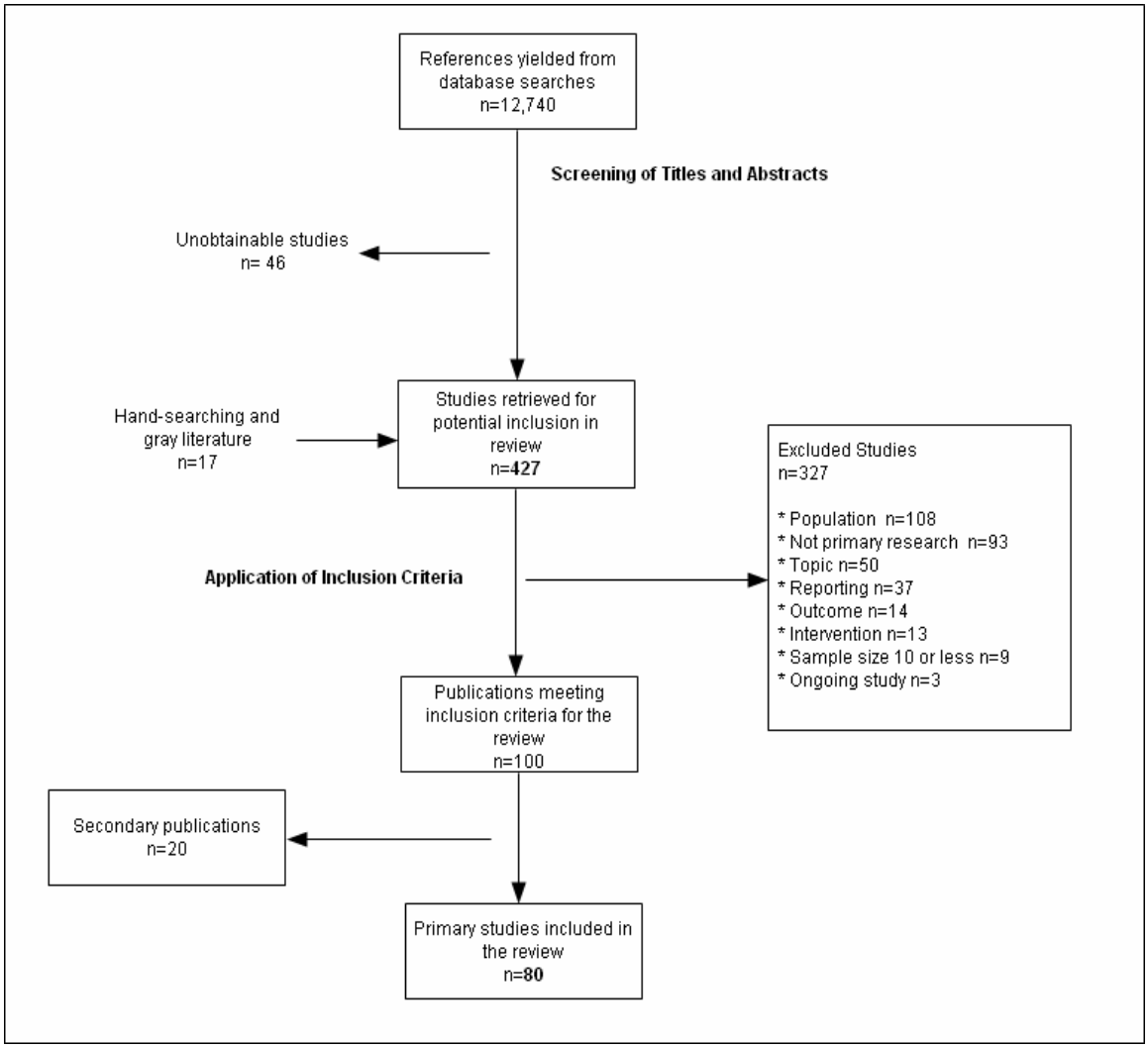
The combined search strategies identified 12,740 citations from electronic databases and 17 references identified by gray literature and hand searching. Through screening titles and abstracts, 473 references were identified for further examination. The manuscripts of 46 articles could not be retrieved (Appendix D).* The majority of these studies were abstracts from conference proceedings and dissertations. They were requested through the university interlibrary loan service, but did not arrive within the 7-month cutoff that we established for article retrieval. Therefore, the full text of 427 potentially relevant articles was retrieved and evaluated for inclusion in the review. The application of the selection criteria to the 427 articles resulted in 100 articles being included and 327 excluded. Figure 2 outlines study retrieval and selection for the review.

From 100 included articles, 14[5,6,9,21,24,28,30,38,52,66,70,79,82,83] were associated with multiple publications that either expanded on the main results of the primary study or reported secondary outcomes not included in the main report. The secondary publications were not considered as unique studies and any information they provided was included with the data reported in the primary study. In most instances, the report that provided data for the longest followup period was regarded as the primary study; otherwise, the study that was published first was considered the main one. Appendix E* identifies the associated secondary publications for each primary study. In total, 80 primary studies were included in this report.[5-84]

The four main reasons for excluding studies from this review were (1) the population did not include children (≤ 18 years) with type 1 diabetes or their families (n = 108), (2) the study was not primary research on diabetes education (e.g., systematic reviews, descriptive studies) (n = 93), (3) the study did not address diabetes education (n = 50), and (4) the study did not include a description of the intervention in sufficient detail to replicate it or report measurable data for outcomes relevant to the review (n = 37). Thirty-eight studies were excluded for other reasons including small sample size (n = 9). The list of excluded studies and reasons for exclusion are identified in Appendix D.*

*Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabedtp.htm

Figure 2. Flow-diagram for study retrieval and selection



Description of Included Studies

Eighty primary studies provided evidence regarding the effectiveness of diabetes education for children with type 1 diabetes and their families. Tables F1 and F2 (Appendix F)* summarize the key characteristics of studies included in the review. Studies were published between 1983 and 2007 (median = 1996 [IQR, 1990 to 2001]). Most of the studies (88 percent) were published as peer reviewed publications; the remainder were theses or dissertations. Studies were conducted in the United States (64 percent), Europe (21 percent), Canada (9 percent), and other regions (6 percent).

Of the 80 included studies, 42 (53 percent) were RCTs. All were parallel trials. Eight of the trials had three arms[5,13,17,32,52,63,82,83] and one had four arms.[24] Eleven (14 percent)

*Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabedtp.htm

of the included studies were CCTs,[7,14,19,42,45,48,51,62,74,76,84] and 20 (25.0 percent) were uncontrolled before-after studies.[11,12,20,27,28,34,35,37,44,50,53,61,64,65,67,68,73,75,77,78] There were seven (9 percent) cohort studies: three prospective cohorts with concurrent controls,[29,66,69] two prospective cohorts with historical controls,[40,54] and two retrospective cohorts.[39,41]

The number of enrolled participants in the studies ranged from 11 to 332 (median = 50 [IQR, 30 to 89]). The mean age of study participants ranged from 2.7 to 16 years. For 28 studies (35 percent), the mean age of participants was less than 12 years.[11,17-19,22,24,26,30,32,35,36,38,40-44,47,49,50,55,66,70,71,77,78,80,84] Ten[17-19,26,30,40,49,66,69,70] studies (13 percent) examined education interventions delivered to children and their families at the time of diagnosis with type 1 diabetes. Fourteen studies[8,13-16,25,28,34,43,51,55,57,76,83](18 percent) examined interventions targeted at children who demonstrated poor metabolic control, which was defined as children with HbA1c above a certain level, as well as, in some studies, problems with adherence control. Although the populations of several other studies had mean HbA1c levels equivalent to or higher than those exhibited by children in studies targeted for poor metabolic control (i.e., greater than 9.0 percent),[5,7,10-12,21,24,25,31-33,36,39,46,47,56,63,72,79,80,82,84] the samples in these studies were not specifically selected on this basis and, therefore, were not included in this grouping.

The interventions examined were diverse. We grouped the interventions into nine broad categories. General diabetes education was assessed in 21 studies (26 percent).[9,15,18,24,30,32,39,41,42,44,50,55,61,65,66,69,71,73,75,77,79] Cognitive behavioral therapy and its variants was evaluated in 24 studies (30 percent).[6-8,13,14,16,17,19-23 25,31,33,45,47,48,54,72,74,76,80] Family therapy interventions were considered in nine studies (11 percent).[5,26,28,36,38,63,70,82,83] Skills training programs were the focus of seven studies (8.8 percent).[11,40,43,49,52,53,57] Programs that were delivered as part of a diabetes camp were assessed in 17 studies (21 percent).[12,29,60,67,78 27,34,35,37,46,58,59,62,64,68,81,84] The remaining interventions included psychotherapy[51,56] and a physical activity program (3 percent).[10]

Only 20 of the included studies (25 percent) explicitly described the theoretical framework upon which they were based (e.g., anchored instruction, social cognitive theory).[9,17,22,26,28-30,33,46,51,58-60,62,64,70,77,80,83,84]

More than half of the interventions (n = 43; 54 percent) were targeted at both children and parents or the family. Thirty-two education programs were delivered directly to the child.[7-10,12-14,21,23,25,27,31,33-35,37,42,45,46,50,57-60,62,64,66-68,81,84] Parents were the target audience in four studies (5 percent).[19,30,36,44] In one study,[20] the intervention focused on the child and a close friend; in another, the intervention was aimed at the child, family, and school staff.[54]

The education interventions were delivered in a variety of settings. Most took place in a health care setting, such as a diabetes center (n = 12, 15 percent), outpatient clinic (n = 9, 11 percent), hospital (n = 10, 13 percent) or a combination of health care setting and other location (n = 15, 19 percent). A diabetes camp was the setting for 17 studies (21 percent). The education program was delivered at home in six studies (8 percent) and at summer school in one study. In 11 studies (14 percent), the setting in which the intervention took place was either not reported or unclear.

The duration of the education intervention ranged from 1 day to 2 years. For 28 studies (35 percent), the interventions were delivered for less than 1 month. For 10 studies (13 percent) the education program took place over 1 year or

longer.[5,6,11,17,18,21,38,54,71,79] The duration of the intervention was not reported in six studies (8 percent).

Followup assessments were defined as those taken at time points after the immediate post-intervention assessment. In 21 studies (26 percent),[6,9-12,20,21,24,27,31,32,38,41,50,57,60,64,73,79,81,118] there were no outcome measurements taken after the post-intervention assessment, including studies in which outcomes were measured throughout the delivery of the education program. In 55 studies that identified specific followup periods, the periods ranged from 2 days to more than 4 years (median = 6 months [IQR, 3 to 12 months]). In two[19,42] studies (3 percent), the followup periods were not consistent among participants and were reported in ranges (i.e., 4 to 22 weeks and 6 to 24 months). In one[54] study, the followup was reported as 248 patient-years with 122 participants completing the study. The followup period was not reported in two[45,68] studies (3 percent). The followup period was less than 3 months in five[23,25,26,58] studies (6 percent). Followup assessments took place between 3 and 5 months in 18 studies (23 percent)[7,8,13,15,16,29,33,36,37,44,46,47,62,67,72,78,80,84] and between 6 and 11 months in 10 studies (13 percent).[22,28,30,56,59,61,63,65,77,83] For the remaining 21 studies (26 percent), the followup assessments were measured at 12 months or more.

Methodological Quality of Included Studies

Randomized Controlled Trials

Overall, the methodological quality of the 42 RCTs was low (median Jadad[101] score = 2/5; IQR, 1 to 2). The Jadad score was 3 for 4 trials,[30,55,57,83], 2 for 31 trials[5,6,10,16-18,21,24-26,31-33,36,38,43,46,47,56,60,72,82 13,15,22,23,58,59,70,71,81] and 1 for 7 trials[8,9,49,52,63,79,80] (Table 3). All were described as randomized; however, the descriptions of randomization varied. Five were adequately randomized;[30,32,55-57,83] the rest were unclear. Two trials reported clear concealment of allocation[30,83] and the remaining trials were unclear. No trials were described as double-blind (patient and outcome assessor blinded). Withdrawals and dropouts were clearly described in 33 trials; in 9 studies, withdrawals and dropouts were not described.[8,9,32,49,52,56,63,79,80] The post hoc assessment of blinding revealed that 11 RCTs had included an attempt to blind outcome assessors.[17,18,21,23,26,52,56,56,59,71,72,80]

The most common source of funding was government (n = 24, 57 percent of RCTs). Three trials (7 percent) received funding from industry.[9,25,43] Other sources of funding included foundations (n = 10, 24 percent), internal (n = 7, 17 percent), and private (n = 4, 10 percent). For nine trials (21 percent), the funding is not known.[13,15,26,32,36,49,79-81] Several trials received funding from multiple sources (Table 3).[5,9,16,17,21,33,38,52,71]

Controlled Clinical Trials

The methodological quality of the 11 CCTs was low (median modified Jadad[101] score = 1/3; IQR, 0 to 1) (Table 4). Seven CCTs (64 percent) obtained only 1 point for the individual components of the Jadad scale, all for the description of withdrawals and dropouts. The remaining four trials did not score any points.[42,45,51,84]

The CCTs received funding from government sources (n = 2), foundations (n = 2), internal (n = 2), and private sources (n = 2) (Table 4). One trial received funding from

multiple sources.[51] For six studies (55 percent), the funding source is not known.[7,42,45,48,62,84]

Before and After Studies

The quality of reporting of the 20 before-and-after studies was evaluated using individual components of the Thomas tool.[105] Overall, the methodological quality of the before-and-after studies was weak (Table 5 and Table F3, Appendix F).* For 10 (50 percent) studies participants were unlikely to be representative of the target population and were rated as weak on the selection bias component. The remaining studies were rated as moderate. Control of potential confounders (age, sex, duration of diabetes, socioeconomic status) was rated as weak for 13 (65 percent) studies. None of the studies reported the blinding of outcome assessors to the intervention. Data collection methods were rated as strong for 12 (60 percent) studies. For the remaining eight, the reliability and validity of the data collection tools was not reported. The risk of attrition bias was moderate with 14 (70 percent) studies rated as strong or moderate on this component. Data analysis was appropriate in most studies. None of the studies provided a sample size calculation. Nine studies reported a statistically significant difference between groups for the primary outcome, five studies found no significant differences, and six studies did not report whether group differences were statistically significant. Overall, the intervention integrity was moderate. For 19 (95 percent) studies, over 80 percent of participants received the allocated intervention. Methods to assess the consistency of the intervention were included in eight (40 percent) studies; for the remainder they were not reported. For most studies (n = 14, 70 percent), it was unlikely that contamination occurred or that there was a cointervention. For the remaining six, there was insufficient information to answer this question. Finally, funding source was disclosed in 70 percent (n = 14) of the before-and-after studies (Table 5).

Cohort Studies

The quality of reporting of the seven cohort studies was evaluated with individual components of the Thomas tool.[105] (Table 5 and Table F3, Appendix F).* Overall, the methodological quality was moderate. Most studies did a reasonable job of protecting against selection bias with five of seven (71 percent) choosing study groups that were at least somewhat representative of the target population. The risk of attrition bias was low; all but one study included a description of the number of withdrawals and the followup rates were unlikely to introduce differences between the comparison groups. Data collection methods were assessed as valid and reliable for six studies (86 percent). Control of potential confounders (age, sex, duration of diabetes, socioeconomic status) either in the design or analysis was rated as weak for six (86 percent) studies and as moderate in one study (14 percent). No studies reported that the ascertainment of outcome exposure was blinded. For all studies data analysis was considered appropriate. None of the studies provided a sample size calculation; however, four studies (57

* Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/diabedtp.htm

percent) reported a statistically significant difference between groups for the primary outcome. Intervention integrity was good. In six studies (86 percent), over 80 percent of participants received the allocated intervention and the risk of contamination or cointervention was low. Finally, three of the cohort studies (43 percent) reported the source of funding (Table 5).

Table 3. Methodological quality and source of funding of randomized controlled trials assessing the effectiveness of diabetes education for children with type 1 diabetes and their families

Author Year	Randomization		Double Blinding		Description of Withdrawals/ Dropouts	Jadad Score (out of 5)	Allocation Concealment	Funding Source
	Stated	Method Described	Stated	Method Described				
Anderson[6] 1989	Yes	No	No	No	Yes	2	Unclear	Government
Anderson[5] 1999	Yes	No	No	No	Yes	2	Unclear	Government, foundation
Boardway[8] 1993	Yes	No	No	No	No	1	Unclear	Government
Brown[9] 1997	Yes	No	No	No	No	1	Unclear	Government, industry
Campaigne[10] 1985	Yes	No	No	No	Yes	2	Unclear	Government
Cigrang[13] 1992	Yes	No	No	No	Yes	2	Unclear	NR
Coupland[15] 1992	Yes	No	No	No	Yes	2	Unclear	NR
Delamater[17] 1990	Yes	No	No	No	Yes	2	Unclear	Government, internal
Delamater[16] 1991	Yes	No	No	No	Yes	2	Unclear	Government, foundation
Dougherty[18] 1999	Yes	No	No	No	Yes	2	Unclear	Government
Grey[21] 2000	Yes	No	No	No	Yes	2	Unclear	Government, foundation, internal
Gross[23] 1983	Yes	No	No	No	Yes	2	Unclear	Internal
Gross[22] 1985	Yes	No	No	No	Yes	2	Unclear	Government
Hackett[24] 1989	Yes	No	No	No	Yes	2	Unclear	Government
Hains[25] 2000	Yes	No	No	No	Yes	2	Unclear	Industry
Hakimi[26] 1998	Yes	No	No	No	Yes	2	Unclear	NR
Hoff[30] 2005	Yes	Yes	No	No	Yes	3	Adequate	Private
Horan[31] 1990	Yes	No	No	No	Yes	2	Unclear	Government
Howe[32] 2005	Yes	Yes	No	No	No	2	Unclear	NR
Kaplan[33] 1985	Yes	No	No	No	Yes	2	Unclear	Government, foundation
Kennedy-Iwai[36] 1991	Yes	No	No	No	Yes	2	Unclear	NR

NR = not reported

Table 3. Methodological quality and source of funding of randomized controlled trials assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Randomization		Double Blinding		Description of Withdrawals/ Dropouts	Jadad Score (out of 5)	Allocation Concealment	Funding Source
	Stated	Method Described	Stated	Method Described				
Laffel[38] 2003	Yes	No	No	No	Yes	2	Unclear	Government, foundation, private
Mann[43] 1984	Yes	No	No	No	Yes	2	Unclear	Industry
Massouh[46] 1989	Yes	No	No	No	Yes	2	Unclear	Hospital
McNabb[47] 1994	Yes	No	No	No	Yes	2	Unclear	Government
Mitchell[49] 1996	Yes	No	No	No	No	1	Unclear	NR
Nordfeldt[52] 2005	Yes	No	No	No	No	1	Unclear	Foundation, government, internal
Nunn[55] 2006	Yes	Yes	No	No	Yes	3	Unclear	Internal
Olmsted[56] 2002	Yes	Yes	No	No	No	2	Unclear	Government
Panagiotopoulos[57] 2003	Yes	Yes	No	No	Yes	3	Unclear	Foundation
Pichert[60] 1993	Yes	No	No	No	Yes	2	Unclear	NR
Pichert[58] 1994a	Yes	No	No	No	Yes	2	Unclear	Government
Pichert[59] 1994b	Yes	No	No	No	Yes	2	Unclear	Government
Satin[63] 1989	Yes	No	No	No	No	1	Unclear	Government
Sundelin[70] 1996	Yes	No	No	No	Yes	2	Unclear	Foundation
Svoren[71] 2003	Yes	No	No	No	Yes	2	Unclear	Government, foundation, private
Szumowski[72] 1990	Yes	No	No	No	Yes	2	Unclear	Foundation
Wadham[79] 2005	Yes	No	No	No	No	1	Unclear	NR
Webb[80] 1999	Yes	No	No	No	No	1	Unclear	NR
Wolanski[81] 1996	Yes	No	No	No	Yes	2	Unclear	NR
Wysocki[83] 2000	Yes	Yes	No	No	Yes	3	Adequate	Government
Wysocki[82] 2007	Yes	No	No	No	Yes	2	Unclear	Government

Table 4. Methodological quality and source of funding for controlled clinical trials assessing the effectiveness of diabetes education for children with type 1 diabetes and their families

Author Year	Randomization		Double Blinding		Description of Withdrawals/ Dropouts	Jadad Score (out of 3)	Allocation Concealment	Funding Source
	Stated	Method Described	Stated	Method Described				
Barglow[7] 1983	NA	NA	No	No	Yes	1	NA	NR
Couper[14] 1999	NA	NA	No	No	Yes	1	NA	Government
Golden[19] 1985	NA	NA	No	No	Yes	1	NA	Internal
Lucey[42] 1985	NA	NA	No	No	No	0	NA	NR
Mason[45] 1985	NA	NA	No	No	No	0	NA	NR
Mendez[48] 1997	NA	NA	No	No	Yes	1	NA	NR
Moran[51] 1991	NA	NA	No	No	No	0	NA	Foundation, private, internal
Remley[62] 1999	NA	NA	No	No	Yes	1	NA	NR
Thomas-Dobersen[74] 1993	NA	NA	No	No	Yes	1	NA	Government
Viner[76] 2003	NA	NA	No	No	Yes	1	NA	Private
Zorumski[84] 1997	NA	NA	No	No	No	0	NA	NR

NA = not applicable; NR = not reported

Table 5. Methodological quality of before-and-after studies and cohort studies

Author Year	Selection Bias	Study Design	Confounders	Blinding	Data Collection Methods	Withdrawals/ Dropouts	Funding Source
Uncontrolled before-and-after studies							
Caravalho[11] 2000	Weak	Weak	Moderate	Weak	Strong	Moderate	NR
Christensen[12] 2000	Weak	Weak	Weak	Weak	Weak	Strong	Government, internal
Greco[20] 2001	Moderate	Weak	Moderate	Weak	Strong	Strong	Foundation
Harkavy[27] 1983	Moderate	Weak	Moderate	Weak	Weak	Strong	Government
Harris[28] 2005	Weak	Weak	Weak	Weak	Strong	Strong	Internal
Karaguzel[34] 2005	Weak	Weak	Weak	Weak	Weak	Strong	Internal
Kemp[35] 1986	Weak	Weak	Weak	Weak	Strong	Weak	Industry
Koontz[37] 2002	Moderate	Weak	Strong	Weak	Strong	Weak	NR
Marteau[44] 1987	Weak	Weak	Weak	Weak	Weak	Strong	NR
Monaco[50] 1996	Moderate	Weak	Weak	Weak	Strong	Strong	NR
Povlsen[61] 2005	Weak	Weak	Weak	Weak	Weak	Moderate	Government, foundation, private
Schlundt[64] 1996	Weak	Weak	Weak	Weak	Strong	Weak	Government
Shobhana[65] 1997	Moderate	Weak	Weak	Weak	Weak	Weak	Industry
Smith[68] 1991	Moderate	Weak	Weak	Weak	Weak	Strong	NR
Smith[67] 1993	Moderate	Weak	Moderate	Weak	Strong	Weak	NR
Templeton[73] 1988	Weak	Weak	Weak	Weak	Weak	Strong	Government
Verrotti[75] 1993	Weak	Weak	Moderate	Weak	Strong	Strong	NR
von Sengbusch[77] 2006	Moderate	Weak	Moderate	Weak	Strong	Strong	Other
Vyas[78] 1988	Moderate	Weak	Weak	Weak	Strong	Moderate	NR
Cohort studies							
Hill[29] 2006	Weak	Weak	Weak	Weak	Strong	Weak	Professional association
Lawson[39] 2000	Weak	Weak	Weak	Weak	Strong	Strong	Foundation
Likitmaskul[40] 2002	Moderate	Weak	Weak	Weak	Strong	Strong	Private
Lipman[41] 1988	Moderate	Weak	Weak	Weak	Strong	Strong	NR
Nordfeldt[54]1999	Strong	Weak	Weak	Weak	Weak	Strong	Foundation
Nordfeldt[53] 2002	Moderate	Weak	Weak	Weak	Strong	Weak	Foundation, government, internal
Siminerio[66] 1999	Moderate	Weak	Moderate	Weak	Strong	Strong	Internal
Srinivasan[69] 2004	Moderate	Weak	Weak	Weak	Strong	Strong	NR

NR = not reported

Results of Included Studies

This section is organized by major outcome categories: HbA1c, health service utilization, complications, knowledge, skills, behavior, psychosocial outcomes, quality of life, and school performance. For each outcome category, we provide a brief overview of the studies that contributed data to the outcome and a qualitative summary of the results. Due to considerable heterogeneity across the studies in terms of specific outcome measures, intervention, study population, and study design, we were unable to pool the results of any of the studies.

HbA1c

Overall, there were 52 studies that assessed the effectiveness of diabetes education in improving metabolic control as measured by HbA1c. Of these, 30 studies assessed the general population of children with type 1 diabetes, 8 studies focused on children with newly diagnosed diabetes, and 14 studied children with poorly controlled diabetes.

General Diabetes Education—HbA1c

Description of studies. We identified 12 studies (7 RCTs,[9,15,18,24,32,55,79] 2 cohorts,[39,69] 3 uncontrolled before-and-after[61,75,77]) that assessed the effectiveness of general diabetes education on HbA1c. Studies were conducted in the United States,[9,32] Europe,[24,61,75,77,79] Canada,[15,18,39] and Australia.[55,69] The median year of publication was 2003 (IQR, 1995 to 2005).

The number of participants enrolled in the studies ranged from 28 to 146 (median = 65 [IQR 35 to 109]). The mean age of participants ranged from 10 to 15.8 years (n = 9 studies). For 3 studies, the mean age was less than 12 years.[18,55,77] Two studies examined education interventions delivered to children and their families at the time of diagnosis.[18,69] Two studies focused on children who demonstrated poor metabolic control.[15,55]

Most interventions were targeted to children and their parents or to the entire family;[9,15,18,32,39,55,61,69,75,77,79] one was delivered to the child.[24] The settings for the interventions were described as a hospital inpatient unit,[61,77] outpatient clinic,[24,79] or home.[9] For 5 studies, the setting was mixed (e.g., diabetes center and home).[18,32,39,55,69] The setting was not clearly described in 2 studies.[15,75]

Five studies did not measure HbA1c beyond the completion of the education program.[9,24,32,55,79] In the 7 studies that reported post-intervention assessments,[15,18,39,61,69,75,77] the median followup period was 12 months and ranged from 3.5 to 36 months.

Results

General population of children with diabetes. Howe et al.[32] randomly assigned 75 patients to one of three treatment groups: standard care (routine quarterly clinic visits), standard care plus one education session on basic diabetes management skills, and standard care plus the education session plus weekly telephone calls to review

management techniques. At 6 months, mean HbA1c levels dropped slightly from baseline (0.3 percent, 0.4 percent, and 0.5 percent, respectively). The differences were not statistically significant; however, they do represent a clinical improvement for the education plus telephone call group. The trial was ended early due to lack of enrolment. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

The retrospective cohort study (n = 28) by Lawson et al.[39] compared intensive, individualized education to group education delivered to patients. The content for both interventions was the same. Both groups showed a statistically significant decrease in mean HbA1c at 3 months; however, over the next 12 months the HbA1c levels increased for both groups. For the individualized education cohort, the mean HbA1c remained significantly lower than at initiation of the program (9.5±0.3 vs. 8.2±0.4 percent, p = 0.001); for the group education cohort, the mean HbA1c was not significantly different than baseline (8.2±0.4 vs. 8.1±0.3 percent). However, the baseline levels for the group education cohort were significantly lower than for the individual education group (p = 0.02). The methodological quality of this study was rated as weak using the Thomas instrument.

Povlsen et al.[61] assessed the effect of an intervention targeted at 37 families from ethnic minority groups in Denmark. The intervention included adapted educational material and guidelines and re-education that focused on increasing knowledge and self-care. The authors reported a significant difference in mean HbA1c levels immediately after the 12-month intervention (9.2±1.4 vs. 8.6±1.0 percent, p = 0.01); however, this improvement disappeared at the 6-month followup. The methodological quality of this study was rated as weak using the Thomas instrument.

In an uncontrolled before-and-after study, von Sengbusch et al.[77] assessed the impact of a mobile diabetes education service in a group of 107 children. Overall HbA1c levels for the whole cohort did not change significantly. The researchers conducted a post hoc subgroup analysis and found that among children with poor metabolic control (defined as HbA1c >8.0 percent), there was improved metabolic control from baseline to 6-month followup (9.4±0.9 vs. 8.6±1.5 percent, p<0.01). The methodological quality of this study was rated as moderate using the Thomas instrument.

Brown et al.[9] randomly assigned 59 children and adolescents to a group that played a video game featuring characters with diabetes who manage their diabetes by monitoring blood glucose, taking insulin injections, and choosing foods, or a group that played a pinball video game with no information on diabetes. At the end of the 6-month study period, both groups exhibited higher levels of HbA1c (i.e., poorer metabolic control). There was no statistically significant difference between groups. The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment).

In the RCT by Hackett et al.,[24] three cohorts of families received educational packages that were delivered over 8 months. The content was the same for all groups and included a nutrition therapy education component; one group (cohort 1) received a second reinforcement package for an additional 8 months. The comparison group did not receive the education package. Overall, the education program did not have an impact on HbA1c levels. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Wadham et al.[79] conducted an RCT (n = 67) to evaluate a 4-session family centered, structured education program for adolescents and parents. The program focused on skill-based sessions and teamwork and communication between parents and adolescents. The control group received routine clinical care. Preliminary results at 6 months did not show any significant change in HbA1c levels for either group. The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment).

In an uncontrolled before-and-after study Verrotti et al.[75] studied 30 adolescents who attended nine education sessions on general diabetes management. At the 12-month followup, mean baseline levels of HbA1c had decreased significantly (11.8±2.8 vs. 10.0±2.7 percent, p = 0.019). The methodological quality of this study was rated as moderate using the Thomas instrument.

Children with newly diagnosed diabetes. Dougherty et al.[18] randomly assigned 63 newly diagnosed patients to a 24-month home-based diabetes education program or to traditional hospitalization and outpatient followup. Treatment differences between the groups consisted of duration of initial hospital stay, timing of initial teaching, and the nature and extent of subsequent nursing followup. Both groups exhibited significantly lower mean HbA1c values at the 3-month followup. These differences were still present at 36 months, 1 year after the intervention ended (10.5±1.3 vs. 6.4±1.4 percent for the home-based group and 10.0±1.3 vs. 7.1±1.3 percent for the hospital-based group). The difference between the two groups at 36 months was statistically significant. The methodological quality of this study was rated as moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

In the prospective cohort study by Srivivasan et al.[69] a group of 61 newly diagnosed patients attended a diabetes day care program (DDCP) at which they received "survival skills" diabetes education. The pre-DDCP cohort comprised 49 patients who were admitted to hospital for 4 to 7 days for a detailed education program. Neither group demonstrated improvement in HbA1c levels at 3, 6 or 12-month followup. The methodological quality of this study was rated as moderate using the Thomas instrument.

Children with poorly controlled diabetes. Nunn et al.[55] randomly assigned 123 patients to receive scheduled telephone calls from a pediatric diabetes educator or standard care (i.e., routine clinic visits but no telephone calls). Over the course of the 8-month study HbA1c levels increased in both groups (i.e., poorer metabolic control). There was no statistically significant difference between groups. The methodological quality of this study was rated as high (3/5 on the Jadad score; unclear allocation concealment).

In the RCT by Coupland[15] adolescents and their families participated in a family-based intervention to improve adherence (n = 15); the comparison group (n = 14) comprised adolescents who were taught stress management techniques. At 6-month followup, both the intervention and comparison groups demonstrated significant improvements in mean HbA1c (11.6±1.41 vs. 9.8±2.23 percent and 11.3±1.22 to 10.5±1.57 percent, respectively). There was no statistically significant difference between groups. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Cognitive Behavioral Therapy—HbA1c

Description of studies. Nineteen studies (14 RCTs,[5,6,8,13,16,17,21,22,25,31,33,47,72,80] 4 CCTs,[7,14,19,76] 1 cohort[54]) examined various interventions that used cognitive behavioral therapy techniques. All but three studies were conducted in the United States; two were conducted in Europe,[54,76] and one was conducted in Australia.[14] The median year of publication was 1992 (IQR, 1989 to 1999) and ranged from 1983 to 2003.

The number of participants enrolled in the studies ranged from 13 to 139 (median = 31 [IQR 20 to 69]). The mean age of participants ranged from 2.7 to 15.4 years (14 studies). For five studies, the mean age was less than 12 years.[17,19,22,47,72] Two studies examined education interventions delivered to children and their families at the time of diagnosis.[17,19] Six studies focused on children who demonstrated poor metabolic control.[8,13,14,16,25,76]

In seven studies the interventions were delivered to children;[7,8,13,14,21,25,31] in two studies they were delivered to parents.[19,33] In the remaining studies parents and children or the entire family were targeted.[5,6,16,17,22,47,54,72,76,80] The settings for the interventions were described as a diabetes center,[5,7,47] hospital inpatient unit,[6,13,25] outpatient clinic,[8,16,72,80] home,[31] or summer school.[33] In four studies, the setting was mixed (e.g., diabetes center and home).[14,17,21,54] Two studies did not report the setting of the intervention.[22,76] All but three studies[6,19,31] conducted post-intervention assessments for HbA1c. The median followup period was 4 months and ranged from 1 month to 14 months.

Results

General population of children with diabetes. Anderson et al.[6] randomized 70 adolescents and parents to a group that received standard care (routine clinic visits) or a group that received standard care plus a problem solving intervention that focused on self-monitoring of blood glucose (SMBG) around meal planning. At completion of the 18-month program, the intervention group exhibited a mean decrease of 0.37 percent in HbA1c levels compared with a mean increase of 0.62 percent in the standard care group. This difference was statistically significant ($p = 0.04$). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

In a subsequent study, Anderson et al.[5] assessed the effectiveness of an intervention for families that focused on teamwork and shared parent-teen responsibility for diabetes tasks. Eighty-nine families were randomly assigned to the intervention group or to one of two comparison groups: standard care (routine clinical care from the diabetes team) or standard care plus didactic diabetes education. At the end of the 12-month program, there was no significant difference in mean HbA1c among the three groups. While the intervention group demonstrated improvement in HbA1c levels at the 12-month followup, there was no significant difference in change scores between the groups (-0.20±1.1 percent for the teamwork group vs. 0.11±1.1 percent for the combined comparison groups). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Grey et al.[21] randomly assigned 77 adolescents to receive intensive diabetes management (IDM) as described in the DCCT or IDM plus a behavioral program of

coping skills training intervention. At the 12-month followup, both groups reported significant decreases in HbA1c levels. The change from baseline measures of HbA1c for the intervention group was greater than the control group and the difference was statistically significant (9.1±1.5 vs. 7.5±1.1 percent and 9.2±1.4 vs. 8.5±1.4 percent, respectively; $p<0.001$). The methodological quality of this study was rated as moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

In the study by Kaplan et al.,[33] 21 patients were randomly assigned to a group that received social skills training or a group that received lectures on diabetes. At the 4-month followup, the social skills group reported improved HbA1c levels compared with the comparison group (12.6±2.4 vs. 11.72 percent [SD not reported] and 13.5±1.6 vs. 14.42 percent [SD not reported]; $p<0.05$). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

In a prospective study with historical controls, Nordfeldt and Ludvigsson[54] examined the effect of multiple dose insulin therapy combined with problem-based training and psychosocial support. The prospective cohort comprised 248 children admitted to hospital in 1994 and 1995. The comparison group (156 patients admitted in 1980-81) received standard clinical care. The researchers reported that the annual mean levels of HbA1c were significantly lower in the cohorts that received intensive diabetes training compared with the historical cohort that did not receive the same level of education and support (6.9±1.3 percent [1994], 7.1±1.1 percent [1995] and 7.4±1.2 [1980-81]; $p = 0.004$). The methodological quality of this study was rated as weak using the Thomas instrument.

In the study by McNabb et al.[47] 24 children were randomly assigned to either a 6-week self-management education program or to receive standard care (routine clinic visits). At the 6-week followup, HbA1c levels had decreased from baseline in both groups; however, the difference was not statistically significant (10.5±2.9 vs. 9.6±1.8 percent and 12.9±3.8 vs. 12.5±3.4 percent, respectively). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Barglow et al.[7] conducted a CCT ($n = 42$) to assess the effectiveness of a 4-month intensive multicomponent treatment and education program. The comparison group received standard care (routine clinic visits). At the 4-month followup both groups reported lower levels of HbA1c (change from baseline = -2.45±2.3 percent and -0.85±3.5 percent, respectively); however, the difference was not statistically significant. The methodological quality of this study was rated as low (1/3 on the modified Jadad score).

In the RCT by Gross et al.[22] 14 children and parents were randomly assigned to either behavior modification training or to a group that included discussion and role-playing. Both the intervention and comparison groups exhibited improvement in metabolic control at the 6-month followup (13.0 vs. 12.5 percent and 13.4 vs. 11.0 percent, respectively). There was no statistically significant difference between the groups at followup. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Szumowski[72] randomly assigned 27 young children to an 8-week behavioral intervention that included information on diabetes management plus instruction and practice in the application of behavioral principles and goal setting to reinforce children's regimen adherence, or to the comparison group that received information on diabetes management but no additional instruction. At the 3-month followup there were no

statistically significant changes from baseline HbA1c levels for either group. The methodological quality of this study was rated as moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Horan et al.[31] conducted an RCT (n = 20) that compared goal setting and problem solving using dynamic computer-assisted teaching modules vs. conventional education using an education booklet. At the end of the 15-week program, there were no significant changes in HbA1c levels in either group. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

In the RCT by Webb,[80] 45 families were assigned to a group that received intensive collaborative goal setting training or a group that used a goal setting worksheet with guidance from a therapist. At the 3-month followup neither group showed a significant change from baseline HbAc1 levels. The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Children with newly diagnosed diabetes. In the CCT by Golden et al.[19] 11 families received an integrated diabetes education and psychosocial support program that was delivered in a motel-like setting. The comparison group (n = 8) received the same training 15 months after diagnosis. Overall, the children whose families received immediate education achieved lower levels of HbA1c at all time points during the study up to 24 months after diagnosis ($p<0.05$). Baseline levels of HbA1c were not reported; therefore, we could not assess whether there was a significant change from baseline for either group. The methodological quality of this study was rated as low (1/3 on the modified Jadad score).

Delamater et al.[17] conducted an RCT (n = 36) that assessed the impact of a family-based self-management training (SMT) program conducted over the 6 months following diagnosis of diabetes. The description of the intervention included a medical nutrition therapy education component. One comparison group received standard care (regular outpatient contact with the health care team); a second comparison group received standard care plus supportive counseling. HbA1c measures taken at 12 and 24 months after diagnosis showed that all three groups improved their metabolic control. The SMT group had significantly lower HbA1c levels than the standard care patients at both 1 and 2 years after diagnosis (10.4±3.1 vs. 8.2±1.5 percent and 12.3±2.5 vs. 9.8±2.4 percent, respectively at 2 years). The SMT group also had lower levels than the supportive care group, but this difference was not statistically significant (10.4±3.1 vs. 8.2±1.5 percent and 11.1±2.4 vs. 9.1±1.7 percent, respectively at 2 years). The methodological quality of this study was rated as moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Children with poorly controlled diabetes. In a CCT by Viner et al.,[76] a 6-week motivational and solution-focused therapy group program was delivered to 21 adolescents and their parents. The control group comprised 20 adolescents who did not receive any intervention. At the 12-month followup, the intervention group demonstrated statistically significant decreases in HbA1c levels compared with the control group (10.2±1.37 vs. 8.9±1.37 percent and 10.0±1.34 vs. 9.9±2.24 percent, respectively). The methodological quality of this study was rated as low (1/3 on the modified Jadad score).

In a three-arm RCT (n = 37), Cigrang[13] investigated the effects of a coping skills program delivered to adolescents with a history of poor metabolic control. There were

two comparison groups: conventional diabetes education and standard care (routine clinic visits). At the 3-month followup, HbA1c levels decreased for all three groups. The change from baseline for each group was clinically significant (1.06±1.31 percent, 0.94±2.25 percent, 0.92±1.74 percent, respectively); however, there were no statistically significant differences among the three groups. It is likely that the study did not have sufficient power to detect a difference among the groups. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Couper et al.[14] evaluated the effects of monthly home visits by a nurse educator plus weekly telephone calls that focused on goal-setting. Thirty-seven adolescents received routine care plus the intervention; 32 received routine clinical care only. At the 6-month followup, the intervention group reported statistically significant lower mean levels of HbA1c compared with the comparison group (11.1±1.3 vs. 9.7±1.6 percent and 10.5±1.6 vs. 10.3±2.2 percent, respectively [p = 0.0001]). The difference between HbA1c levels at baseline and the 18-month assessment in the intervention group were clinically, but not statistically, significant (11.1±1.3 vs. 10.0±1.5 percent [0.06][1190.06]). The methodological quality of this study was rated as low (1/3 on the modified Jadad score; unclear allocation concealment).

Delamater et al[16] randomized 13 adolescents to receive a 2-month family-based behavior therapy program or to standard outpatient care. The description of this intervention included details of a medical nutrition therapy component. There were no significant changes in HbA1c levels in either group at the 4-month followup (11.5±2.1 vs. 11.0±2.4 percent and 10.4±0.8 vs. 10.3±1.5 percent, respectively). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

In the RCT (n = 19) by Boardway et al.[8] a 3-month stress management training program for adolescents was compared to standard outpatient care. The intervention was not effective in reducing HbA1c levels. For the intervention group HbA1c increased (i.e., poorer metabolic control) at the 6-month followup; there was no change in HbA1c levels for the control group (13.98±2.41 vs. 16.4±2.41 percent and 15.75±3.52 vs. 15.69±2.76 percent, respectively). The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment).

Hains et al.[25] randomly assigned 15 adolescents to a cognitive behavioral stress training program or to a control group that did not receive any intervention. At 1-month followup there were no significant changes in HbA1c levels for either group. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Family Therapy—HbA1c

Description of studies. Seven studies (6 RCTs,[36,38,63,70,82,83] 1 uncontrolled before-and-after[28]) assessed interventions that focused on family dynamics. Six studies were conducted in the United States; one took place in Europe.[70] The median year of publication was 2000 and ranged from 1996 to 2007.

The number of participants enrolled in the studies ranged from 18 to 119 (median = 38 [IQR 19 to 105]). The mean age of participants ranged from 6.0 to 14.6 years. In three studies, the mean age was less than 12 years.[28,36,70] Two studies examined education

interventions delivered to children and their families at the time of diagnosis.[36,70] Two studies focused on children who demonstrated poor metabolic control.[28,83]

The interventions were targeted at the entire family in six studies; in one study the intervention was delivered to the parents only.[36] The settings for the interventions were described as a diabetes center,[82] hospital inpatient unit,[63] the doctor's office,[83] or home.[28,36] For two studies, the setting was mixed (e.g., diabetes center and home).[38,70] Two studies reported HbA1c levels immediately following the intervention.[38,83] Four studies conducted post-intervention assessments for HbA1c.[28,63,70,82] The median followup period was 6 months and ranged from 3 to 24 months.

Results

General population of children with diabetes. Wysocki et al.[82] randomized 104 families to one of three groups: standard care plus behavioral family systems therapy (BFST), standard care plus family education and support, or standard care (physician directed clinical care). At the completion of the 6-month intervention, all groups showed improvement in mean HbA1c levels. However, only the BFST group maintained their improved HbA1c levels at 12-month followup, while both comparison groups reverted toward their baseline levels (BFST group: 9.6±1.6 percent at baseline vs. 8.8±1.5 percent at 12 months). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Satin et al.[63] randomly assigned 32 adolescents and their parents to one of three groups. One group received multifamily training on family teamwork (MF). For the second group, families received the same content as group 1 plus simulation activities for parents (MF+S). The control group received no education intervention. At the 6-month followup, the MF+S group demonstrated a statistically significant improvement in HbA1c levels compared to the control group (WMD -1.09 percent; 95% CI, -2.11, -0.07). Similarly the MF group also showed improvement in HbA1c levels; however, the results were not statistically significant (WMD -0.31 percent; 95% CI, -1.40, 0.78). The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment).

Laffel et al.[38] randomly assigned 105 families to a family-focused teamwork intervention (TW) or to standard care (i.e., routine multidisciplinary clinical care). At the end of the 12-month program, the TW group showed improved HbA1c levels (8.4±1.3 percent at baseline vs. 8.2±1.1 percent) compared to the control group (8.3±1.0 percent at baseline vs. 8.7±1.5 percent). In a multivariable regression analysis that controlled for age, duration of diabetes, and diabetes management, the change in HbA1c level after 1 year was 0.5 percent better in the TW group than in the control group ($R^2 = 0.17$, $p = 0.04$). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Children with newly diagnosed diabetes. The RCT by Sundelin et al.[70] compared conventional inpatient education (n = 19 families) to a multidisciplinary program for family-oriented crisis intervention delivered in an outpatient setting (n = 19 families). There were no statistically significant differences in HbA1c levels between the two groups up to 5 years following diagnosis; both groups demonstrated improved levels in HbA1c levels compared to baseline measures. The mean baseline measure for the

intervention group was 9.6±0.14 percent and at 5 years, it was 7.6±15 percent; for the control group, baseline HbA1c level was 9.8±0.74 percent and at 5 years it was 7.2±1.5 percent. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Kennedy-Iwai[36] randomly assigned 19 families to receive standard care (standard clinical treatment and diabetes education) or standard care plus a couple communication program delivered to parents. There was no improvement in HbA1c levels at the post-treatment assessment for children in either group. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Children with poorly controlled diabetes. Wysocki et al.[83] randomly assigned 119 children to 3 groups: standard care (physician directed clinical therapy), education and support (standard care plus 10 sessions of a diabetes support group), and BFST (standard care plus family problem-solving and communication training and individualized treatment plan). At the end of the 3-month intervention none of the groups demonstrated any significant change from their baseline HbA1c levels. The methodological quality of this study was rated as high (3/5 on the Jadad score; adequate allocation concealment).

In an uncontrolled before-and-after study, Harris et al.[28] reported 6-month followup data for 18 adolescents and their families who enrolled in a BFST program. HbA1c levels were unchanged from baseline levels. The methodological quality of this study was rated as weak using the Thomas instrument.

Skills Training—HbA1c

Description of studies. Six studies (3 RCTs,[43,49,57] 2 cohorts,[40,53] 1 uncontrolled before-and-after[11]) examined various interventions that focused on skills training. Studies were conducted in the United States,[11] Canada,[49,57] Europe,[43,53] and Thailand.[40] The median year of publication was 2001 and ranged from 1983 to 2003.

The number of participants enrolled in the studies ranged from 32 to 130 (median = 51 [IQR 39 to 56]). The mean age of participants ranged from 7.1 to 14.4 years. For three studies, the mean age was less than 12 years.[11,40,49] Two studies examined education interventions delivered to children and their families at the time of diagnosis.[40,49] Two studies focused on children who demonstrated poor metabolic control.[43,57]

Most interventions were targeted at children and their parents or the entire family; in one study the intervention was delivered to the child.[57] The settings for the interventions were described as a diabetes center,[49] hospital inpatient unit,[40] or home.[53] For three studies, the setting was mixed (e.g., diabetes center and home).[11,43,57] All studies conducted post-intervention assessments for HbA1c. The median followup period for the studies was 18 months and ranged from 6 to 43.5 months.

Results

General population of children with diabetes. Nordfeldt and Ludvigsson[53] evaluated the effect of self-study material on diabetes education aimed at self-management skills and the prevention of hypoglycemia. Over a 3-year period (1997 to 1999) brochures and videos were distributed to approximately 130 patients and families

each year. HbA1c levels were compared to the mean levels for 1996 (prior to the distribution of the brochures). Mean HbA1c levels in 1997 were statistically significantly lower than those reported in 1996 (6.5±1.1 vs. 6.8±1.2 percent, respectively); similar results were reported comparing 1998 and 1996 (6.4±1.1 vs. 6.8±1.2 percent, respectively). The methodological quality of this study was rated as weak using the Thomas instrument.

In an uncontrolled before-and-after study by Caravalho and Saylor,[11] 56 children and their parents were taught insulin adjustment procedures and received group support and education to improve self-management. Among the 38 patients who were assessed at 6 months, there was no significant improvement in HbA1c levels from baseline to post-intervention (9.15±2.32 vs. 8.99±1.79 percent). The methodological quality of this study was rated as weak using the Thomas instrument.

Children with newly diagnosed diabetes. Likitmaskul et al.[40] conducted a nonconcurrent cohort study to compare the effect of a multidisciplinary team approach to diabetes education to conventional education that focused on insulin injection and how to control diet. The 28 children who received conventional education were diagnosed with diabetes prior to 1996 and served as a historical comparison group to the 24 children who were diagnosed after 1996. The children who received the multidisciplinary education program demonstrated significantly lower levels of HbA1c up to 3 years after diagnosis (12.4±2.7 vs. 13.6±5.4 percent, respectively [p = 0.03]). The methodological quality of this study was rated as moderate using the Thomas instrument.

In the study by Mitchell,[49] 32 children were randomly assigned to either the intervention or the control group. The intervention group received standard multidisciplinary education and support plus a booklet targeted at improving compliance with treatment. The control group received standard education and support. The intervention group showed a general trend to lower HbA1c values over the 24-month followup; however, the differences were not statistically significant except at 10 to 13 months post-diagnosis. The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment). Both the intervention and control groups had substantial dropouts over the study period (47 and 53 percent, respectively).

Children with poorly controlled diabetes. Children with poorly controlled diabetes were targeted in the RCT by Mann et al.[43] Children in the intervention group (n = 19) received intensive diabetes education combined with regular SMBG. Children in the control group (n = 20) received intensive education only. At the end of the study, there was no significant change in HbA1c levels from baseline to 18 months in either group (14.1±1.3 vs. 14.3±1.9 percent for the intervention group; 12.7±2.0 vs. 12.8±2.4 percent for the control group). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

In the RCT by Panagiotopoulos et al.[57] 25 children received weekly telephone calls and guidance with SMBG, while 25 children received standard care (i.e., routine clinical care). The authors reported that at 6 months, HbA1c levels decreased significantly from baseline in both the intervention and control groups (9.7±1.2 to 8.8±1.3 percent and 9.6±1.3 to 9.1±1.4 percent, respectively). However, the magnitude of change between the two groups was not statistically significant. In a post hoc subgroup analysis of children with HbA1c levels greater than 9.5 percent at baseline, the authors found that HbA1c levels decreased significantly in the intervention group. Six months after study

completion, this subset continued to have improved HbA1c levels compared to the control group (from 10.5±1.0 to 9.3±0.9 vs. 10.6±1.0 to 10.4±1.5, respectively). The methodological quality of this study was rated as high (3/5 on the Jadad score; unclear allocation concealment).

Diabetes Camp—HbA1c

Description of studies. In five studies (1 RCT,[46] 2 CCTs,[62,84] 2 uncontrolled before-and-after studies[34,35]) the education intervention was delivered as part of a diabetes camp program. Four studies were conducted in the United States and one took place in Europe.[34] The median year of publication was 1997 and ranged from 1986 to 2005.

The number of participants enrolled in the studies ranged from 25 to 237 (median = 42 [IQR 33 to 56]). The mean age of participants ranged from 10.0 to 14.5 years. In two studies, the mean age was less than 12 years.[35,84] One study focused on children who demonstrated poor metabolic control.[34] All interventions were delivered to the children. All studies conducted post-intervention assessments for HbA1c; the median followup period was 3.5 months and ranged from 3 to 12 months.

Results

General population of children with diabetes. The specific interventions that were delivered during the diabetes camps were diverse. In the trial by Massouh et al.,[46] 34 adolescents were randomly assigned to a group that received a daily 1-hour teaching session about diabetes or to a group that received the lecture plus a social learning intervention (relationship skills) that involved role playing. Both groups demonstrated increases (i.e., poorer control) in HbA1c levels at 3.5 months following the end of camp (1.5 percent [p = 0.008] for the intervention group; 1.2 for the comparison group [p = 0.14]). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Remley[62] conducted a CCT to compare a social cognitive theory-based program with a standard non-theory based camp education program. Eight 1-week camps across the United States were designated deliver the either the theory-based intervention or the standard program. At the 3-month followup, there was no significant change in HbA1c levels for either group. The attrition rate for both groups was high (40 percent). The methodological quality of this study was rated as low (1/3 on the modified Jadad score; unclear allocation concealment).

Zorumski[84] investigated the effects of self-care training for 49 children. All children received basic self-care training from their physicians; 27 also attended a 1-week day camp that provided additional self-care instruction. At the 4-month followup, there was no significant change from baseline HbA1c levels for either group (9.93±2.9 vs. 10.49±2.7 percent [intervention group] and 10.85±2.14 vs. 10.47±2.8 percent [comparison group]). The methodological quality of this study was rated as low (0/3 on the modified Jadad score).

In an uncontrolled before-and-after study Kemp et al.[35] assessed the effectiveness of diabetes education and carefully monitored blood glucose control among 42 children who attended a 2-week summer camp. One year later, HbA1c levels had increased (i.e., poorer

control) from the baseline measure (8.1±1.9 vs. 10.1±1.9 percent). The methodological quality of this study was rated as weak using the Thomas instrument.

Children with poorly controlled diabetes. In an uncontrolled before-and-after study (n = 25), Karaguzel et al.[34] examined the effect of a 1-week diabetes camp that incorporated intensive insulin treatment into a general diabetes program (n = 25). There was a statistically significant decrease in HbA1c levels from baseline to 12-months post-intervention (9.3±2.5 vs. 8.2±1.5 percent, $p<0.05$). The methodological quality of this study was rated as weak using the Thomas instrument.

Other Interventions—HbA1c

General population of children with diabetes. Campaigne et al.[10] assessed the effects of physical training on HbA1c levels. Fourteen adolescents were randomly assigned to either a 12-week exercise program or to a control group that did not modify the usual exercise routine. At the end of the program, HbA1c levels remained unchanged in both groups. The methodological quality of the study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

The RCT by Olmsted et al.[56] evaluated the effect of a 6-session intervention for eating disorders for young women with disturbed eating habits. Eighty-five patients were randomized to the psychoeducation program or to routine care at the diabetes center. At the 6-month followup neither group demonstrated any significant improvement in HbA1c levels. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Children with poorly controlled diabetes. In a CCT, Moran et al.[51] compared two equivalent groups of 11 children with a history of poor metabolic control. One group received an intensive inpatient psychotherapy program; the comparison group comprised children who were admitted to hospital for medical treatment of diabetes-related complications. Both groups received diabetes education while in hospital. HbA1c levels were significantly improved at the 12-month followup for the intervention group (14.3 vs. 11.5 percent); there was no change in HbA1c levels for the comparison group (13.7 vs. 13.5 percent). The methodological quality of the study was low (0/3 on the modified Jadad score).

Summary of Results—HbA1c

Overall, we identified 52 studies that assessed the effectiveness of diabetes education programs in controlling HbA1c levels (Table 6). Of these, 30 studies (19 RCTs, 3 CCTs, 3 cohorts, 5 uncontrolled before-and-after) examined the general population of children with type 1 diabetes, 8 (5 RCTs, 1 CCT, 2 cohorts) focused on children with newly diagnosed diabetes, and 14 (9 RCTs, 3 CCTs, 2 uncontrolled before-and-after) considered children with poorly controlled diabetes. Due to substantial differences across studies in terms of population, interventions, comparison groups, duration of intervention, and followup time points, we were not able to pool the results of any of the studies.

General population of children with diabetes. Overall, 30 studies (19 RCTs,[5,6,9,10,21,22,24,31-33,38,46,47,56,63,72,79,80,82] 3 CCTs,[7,62,84] 3 cohorts,[39,53,54] 5 uncontrolled before-and-after[11,35,61,75,77]) assessed the effectiveness of diabetes education in controlling

HbA1c levels in the general population of children with diabetes (Table 6). Interventions that were assessed included general diabetes education,[9,24,32,39,61,75,77,79] cognitive behavioral therapy,[5-7,21,22,31,33,47,54,72,80] family therapy,[38,63,82] skills training,[11,53] diabetes camp,[35,46,62,84] physical training,[10] and psychoeducation.[56] Overall the methodological quality of the studies was low. Three RCTs were rated as moderate (Grey et al.,[21] Olmsted et al.,[56] and Szumowski[72]) and two uncontrolled before-and-after studies (Verrotti,[75] von Sengbusch et al.[77]) were assessed as moderate.

Results

The results of the studies rated as moderate quality were mixed. Grey et al.[21] found that the intervention group that received intensive diabetes management plus coping skills training had significantly lower HbA1c levels than the group that received intensive management only. Szumowski[72] found no change from baseline levels of HbA1c for the intervention group that received goal setting training or the control group. Similarly, Olmsted et al.[56] reported no difference in HbA1c levels among diabetic patients with eating disorders comparing a psychoeducation intervention with routine care. The uncontrolled before-and-after study by Verrotti et al.[75] found decreased levels of HbA1c among teenagers who received general diabetes education. In contrast, the uncontrolled before-and-after study by von Sengbusch et al.[77] assessed a mobile diabetes education program and found no change in HbA1c following the intervention.

The results of the remaining studies were inconsistent. Seven studies[6,33,38,53,54,63,82] reported that HbA1c levels decreased significantly following the diabetes education intervention. Three of these studies assessed cognitive behavioral therapy,[6,33,54] three studies assessed family therapy programs[38,63,83] and one assessed skills training.[53] Six studies[5,7,22,32,47,61] found that HbA1c levels improved significantly for both the intervention and control groups; however, the differences between groups were not statistically significant. Four of these studies assessed cognitive behavioral therapy[5,7,22,47] and two assessed general diabetes education.[32,61] The remaining studies[9-11,24,31,35,46,62,79,80,84] reported that diabetes education had no significant effect on improving HbA1c levels.

Children With Newly Diagnosed Diabetes

Overall, 8 studies (5 RCTs,[17,18,36,49,70] 1 CCT,[19] 2 cohorts[40,69] assessed the effectiveness of diabetes education among children with newly diagnosed diabetes (Table 6). Interventions that were assessed were general diabetes education,[18,69] cognitive behavioral therapy,[17,19] family therapy,[36,70] skills training.[40,49] In general, the methodological quality was low; two RCTs (Delamater et al.[17] and Dougherty et al.[18]) and the two cohort studies (Likitmaskul et al.[40] and Srinivasan et al.[69]) were assessed as being of moderate quality.

Results. Three studies (Dougherty et al.,[18] Sundelin et al.,[70] Srinivasan et al.[69] compared general diabetes education programs[18,69] or family therapy programs[70] that were delivered in an ambulatory setting vs. the same program to delivered during hospitalization. The findings of the studies were inconsistent (Table 6). Dougherty et al.[18] reported that the decrease in HbA1c levels was significantly greater for the home-based

group compared with the inpatient group. Sundelin et al.[70] and Srinivasan et al.[69] found no significant differences in HbA1c levels between groups.

The RCT by Delamater et al.[17] found that self-management training group had significantly lower HbA1c levels compared with the control group. Similarly, the cohort study by Likitmaskul et al.[40]) found that HbA1c levels were significantly lower in the cohort that received skills training. Mitchell[49] assessed skills training and reported that HbA1c levels improved significantly for both the intervention and control groups; however, the difference was not statistically significant. The sample size was small and there may not have been sufficient statistical power to detect a difference. The remaining study that assessed a family therapy program delivered to parents[36] reported that diabetes education had no significant effect on improving HbA1c levels in children with newly diagnosed diabetes.

Children With Poorly Controlled Diabetes

Overall, 14 studies (9 RCTs,[8,13,15,16,25,43,55,57,83] 3 CCTs,[14,51,76] 2 uncontrolled before-and-after[28,34]) assessed the effectiveness of diabetes education among children with poorly controlled diabetes (Table 6). Interventions that were assessed included general diabetes education,[15,55] cognitive behavioral therapy,[8,13,14,16,76] family therapy,[28,83] skills training,[43] diabetes camp,[34] and psychoeducation.[51] In general, the methodological quality of the studies was low; three RCTs were assessed as being of high quality (Nunn et al.,[55] Panagiotopoulos et al.,[57]Wysocki et al.[83]).

Results. Two large high-quality RCTs that assessed general diabetes education (Nunn et al.,[55]) and family therapy (Wysocki et al.[83]) reported that diabetes education had no significant impact on HbA1c levels. The RCT by Panagiotopoulos et al.[57] found HbA1c levels decreased for both groups, but the difference was not significant.

The results of the remaining studies were inconsistent. Four studies[14,51,76] reported that HbA1c levels decreased significantly following the diabetes education intervention. Two RCTs[13,15] found that HbA1c levels improved significantly for both the intervention and control groups; however, the differences were not statistically significant. Both studies had small samples (less than 40 participants each) and may not have had sufficient statistical power to detect a difference. The remaining studies[8,16,25,28,43] reported that diabetes education had no significant effect on improving HbA1c levels in this patient population.

Table 6. Summary of results for studies assessing the effect of diabetes education on HbA1c

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes				
Anderson[6] 1989	Cognitive behavioral therapy	RCT 70	Low	IG had significantly lower HbA1c than CG at 18 mo.
Anderson[5] 1999	Cognitive behavioral therapy	RCT (3 arms) 89	Low	IG had lower HbA1c than CG at 24 mo.; the difference between groups was NS
Barglow[7] 1983	Cognitive behavioral therapy	CCT 42	Low	HbA1c levels decreased for both groups at 4 mo.; difference between groups was NS
Brown[9] 1997	General diabetes education	RCT 59	Low	No significant improvement for either group at 6 mo.
Campaigne[10] 1985	Physical training	RCT 16	Low	No significant change for either group at 12 wk.
Caravalho[11] 2000	Skills	Before-after 56	Low	No significant change in HbA1c at 6 mo.

CG = control group; IG = intervention group; NS = not significant

Table 6. Summary of results for studies assessing the effect of diabetes education on HbA1c (continued)

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes (continued)				
Grey[21] 2000	Cognitive behavioral therapy	RCT 77	Moderate	IG had significantly lower HbA1c than CG at 12 mo.
Gross[22] 1985	Cognitive behavioral therapy	RCT 14	Low	HbA1c levels decreased for both groups at 6 mo.; difference between groups was NS
Hackett[24] 1989	General diabetes education	RCT (4 arms) 119	Low	No significant change for any of the groups at 8 mo.
Horan[31] 1990	Cognitive behavioral therapy	RCT 20	Low	No significant change in HbA1c for either group at 15 wk.
Howe[32] 2005	General diabetes education	RCT (3 arms) 89	Low	HbA1c levels decreased for all groups at 6 mo.; differences between groups were NS
Kaplan[33] 1985	Cognitive behavioral therapy	RCT 21	Low	IG had significantly lower HbA1c than CG at 4 mo.
Kemp[35] 1986	Diabetes camp	Before-after 42	Low	No significant improvement in HbA1c at 12 mo.
Laffel[38] 2003	Family therapy	RCT 105	Low	IG had significantly lower HbA1c than CG at 12 mo.
Lawson[39] 2000	General diabetes education	Cohort 28	Low	HbA1c levels decreased in IG at 12 mo.; no change for comparison group; however, groups had baseline differences
Massouh[46] 1989	Diabetes camp	RCT 33	Low	No significant improvement in HbA1c for either group at 3.5 mo.
McNabb[47] 1994	Cognitive behavioral therapy	RCT 24	Low	HbA1c levels decreased for both groups at 6 wk.; difference between groups was NS
Nordfeldt[54]1999	Cognitive behavioral therapy	Cohort 139	Low	1994-5 cohort (IG) had significantly lower HbA1c than 1980-1 cohort
Nordfeldt[53] 2002	Skills	Cohort 130	Low	1997 and 1998 cohorts (IG) had significantly lower HbA1c than the1996 cohort
Olmsted[56] 2002	Psychoeducation	RCT 85	Moderate	No significant change for either group at 6 mo.
Povlsen[61] 2005	General diabetes education	Before-after 37	Low	Significant decrease in HbA1c immediately after intervention; no change at 3 and 6 mo.
Remley[62] 1999	Diabetes camp	CCT 237	Low	No significant change in HbA1c for either group at 3 mo.
Satin[63] 1989	Family therapy	RCT (3 arms) 32	Low	IG had significantly lower HbA1c than CG at 6 mo.

Table 6. Summary of results for studies assessing the effect of diabetes education on HbA1c (continued)

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes (continued)				
Szumowski[72] 1990	Cognitive behavioral therapy	RCT 27	Moderate	No significant change in HbA1c for either group at 3 mo.
Verrotti[75] 1993	General diabetes education	Before-after 30	Moderate	Significant decrease in HbA1c at 12 mo.
von Sengbusch[77] 2006	General diabetes education	Before-after 107	Moderate	No significant change in HbA1c at 12 mo.
Wadham[79] 2005	General diabetes education	RCT 67	Low	No significant change in HbA1c for either group at 6 mo.
Webb[80] 1999	Cognitive behavioral therapy	RCT 66	Low	No significant change in HbA1c for either group at 3 mo.
Wysocki[82] 2007	Family therapy	RCT (3 arms) 104	Low	IG had significantly lower HbA1c than either CG at 12 mo.
Zorumski[84] 1997	Diabetes camp	CCT 56	Low	No significant change in HbA1c for either group at 4 mo.
Children with newly diagnosed diabetes				
Delamater[17] 1990	Cognitive behavioral therapy	RCT (3 arms) 36	Moderate	IG had significantly lower HbA1c than both CG at 24 mo.
Dougherty[18] 1999	General diabetes education	RCT 63	Moderate	HbA1c levels decreased for both groups at 3 mo.; differences still present at 36 mo.; IG had significantly lower HbA1c compared to CG at 24–36 mo.
Golden[19] 1985	Cognitive behavioral therapy	CCT 19	Low	HbA1c levels were significantly lower for IG than CG over 15 mo.; no data provided to assess the change from baseline for HbA1c
Kennedy-Iwai[36] 1991	Family therapy	RCT 19	Low	No significant change in HbA1c for either group at 3 mo.
Likitmaskul[40] 2002	Skills	Cohort 52	Moderate	Post-1996 cohort (IG) had significantly lower HbA1c than the pre-1996 cohort over 3 yr.
Mitchell[49] 1996	Skills	RCT 32	Low	HbA1c levels were lower for IG than CG over 24 mo.; difference between groups was NS except at 10–13 mo.
Srinivasan[69] 2004	General diabetes education	Cohort 110	Moderate	No significant change in HbA1c in either cohort at 3, 6 and 12 mo.

Table 6. Summary of results for studies assessing the effect of diabetes education on HbA1c (continued)

Author Year	Intervention	Study design Sample size	Quality	Conclusion
Children with newly diagnosed diabetes (continued)				
Sundelin[70] 1996	Family therapy	RCT 38	Low	HbA1c levels decreased for both groups up to 5 yr.; differences between groups were NS
Children with poorly controlled diabetes				
Boardway[8] 1993	Cognitive behavioral therapy 77	RCT 31	Low	No significant change in HbA1c for either group at 6 mo.
Cigrang[13] 1992	Cognitive behavioral therapy	RCT (3 arms) 37	Low	HbA1c levels decreased for all groups at 3 mo.; differences among groups were NS
Couper[14] 1999	Cognitive behavioral therapy	CCT 69	Low	HbA1c levels decreased in IG at 6 and 18 mo.; no change in CG
Coupland[15]1992	General diabetes education	RCT 32	Low	Significant decreases at 6 mo. in both groups; difference between groups was NS
Delamater[16] 1991	Cognitive behavioral therapy	RCT (3 arms) 13	Low	No significant change in HbA1c for either group at 4 mo.
Hains[25] 2000	Cognitive behavioral therapy	RCT 15	Low	No significant change in HbA1c for either group at 1 mo.
Harris[28] 2005	Family therapy	Before-after 18	Low	No significant change in HbA1c at 6 mo.
Karaguzel[34] 2005	Diabetes camp	Before-after 25	Low	Significant decrease in HbA1c at 6 and 12 mo.
Mann[43] 1984	Skills training	RCT 39	Low	No significant change in HbA1c for either group at 18 mo.
Moran[51] 1991	Psychoeducation	CCT 22	Low	HbA1c levels decreased in IG at 12 mo.; no change in CG
Nunn[55] 2006	General diabetes education	RCT 123	High	No significant change at 8 mo. for either group
Panagiotopoulos[57] 2003	Skills	RCT 50	High	HbA1c levels decreased for both groups at 6 mo.; difference between groups was NS
Viner[76] 2003	Cognitive behavioral therapy	CCT 21	Low	IG had significantly lower HbA1c than CG at 12 mo.
Wysocki[83] 2000	Family therapy	RCT (3 arms) 119	High	No significant change in HbA1c for either group at 3 mo.

Health Services Utilization

Overall, we identified 11 studies that assessed the impact of diabetes education on health service utilization. Health service utilization was measured in a variety of ways: length of stay, hospital or ED admissions for diabetes- and non-diabetes-related complications. Of the 11, 4 examined the general population of children with diabetes, 4 focused on children with newly diagnosed diabetes and 3 targeted children with poorly controlled diabetes.

General Diabetes Education—Health Services Utilization

Description of studies. We identified 6 studies (3 RCTs,[9,55,71] 2 cohorts,[41,66] 1 uncontrolled before-and-after[77]) that assessed the effect of general diabetes education programs on health service utilization. Studies were conducted in the United States,[9,41,66,71] Australia[55] and Europe.[77] The median year of publication was 2001 and ranged from 1988 to 2006.

The number of participants in the studies ranged from 30 to 301 (median = 83 [IQR 32 to 146]). The mean age of participants ranged from 7.4 to 11.9 years (n = 5 studies). Two studies focused on children with newly diagnosed diabetes.[41,66] One study examined an education intervention delivered to children who demonstrated poor metabolic control.[55]

Five of the intervention programs targeted children and their parents or the family; one was delivered to children only.[9] The settings for interventions were described as a hospital inpatient unit,[41,77] diabetes center,[71] home,[9] or mixed (e.g., diabetes center and home).[55,66] Three studies reported post-intervention assessments of 1 month,[66] 6 months[77] and 24 months.[71]

Results

General population of children with diabetes. Svoren et al.[71] randomly assigned 299 patients to one of three groups: a case manager or "care ambassador" whose role was to monitor clinic attendance and provide telephone outreach to families (CA), a care ambassador plus eight psychoeducational modules on diabetes care that were delivered during visits to the diabetes clinic (CA+), or standard care (routine clinical care). At the end of the 24-month program, the CA+ group had a significantly lower rate of hospitalizations than the combined comparison groups (8.9 per 100 patient-years vs. 15.3 per 100 patient-years, respectively [p = 0.04]). The rate of emergency department (ED) visits was also lower in the CA+ group than for the comparison groups (21.0 per 100 patient-years vs. 34.9 per 100 patient-years, respectively [p = 0.004]). The methodological quality of the study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Brown et al.[9] randomly assigned 59 children and adolescents to a group that played a video game featuring characters with diabetes or a group that played a pinball video game with no information on diabetes. At the end of the 6-month study period, the number of

unscheduled urgent visits to the physician for diabetes-related problems declined in the intervention group (0.57 visits per child vs. 0.13 visits). For the comparison group, the number of visits increased (0.61 visits per child vs. 0.64). However, the difference in the change from baseline for the two groups was not statistically significant (p = 0.08). The methodological quality of the study was low (1/5 on the Jadad score; unclear allocation concealment).

In an uncontrolled before-and-after study, von Sengbusch et al.[77] assessed the impact of a mobile diabetes education service in a group of 107 children living in rural areas. At 24 months, the number of hospitalizations decreased significantly from 17 (16.2 percent) at baseline to 7 (6.8 percent). The methodological quality of the study was moderate based on the Thomas instrument.

Children with newly diagnosed diabetes. In a retrospective cohort study (n = 30), Lipman[41] compared the effect of diabetes education delivered by a clinical nurse specialist compared to the same program delivered by staff nurses. The authors reported that the length of hospitalization was significantly shorter for the intervention group than for the comparison group. (6.2±1.8 days vs. 8.4±1.8 days,[p<0.01], respectively). The methodological quality of the study was moderate based on the Thomas instrument.

In a prospective cohort study, Siminerio et al.[66] examined differences between outpatient and inpatient programs for newly diagnosed children (n = 32). In the month following diagnosis, none of the children in either group reported any diabetes-related hospital or ED visits. The methodological quality of the study was moderate based on the Thomas instrument.

Children with poorly controlled diabetes. Nunn et al.[55] randomly assigned 123 patients to receive telephone calls from a pediatric diabetes educator or standard care (i.e., routine clinic visits but no telephone calls). Over the course of the 8-month study, both groups showed an increase in hospitalizations of 0.02 per year; however, the difference in the change from baseline between the groups was not statistically significant (p = 0.57). The methodological quality of the study was high (3/5 on the Jadad score; unclear allocation concealment).

Cognitive Behavioral Therapy—Health Services Utilization

Children with newly diagnosed diabetes. One CCT by Golden et al.[19] examined the effect of an intervention that used cognitive behavioral therapy techniques. Eleven families received an integrated diabetes education and psychosocial support program that was delivered in a motel-like setting. The comparison group (n = 8) received the same training 15 months after diagnosis. Over 24 months following diagnosis, the intervention group experienced 1 hospitalization for hypoglycemia compared with 11 hospitalizations for the comparison group. The methodological quality of the study was low (1/3 on the modified Jadad score).

Skills Training—Health Services Utilization

Children with newly diagnosed diabetes. Likitmaskul et al.[40] conducted a nonconcurrent cohort study to compare the effect of a multidisciplinary team approach to diabetes education to conventional education that focused on insulin injection and how to control diet. The 28 children who received conventional education were diagnosed with diabetes prior to 1996 and served as a historical comparison group to the 24 children who were diagnosed after 1996. Based on a review of medical records, the hospital length of stay after initial diagnosis was significantly shorter for children who received the multidisciplinary education program than for the comparison group (17.6±9.5 days vs. 36.0±46.5 days, respectively). The methodological quality was rated as moderate using the Thomas instrument.

Children with poorly controlled diabetes. In the RCT by Mann et al.[43] children in the intervention group (n = 19) received intensive diabetes education combined with regular SMBG; children in the control group (n = 20) received intensive education only. Over the 18-month followup, the group that received education only had 4 diabetes-related hospital admissions; the SMBG group reported no admissions ($p< 0.04$). The methodological quality of the study was low (2/5 on the Jadad score; unclear concealment of allocation).

Diabetes Camp—Health Services Utilization

General population of children with diabetes. In an uncontrolled before-and-after study, Koontz[37] examined the effect of a general diabetes education program delivered at a 1-week camp (n = 112). The mean age of the children was 5.0 years. At the 3-month followup, there were no hospitalizations reported for the 29 children who responded to the followup questionnaire. Three children reported physician visits for reasons other than their regular checkup. No baseline data were provided, therefore we do not know if this was different from their pre-camp experience. The methodological quality of the study was rated as moderate based on the Thomas instrument.

Other Interventions—Health Services Utilization

Children with poorly controlled diabetes. In the CCT by Moran et al.[51] a group of 11 children received an intensive inpatient psychotherapy program; the comparison group comprised 11 children who were admitted to hospital for medical treatment of diabetes-related complications. Both groups received diabetes education while in hospital. At the 12-month followup there was no significant difference in the number of overall hospitalizations (1.0±1.4 admissions per child vs. 0.9±0.9 [comparison group]). When the number of diabetes-related hospital admissions was compared, the intervention group had significantly fewer admissions than the comparison group (0.3±0.5 admissions per child vs. 0.9±0.9 [$p<0.05$], respectively). The methodological quality of the study was low (0/3 on the modified Jadad score).

Summary of Results—Health Services Utilization

We identified 11 studies that assessed the impact of diabetes education on health services utilization (Table 7). Of these, four studies (2 RCTs, 2 uncontrolled before-and-after) examined the general population of children with type 1 diabetes, four (1 CCT, 3 cohort) focused on children with newly diagnosed diabetes, and three (2 RCTs, 1 CCT) considered children with poorly controlled diabetes. Health services utilization was measured in a variety of ways: length of stay, hospital or ED admissions for diabetes- and non-diabetes-related complications.

General population of children with diabetes. Four studies (2 RCTs,[9,71] 2 uncontrolled before-and-after[37,77]) assessed the effect of diabetes education on health services utilization in the general population of children with diabetes (Table 7). Three studies assessed general diabetes education programs[9,71,77] and one assessed a diabetes camp program.[37] In general, the methodological quality of the studies was moderate; only one RCT[9] was rated as being of low quality.

Results. There is some evidence that diabetes education has an impact on health services utilization in this patient population. The RCT by Svoren et al.[71] reported hospital and ED admissions were significantly reduced in the intervention group that were supported by a case manager plus psychoeducation training. The uncontrolled before-and-after study by von Sengbusch et al.[77] reported statistically significant reductions in hospital admissions following the intervention. The study by Koontz[37] did not report baseline information; however, there were no hospital or ED admissions 3 months following the diabetes camp. The RCT by Brown et al.[9] reported a non-significant reduction in physician visits.

Children with newly diagnosed diabetes. Four studies (1 CCT,[19] 3 cohorts[40,41,66]) assessed the effect of diabetes education on health service utilization among children with newly diagnosed diabetes (Table 7). Overall, the methodological quality of the studies was moderate, with all but one[19] rated as moderate quality. Two cohort studies assessed a skills training program (Likitmaskul et al.[40]) and a general diabetes education program (Lipman et al.[41]); both found that the length of stay for initial hospitalization was shorter for the intervention groups than the comparison groups. The cohort study by Siminerio et al.[66] compared inpatient vs. ambulatory delivery of general diabetes education and reported that neither study group had any diabetes-related hospital or ED admissions. The RCT by Golden et al.[19] reported significantly fewer hospital admissions for the intervention group.

Children with poorly controlled diabetes. The large high-quality RCT by Nunn et al,[55] reported increased rates of hospital admission for both the intervention group that received general diabetes education plus telephone followup and the control group (i.e., the intervention was not effective) (Table 7). In contrast, the two studies of low methodological quality[43,51] reported that their intervention groups had significantly fewer hospital admissions than the control groups.

Table 7. Summary of results for studies assessing the effect of diabetes education on health services utilization

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes				
Brown[9] 1997	General diabetes education	RCT 59	Low	IG reported fewer physician visits while CG visits increased at 6 mo.; difference was NS
Koontz[37] 2002	Diabetes camp	Before-after 112	Moderate	No hospitalizations or physician visits reported at 3 mo.; however, no baseline data were provided
Svoren[71] 2003	General diabetes education	RCT (3 arms) 299	Moderate	IG had significantly fewer hospital and ED admissions than either CG at 24 mo.
von Sengbusch[77] 2006	General diabetes education	Before-after 107	Moderate	Number of hospitalizations decreased significantly at 24 mo.
Children with newly diagnosed diabetes				
Golden[19] 1985	Cognitive behavioral therapy	CCT 19	Low	IG had significantly fewer hospital admissions than CG at 24 mo.
Likitmaskul[40] 2002	Skills training	Cohort 52	Moderate	LOS for initial hospitalization was significantly shorter for IG compared to CG
Lipman[41] 1988	General diabetes education	Cohort 30	Moderate	LOS for initial hospitalization was significantly shorter for IG compared to CG
Siminerio[66] 1999	General diabetes education	Cohort 32	Moderate	No reported diabetes-related hospital or ED admissions for either group at 1 mo.
Children with poorly controlled diabetes				
Mann[43] 1984	Skills training	RCT 39	Low	IG had significantly fewer diabetes-related hospital admissions than CG at 18 mo.
Moran[51] 1991	Psychoeducation	CCT 22	Low	IG had significantly fewer diabetes-related hospital admissions at 12 mo.
Nunn[55] 2006	General diabetes education	RCT 123	High	IG and CG reported increased rates of hospitalization at 8 mo.; difference was NS

CG = control group; DCCT = Diabetes Control and Complications Trial; ED = emergency department; IG = intervention group; LOS = length of stay; NS = not significant

Complications

Overall, we identified 15 studies that assessed the effectiveness of diabetes education in controlling complications. While one of the objectives of this evidence report was to assess the effect of diabetes education on both long- and short-term complications, all of the complications reported in the included studies were short-term. Of the 15 identified studies, 11 looked at the general population of children with diabetes, 3 focused on children with newly diagnosed diabetes and 1 examined children with poorly controlled diabetes.

General Diabetes Education—Complications

Description of studies. We identified 6 studies (2 RCTs,[18,71] 1 retrospective cohort,[39] 3 uncontrolled before-and-after[61,75,77]) that assessed the effect of general diabetes education programs on short-term complications. Studies were conducted in the United States,[71] Canada,[18,39] and Europe.[61,75,77] The median year of publication was 2001 and ranged from 1993 to 2006.

The number of participants in the studies ranged from 28 to 301 (median = 50 [IQR 30 to 107]). The mean age of participants ranged from 9.8 to 15.8 years (n = 5 studies). For three studies, the mean age was less than 12 years.[18,71,77] One study examined education intervention delivered to children and their families at the time of diagnosis.[18]

All interventions were targeted to children and their parents or to the family. The settings for interventions were described as a hospital inpatient unit,[61,77] diabetes center,[71] or mixed (e.g., diabetes center and home).[18,39] The setting was not clearly described in one study.[75] All six studies reported post-intervention assessments; the median followup period was 12 months and ranged from 6 to 36 months.

Results

General population of children with diabetes. Svoren et al.[71] randomly assigned 299 patients to one of three groups: a case manager or "care ambassador" whose role was to monitor clinic attendance and provide telephone outreach to families (CA), a care ambassador plus eight psychoeducational modules on diabetes care that were delivered during visits to the diabetes clinic (CA+), or standard care (routine clinical care). At the end of the 24-month program, the CA+ group had significantly reduced rates of severe hypoglycemic events compared with either the CA or standard care group (0.45 events per person-year vs. 0.56 events or 0.65 events, respectively [p = 0.02]). The methodological quality of the study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

The retrospective cohort study (n = 28) by Lawson et al.[39] compared intensive, individualized education to group education delivered to patients. The content for both interventions was the same. After 12 months, two children (12 percent) in the intervention group experienced severe hypoglycemic reactions; there were no severe reactions in the comparison group. The difference was not statistically significant (p =

0.13). There were no episodes of DKA in either group. The methodological quality of the study was weak based on the Thomas instrument.

Povlsen et al.[61] assessed the effect of an intervention targeted on 37 families from ethnic minority groups in Denmark. The intervention included adapted educational material and guidelines and re-education that focused on increasing knowledge and self-care. The authors observed that the number of severe hypoglycemia episodes increased from 3 to 10; however, the increase was not statistically significant. There was one DKA event during the intervention. The methodological quality of the study was weak based on the Thomas instrument.

In an uncontrolled before-and-after study Verrotti et al.[75] studied 30 adolescents who attended nine education sessions on general diabetes management. At the 12-month followup, the number of severe hypoglycemia episodes decreased significantly from 2.9±2.2 events to 1.1±1.3 events ($p = 0.002$). The methodological quality of the study was moderate based on the Thomas instrument.

In an uncontrolled before-and-after study, von Sengbusch et al.[77] assessed the impact of a mobile diabetes education service in a group of 107 children. At the 6-month followup the number of episodes of severe hypoglycemia did not change significantly from baseline measures (0.23 events per 100 patient-years to 0.21 events). The methodological quality of the study was moderate based on the Thomas instrument.

Children with newly diagnosed diabetes. Dougherty et al.[18] randomly assigned 63 newly diagnosed patients to a 24-month home-based diabetes education program or to traditional hospitalization and outpatient followup. Treatment differences between the groups included duration of initial hospital stay, timing of initial teaching, and the nature and extent of subsequent nursing followup. Over the 24-month followup period, the authors reported no statistically significant differences between the groups in the number or rate of diabetes-related adverse events (severe hypoglycemia, hyperglycemia and ketosis, DKA, chronic hyperglycemia). The rate in the home-based group was 0.34 events per patient compared with 0.26 in the hospital-based group (RR = 1.45 [95% CI: 0.59 to 3.6]). The methodological quality of the study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Cognitive Behavioral Therapy—Complications

Description of studies. We identified four studies (2 RCTs,[21,72] 1 CCT,[19] 1 prospective cohort[54]) that examined the effect of interventions that used cognitive behavioral therapy techniques. Studies were conducted in the United States[19,21,72] and Europe.[54] The median year of publication was 1995 and ranged from 1985 to 2000.

The median number of participants in the studies was 52 and ranged from 27 to 139. The mean age of participants ranged from 2.7 to 14.7 years. For two studies, the mean age was less than 12 years.[19,72] One study examined education intervention delivered to children and their families at the time of diagnosis.[19]

Interventions were delivered to children,[21] parents,[19] or to both parents and children or the entire family.[54,72] The settings for interventions were described as an outpatient clinic,[72] or mixed (e.g., diabetes center and home).[21,72] The setting was not clearly

described in one study.[19] All but one study[19] reported post-intervention assessments; the followup periods were 3 months,[72] 12 months,[21] and 248 patient years.[54]

Results

General population of children with diabetes. Grey et al.[21] randomly assigned 77 adolescents to receive intensive diabetes management (IDM) as described in the DCCT or IDM plus a behavioral program of coping skills training intervention (IDM+). At the 12-month followup, the IDM+ group reported statistically lower rates for adverse events than the control group (severe hypoglycemia: 1.1 per patient year vs. 1.2 per patient year, respectively [$p<0.001$]; DKA: 0.02 vs. 0.06 events per patient year, respectively [$p<0.001$]). The authors observed that the incidence of hypoglycemia significantly decreased in females but not in males in the IDM+ group. Overall, the rate of complications was higher than that reported by the DCCT. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

In a prospective study with historical controls, Nordfeldt and Ludvigsson[54] examined the effect of multiple dose insulin therapy combined with problem-based training and psychosocial support. The prospective cohort comprised 248 children admitted to hospital in 1994 and 1995. The comparison group (156 patients admitted in 1980-81) received standard clinical care. The annual incidence of severe hypoglycemia with unconsciousness was 0.17 events per patient-year for the intervention group compared with 0.23 events per patient-year for the 1980-81 cohort ($p<0.05$). The incidence of DKA requiring hospitalization during 1994-95 was 0.015 episodes per patient-year (not reported for the 1980-81 cohort). The methodological quality of the study was weak based on the Thomas instrument.

Szumowski[72] randomly assigned 21 young children to an 8-week behavioral intervention that included information on diabetes management plus instruction and practice in the application of behavioral principles and goal setting to reinforce children's regimen adherence. The comparison group received information on diabetes management but no additional instruction. At the 3-month followup there was no significant difference in the number of hypoglycemic episodes experienced by either group, nor was the change from baseline significantly different for either group. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Children with newly diagnosed diabetes. In the CCT by Golden et al.[19] 11 families received an integrated diabetes education and psychosocial support program that was delivered in a motel-like setting. The comparison group ($n = 8$) received the same training 15 months after diagnosis. At 12-month followup, the rate of severe hypoglycemia episodes reported by the intervention group was significantly lower than the comparison group (0.25 per patient vs. 1.1 per patient, respectively [$p<0.01$]). The methodological quality of the study was low (1/3 on the modified Jadad score).

Skills Training—Complications

Three studies (1 RCT,[52] 2 cohorts[40,53]) examined the effect of skills training on short-term complications. The studies were conducted in Europe and were published in 2002[40,53] and 2005.[52]

Results

General population of children with diabetes. In the RCT by Nordfeldt et al.,[52] three groups of patients (n = 332; mean age = 5.3 years) were randomized to receive either videotapes and a brochure with information about practical skills for self-control and treatment (intervention group), a videotape and brochure with general diabetes information, or routine clinical care. Outcomes were assessed at 12 and 24 months following distribution of the education materials. At 12 months there was a reduction in the annual incidence of severe hypoglycemia in the intervention group; there was no significant change for either of the controls groups. This reduction was still present at 24 months; the incidence of severe hypoglycemia in the intervention group decreased from 42 percent to 25 percent ($p = 0.023$) in the intervention group. The methodological quality of the study was low (1/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Nordfeldt and Ludvigsson[53] evaluated the effect of self-study material on diabetes education aimed at self-management skills and the prevention of hypoglycemia. Over a 3-year period (1997 to 1999) brochures and videos were distributed to the homes of approximately 130 patients and families each year. The mean age of the children was 4.6 years. The mean incidence of severe hypoglycemia with unconsciousness was lower during the 1997-1999 cohort compared to 1994-1996 (pre-intervention); however, the difference was not statistically significant (0.14 to 0.16 events per patient-year vs. 0.17 to 0.22 events per patient-year, respectively). The methodological quality of the study was weak based on the Thomas instrument.

Children with newly diagnosed diabetes. Likitmaskul et al.[40] conducted a nonconcurrent cohort study to compare the effect of a multidisciplinary team approach to diabetes education to conventional education that focused on insulin injection and how to control diet. The 28 children who received conventional education were diagnosed with diabetes prior to 1996 and served as an historical comparison group to the 24 children who were diagnosed after 1996. The children who received the multidisciplinary education program had a 4 percent readmission rate for recurrent DKA or hyperglycemia during the first year following diagnosis compared with 18 percent for the comparison group. This difference between groups continued up to 4 years post-diagnosis. The methodological quality of the study was moderate based on the Thomas instrument.

Diabetes Camp—Complications

Children with poorly controlled diabetes. In an uncontrolled before-and-after study, Karaguzel et al.[34] examined the effect of a 1-week diabetes camp that incorporated intensive insulin treatment into a general diabetes program (n = 25). The mean age of the children was 5.0 years. Over the 12-month followup, no severe hypoglycemic episodes were detected. As no baseline data were provided, we cannot determine if this was a change from pre-intervention. The methodological quality of the study was weak based on the Thomas instrument.

Other Interventions—Complications

General population of children with diabetes. Campaigne et al.[10] assessed the effects of physical training on short-term complications. Fourteen adolescents were randomly assigned to either a 12-week exercise program or to a control group that did not modify the usual exercise routine. At the end of the program, there was no change in the occurrence of hypoglycemia in either group. The methodological quality of the study was low (2/5 on the Jadad score; unclear allocation concealment).

Summary of Results—Complications

Overall, we identified 15 studies that assessed the effectiveness of diabetes education in controlling complications. Of these, 11 (5 RCTs, 3 cohorts, 3 uncontrolled before-and-after) examined the general population of children with type 1 diabetes, 3 studies (1 RCT, 1 CCT, 1 cohort) focused on children with newly diagnosed diabetes, and 1 uncontrolled before-and-after study considered children with poorly controlled diabetes (Table 8). While one of the objectives of this evidence report was to assess the effect of diabetes education on both long- and short-term complications, all of the complications reported in the included studies were short-term. Most studies reported on the incidence of severe hypoglycemia. Six studies reported the incidence of DKA and one study measure chronic hyperglycemia.

General population of children with diabetes. Overall, 11 studies (5 RCTs,[10,21,52,71,72] 3 cohorts,[39,53,54] 3 uncontrolled before-and-after[61,75,77]) assessed the effect of diabetes education on short-term complications among the general population of children with diabetes (Table 8). Three studies examined interventions based on cognitive behavioral therapy,[21,54,72] five studied general diabetes education interventions,[39,61,71,75,77] 2 assessed skills training[52,53] and one assessed a physical training program.[10] Overall the methodological quality was low; only two RCTs (Grey et al.,[21] Szumowski[72] and two uncontrolled before-and-after studies (Verrotti,[75] von Sengbusch et al.[77]) were rated as being of moderate quality.

Results

Grey et al.[21] reported that the event rate for severe hypoglycemic events decreased significantly following diabetes education. Verrotti et al.[75] also reported that the event rate for severe hypoglycemic events decreased significantly following diabetes education. In contrast Szumowski[72] and von Sengbusch et al.[77] found that diabetes education had no significant impact on the rate for severe hypoglycemia.

The results of the remaining studies were inconsistent. Three studies[52,54,71] reported that the event rate for severe hypoglycemic events decreased significantly following diabetes education. Nordfeldt and Ludvigsson[53] found that the annual event rate for severe hypoglycemia decreased for both the skills training and comparison groups; however, the difference was not statistically significant. The remaining studies reported that diabetes education had no significant impact on short-term complications.[10,39,61]

Children with newly diagnosed diabetes. Overall three studies (1 RCT,[18] 1 CCT,[19] 1 cohort[40]) assessed the effect of diabetes education on short-term complications among children with newly diagnosed diabetes (Table 8). One study (Likitmaskul et al.[40]), which was assessed as being of moderate quality, reported that the event rate for severe hypoglycemic events and the number of readmissions for DKA decreased significantly following a skills training intervention. Dougherty et al.[18] reported that setting for delivery of general diabetes education (i.e., inpatient vs. ambulatory) had no significant impact on short-term complications. The low quality RCT by Golden et al.[19] reported that the event rate for severe hypoglycemic events decreased significantly following a cognitive behavioral therapy intervention.

Children with poorly controlled diabetes. One uncontrolled before-and-after study assessed the effect of a diabetes camp[34] on short-term complications among children with poorly controlled diabetes (Table 8). No adverse events were reported by Karaguzel et al.[34] during followup.

Table 8. Summary of results of studies assessing the effect of diabetes education on short-term complications

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes				
Campaigne[10] 1985	Physical training	RCT 16	Low	No significant difference between IG and CG in event rate for hypoglycemia at 12 wk.
Grey[21] 2000	Cognitive behavioral therapy	RCT 77	Moderate	IG reported statistically lower event rates for severe hypoglycemia and DKA at 12 mo.; rates were higher than those reported by the DCCT (i.e., poorer control)
Lawson[39] 2000	General diabetes education	Cohort 28	Low	No significant difference between IG and CG in event rate for hypoglycemia at 12 mo.
Nordfeldt[54] 1999	Cognitive behavioral therapy	Cohort 139	Low	Annual event rate for severe hypoglycemia was significantly lower for IG
Nordfeldt[53] 2002	Skills	Cohort 130	Low	Annual event rate for severe hypoglycemia lower for IG; difference between groups NS
Nordfeldt[52] 2005	Skills	RCT (3 arms) 332	Low	Event rate for severe hypoglycemia significantly reduced in IG compared with either CG at 12 and 24 mo.
Povlsen[61] 2005	General diabetes education	Before-after 37	Low	Number of severe hypoglycemic events increased at 6 mo.; difference was NS
Svoren[71] 2003	General diabetes education	RCT (3 arms) 299	Low	Event rate for severe hypoglycemia significantly reduced in IG compared with either CG at 24 mo.
Szumowski[72] 1990	Cognitive behavioral therapy	RCT 27	Moderate	No significant change in event rate for severe hypoglycemia for either group at 3 mo.
Verrotti[75] 1993	General diabetes education	Before-after 30	Moderate	Significant decrease in number of severe hypoglycemic events at 12 mo.
von Sengbusch[77] 2006	General diabetes education	Before-after 107	Moderate	No significant change in event rate for severe hypoglycemia at 6 mo.

CG = control group; DCCT = Diabetes Control and Complications Trial; IG = intervention group; NS = not significant

Table 8. Summary of results of studies assessing the effect of diabetes education on short-term complications (continued)

Author Year	Intervention	Study design Sample size	Quality	Conclusion
Children with newly diagnosed diabetes				
Dougherty[18] 1999	General diabetes education	RCT 63	Moderate	No significant difference between IG and CG in rate of adverse events (severe hypoglycemia, hyperglycemia and ketosis, DKA, chronic hyperglycemia) at 24 mo.
Golden[19] 1985	Cognitive behavioral therapy	CCT 19	Low	Event rate for severe hypoglycemia was significantly lower in IG compared with CG at 12 mo.
Likitmaskul[40] 2002	Skills	Cohort 52	Moderate	IG had significantly fewer readmissions for DKA or hyperglycemia and severe hypoglycemia than CG at 12 mo. and 4 yr. following diagnosis
Children with poorly controlled diabetes				
Karaguzel[34] 2005	Diabetes camp	Before-after 25	Low	No severe hypoglycemic events were detected at 12 mo.

Knowledge

Overall 30 studies assessed the effect of diabetes education on knowledge. Of these, 24 examined the general population of children with diabetes, 3 targeted children with newly diagnosed diabetes and 3 considered children with poorly controlled diabetes.

General Diabetes Education—Knowledge

Description of studies. We identified 13 studies (5 RCTs,[9,18,24,32,55] 2 cohorts,[66,69] 4 uncontrolled before-and-after,[61,65,75,77] 2 CCTs,[42,45]) that assessed the effectiveness of general diabetes education on diabetes-related knowledge. The studies were conducted in the United States,[9,32,45,66] Europe,[24,42,61,75,77] Canada,[18] India,[65] and Australia.[55,69] The median year of publication was 1999 (IQR, 1993 to 2005).

The number of study participants ranged from 30 to 146 (median = 63 [IQR 37 to 107]). The mean age of participants ranged from 10.1 to 15.4 (n = 8 studies). The mean age was less than 12 years in six studies.[18,24,42,55,66,77] Three studies assessed education interventions delivered to children and their families at the time of diagnosis.[18,66,69] One study examined children who demonstrated poor metabolic control.[55]

All of the interventions were aimed at children and their parents or to the entire family. The interventions were delivered in a variety of settings including hospital inpatient units,[61,77] home,[9] and an outpatient clinic.[24] In seven studies, the setting was mixed (e.g., hospital and home)[18,32,45,55,65,66,69] and not reported in two studies.[42,75]

There were four studies in which knowledge was not measured beyond completion of the education program.[9,24,32,55] In the eight studies that reported post-intervention assessments,[18,42,61,65,66,69,75,77] ranged from 1 to 36 months.

Results

General population of children with diabetes. Brown et al.[9] randomly assigned 59 children and adolescents to a group that played a video game with a focus on nutritional education featuring characters with diabetes or a group that played a pinball video game with no information on diabetes. At the end of the 6-month study period, the intervention group reported more gains in knowledge compared to the control group when assessed using the Diabetes Knowledge Test. The methodological quality of this study was low (1/5 on the Jadad score; unclear concealment of allocation).

In the RCT by Hackett et al.,[24] three cohorts of families received educational packages that were delivered over 8 months. The content was the same for all groups; one group (cohort 1) received a second reinforcement package for an additional 8 months. The comparison group did not receive the education package. The education program led to an increase in mean knowledge scores, as measured by a multiple choice test, across all cohorts. However, the knowledge was poorly retained by fathers. The methodological quality of this study was low (2/5 on the Jadad score; unclear concealment of allocation).

Howe et al.[32] randomly assigned 75 patients to one of three treatment groups: : standard care (routine quarterly clinic visits), standard care plus one education session on basic diabetes management skills, and standard care, the education session plus weekly telephone calls to review management techniques. From results of the KNOW test (46 multiple choice questions) there were no statistically significant differences found in knowledge among the groups. The trial was ended early due to lack of enrolment. The methodological quality of this study was low (2/5 on the Jadad score; unclear concealment of allocation).

In the CCT by Lucey and Wing,[42] a general education intervention was delivered to 49 families in the form of two 6-hour group sessions. In the followup period, which ranged from 2 to 44 weeks, the children in the intervention group performed better on a multiple choice questionnaire that tested knowledge than children in the comparison group. The methodological quality of this study was low (0/3 on the modified Jadad score).

Mason[45] examined a two to four player board game played by 93 groups of parents and children. The children would collect cards (tools) that could be used for continued control of diabetes. According to a questionnaire, there was no significant difference in knowledge between groups that played the game and those who did not play the game, though both groups significantly improved knowledge from baseline. The methodological quality of this study was low (0/3 on the modified Jadad score).

Povlsen et al.[61] assessed the effect of an intervention targeted at 37 families from ethnic minority groups in Denmark. The intervention included adapted educational material and guidelines and re-education that focused on increasing knowledge and self-care. Using the results of a questionnaire, the authors reported a mean increase in knowledge from baseline; however, the differences between families were considerable

at the 6-month followup. The methodological quality of this study was weak based on the Thomas instrument.

In the study by Shobhana et al.[65] a 1-hour didactic lecture on injection and monitoring skills and individualized diet counseling was delivered to 37 parent and child groups by a multidisciplinary team. A short questionnaire found that immediately post-intervention and at 3 months, there were significant increases in knowledge about diabetes, injections and hypoglycemia. At the 6-month followup, knowledge in all areas increased except with regard to self-monitoring. The methodological quality of this study was weak based on the Thomas instrument.

In an uncontrolled before-and-after study Verrotti et al.[75] studied 30 adolescents who attended nine education sessions on general diabetes management. At the 12-month followup, a 20-item multiple choice questionnaire showed that the participants had statistically higher knowledge scores compared to baseline values. The methodological quality of this study was moderate based on the Thomas instrument.

In an uncontrolled before-and-after study, von Sengbusch et al.[77] assessed the impact of a mobile diabetes education service in a group of 107 children. There was a statistical improvement in children's knowledge at the 6-month followup according to the results of an age-adapted questionnaire. The methodological quality of this study was moderate based on the Thomas instrument.

Children with newly diagnosed diabetes. Dougherty et al.[18] randomly assigned 63 newly diagnosed patients to a 24-month home-based diabetes education program or to traditional hospitalization and outpatient followup. Treatment differences between the groups consisted of duration of initial hospital stay, timing of initial teaching, and the nature and extent of subsequent nursing followup. The Diabetes Knowledge Scale found no significant difference between the groups. The methodological quality of this study was moderate (2/5 on the Jadad score; unclear concealment of allocation; blinding of outcome assessors).

Siminerio et al.[66] conducted a prospective cohort study in which a group of 32 newly diagnosed children and their parents and peers received 10 to 12 hours of inpatient or outpatient education sessions over three days. The education addressed aspects of basic diabetes knowledge such as self-management skills, nutrition and exercise. The Test of Diabetes Knowledge found that there was no significant difference in knowledge between the inpatient and outpatient groups. The methodological quality of this study was moderate based on the Thomas instrument.

In the prospective cohort study by Srivivasan et al.[69] a group of 61 newly diagnosed patients attended a diabetes day care program (DDCP) at which they received "survival skills" diabetes education. The pre-DDCP cohort comprised 49 patients who were admitted to hospital for 4 to 7 days for a detailed education program. There was no significant difference between the groups' results on the Test of Diabetes Knowledge. The methodological quality of this study was moderate based on the Thomas instrument.

Children with poorly controlled diabetes. Nunn et al.[55] randomly assigned 123 patients to receive scheduled telephone calls from a pediatric diabetes educator or standard care (i.e., routine clinic visits but no telephone calls). The intervention was provided for five to eight months. Immediately after the intervention, authors measured knowledge using a modified test of diabetes knowledge and found there to be no

significant differences between groups. The methodological quality of this study was high (3/5 on the Jadad score; unclear concealment of allocation).

Cognitive Behavioral Therapy—Knowledge

Description of studies. Seven studies (3 RCTs,[22,31,72] 3 CCTs,[14,48,74] and 1 controlled before-and-after[20]) examined various interventions that used cognitive behavioral therapy techniques to increase knowledge. All but two studies were conducted in the United States; 1 was conducted in Europe[48] and 1 was conducted in Australia.[14] The median year of publication was 1993 (IQR, 1990 to 1998) and ranged from 1985 to 2001.

The number of participants enrolled in the studies ranged from 14 to 69 (median = 23 [IQR 20 to 32]). The mean age of participants ranged from 6.5 to 14.2 years (5 studies). For 2 studies, the mean age was less than 12 years.[22,72] One study examined education interventions delivered to children who had poor metabolic control.[14]

In three studies the interventions were delivered to children[14,22,74] and to parents as well as children in four studies.[20,31,48,72] The settings for the interventions were described as an outpatient clinic,[20,48,72] or home.[31] For one study, the setting was mixed (e.g., diabetes center and home).[14] Two studies did not report the setting of the intervention.[22,74] All but 2 studies[20,31] conducted post-intervention assessments for knowledge. The median followup period was 12 months and ranged from 3 to 13 months.

Results

General population of children with diabetes. In the RCT by Gross et al.[22] 14 children and parents were randomly assigned to either behavior modification training or to a group that included discussion and role-playing. At 6-month follow up, the intervention group scored significantly higher on the Behavior Modification Test than the control group ($p<0.01$). The methodological quality of this study was low (2/5 on the Jadad score; unclear allocation concealment).

Szumowski[72] randomly assigned 21 young children to an 8-week behavioral intervention that included information on diabetes management plus instruction and practice in the application of behavioral principles and goal setting to reinforce children's regimen adherence. The comparison group received information on diabetes management but no additional instruction. At the 3-month followup parents were assessed using the Knowledge of behavioral principles as applied to children (KBPAC) and the Test of Diabetes Knowledge while children's knowledge was assessed using the Children's Diabetes Quiz. The authors found that there was a significant group by time interaction ($p<0.008$) for both groups at 3 months. Both children and parents increased their knowledge scores from baseline to 3 months but statistical significance was not reported. The methodological quality of this study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Horan et al.[31] conducted an RCT (n = 20) that compared goal setting and problem solving using dynamic computer-assisted teaching modules vs. conventional education using an education booklet. At the end of the 15-week program, assessments of diabetes knowledge were made using multiple choice questions modified from the Test of Diabetes Knowledge. There was no significant difference between the groups with

regards to their applied knowledge of diabetes. However more individuals in the intervention group showed improvement in their factual diabetes knowledge than individuals in the control group. The methodological quality of this study was low (2/5 on the Jadad score; unclear allocation concealment).

In a controlled clinical trial, Mendez and Belendez[48] delivered 12 sessions to children (n = 37) that provided them with audiovisual and print material and also allowed them to practice their skills. Their parents were taught to reinforce adherence behaviors rather than punish non-compliance. Immediately after the sessions ended, the intervention group had significantly higher results on the Diabetes Information Survey for Children (DISC) ($p < 0.001$) but at 13 months, the difference between the intervention and control group was not significant ($p = 0.087$). The methodological quality of this study was low (1/3 on the modified Jadad score).

Thomas-Dobersen et al.[74] conducted a controlled clinical trial in which 20 adolescents received 14 sessions over three months addressing various areas of diabetes management such as diet and knowledge of hypoglycemia. Youth Evaluation Scales (YES) found that at 1-year followup, the intervention group showed a statistically significant increase in knowledge compared to the control group ($p<0.01$). The methodological quality of this study was low (1/3 on the modified Jadad score).

Greco at al.[20] conducted an uncontrolled before-and-after study that aimed to implement a structured intervention for integrating peers into diabetes care in a healthy and adaptive manner. There were 23 pairs of patients and peers who were assessed using the Diabetes Education and Support Assessment (DESAT) tool. After the 4-week intervention, the children as well as their peers experienced a significant increase in knowledge compared to baseline ($p<0.0001$). The methodological quality of this study was moderate based on the Thomas instrument.

Children with poorly controlled diabetes. Couper et al.[14] evaluated the effects of monthly home visits by a nurse educator plus weekly telephone calls that focused on goal-setting. Thirty-seven adolescents received routine care plus the regular intervention; 32 received routine clinical care only. At the 6-month followup, both parents and children in the intervention groups, assessed with the Diabetes Knowledge Assessment Scale, had significantly higher knowledge scores than those in the control group ($p = 0.001$). At 12 months, only the parents maintained this difference between the groups ($p = 0.005$). The methodological quality of this study was low (1/3 on the modified Jadad score).

Diabetes Camp—Knowledge

Description of studies. In eight studies (3 RCTs[58-60], 1 CCT,[62] and 4 uncontrolled before-and-after studies[12,27,34,35]) the education intervention was delivered as part of a diabetes camp program. Seven studies were conducted in the United States; one took place in Europe.[34] The median year of publication was 1994 and ranged from 1983 to 2005.

The number of participants enrolled ranged from 25 to 237 (median = 76.5 [IQR 61 to 86]). The mean age of participants ranged from 10.0 to 14.83 years. For 1 study, the mean age was less than 12 years.[35] One study focused on children who demonstrated poor metabolic control.[34]

In one study, the intervention was aimed at families[35] while the rest of the interventions were targeted only at children. Only three studies conducted assessments immediately after the intervention.[12,27,60] The remaining five studies conducted post-intervention assessments for knowledge; the median followup period was 8 months and ranged from 2 days to 12 months.

Results

General population of children with diabetes. In the uncontrolled before-and-after study by Christensen et al.[12] the campers attended two sessions on carbohydrate counting and two sessions on food portioning. They used flash cards, practiced reading labels, measuring utensils, used scales with real food and played a card game. The authors used laboratory values to assess the correlations between HbA1c and knowledge and found that the correlation was not statistically significant ($p = 0.09$). The methodological quality of this study was weak based on the Thomas instrument.

The campers in the controlled before-and-after study by Harkavy et al.[27] received informal and formal teaching sessions which covered diabetes etiology/pathology, self-management skills, effects of diabetes on stress and social issues. Immediately after the 2-week camp was over, campers completed a multiple choice questionnaire to assess their knowledge of etiology, pathophysiology and diabetes in general. The authors found that campers 12–13 years and 14–15 years of age showed a significant improvement in knowledge. There was no significant difference found in the 10–11 year olds. The methodological quality of this study was weak based on the Thomas instrument.

In an RCT by Pichert et al.,[60] 64 campers were randomly assigned to one of two groups: four 45-minute problem-solving sessions where they learned about metabolic management skills, diabetes and exercise guidelines and the social issues surrounding diabetes or the control group that received traditional instruction that did not emphasize problem solving. Immediately following the camp, the campers were asked to complete multiple choice and short answer tests to assess their factual knowledge of and ability to apply diabetes-related exercise guidelines. Repeated measures analysis of variance revealed that problem-solving groups gained more in factual knowledge and the ability to apply it to new problems than did the control group. The methodological quality of this study was low (2/5 on the Jadad score; unclear allocation concealment).

In another RCT by Pichert et al.,[58] 69 campers were randomized either to the intervention group comprising three 45-minute groups sessions using a problem-solving format devoted to nutrition-related skills and knowledge, or to the control group that received conventional direct instruction. When assessments were performed 2–4 or 5–6 days post-intervention, there was significant improvement in the knowledge in both groups when they were asked to complete a personal meal plan recall, but there was no significant difference between groups. The methodological quality of this study was low (2/5 on the Jadad score; unclear allocation concealment).

In the third RCT by Pichert et al.,[59] 81 campers were randomized to participate in two 45-minute sessions on sick day management that were taught via a problem-solving format, or to the control group that received conventional direct instruction. Knowledge was assessed using a Sick Day Knowledge Test and a Sick Day Problem Solving Test. At the 8-month followup, there was no significant difference between groups; however, the

intervention group was better able to explain why the management guidelines applied to a hypothetical example. The methodological quality of this study was moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Remley[62] conducted a CCT to compare a social cognitive theory-based program with a standard non-theory based camp education program. Eight 1-week camps across the United States were designated deliver either the theory-based intervention or the standard program. At the 3-month followup, there was no significant change in knowledge levels for either group. The attrition rate for both groups was high (40 percent). The methodological quality of this study was low (1/3 on the modified Jadad score).

In an uncontrolled before-and-after study, Kemp et al.[35] assessed the effectiveness of diabetes education and carefully monitored blood glucose control among 42 children who attended a 2-week summer camp. One year later, there was a significant improvement in knowledge when comparing pre to post intervention groups ($p<0.01$ vs. pre-camp). The methodological quality of this study was weak based on the Thomas instrument.

Children with poorly controlled diabetes. In an uncontrolled before-and-after study (n = 25), Karaguzel et al.[34] examined the effect of a 1-week diabetes camp that incorporated intensive insulin treatment into a general diabetes program which included dietary education. There was a statistically significant increase in knowledge about diabetes and diabetes nutrition at 6 and 12 month followup. The methodological quality of this study was weak based on the Thomas instrument.

Skills Training—Knowledge

Results

General population of children with diabetes. In the uncontrolled before-and-after study by Monaco et al.,[50] children were divided into two groups, ages 6–8 years and 9–11 years, to receive one session in which they were instructed in the use of injection site charts and injection site bears. The authors found that children in both age groups committed significantly fewer injection site identification errors when using the injection bears compared to using the chart. The methodological quality of this study was moderate based on the Thomas instrument.

In the uncontrolled before-and-after study by Templeton et al.,[73] adolescents attended one 90-minute session in which they were taught skills that would help them monitor their blood glucose. Immediately after the session they were asked to complete a five item true/false test. While the authors provided data on the percentages of questions correct, they did not comment on the statistical significance of results. The methodological quality of this study was weak based on the Thomas instrument.

Summary of Results—Knowledge

Overall, we identified 30 studies that assessed the effectiveness of diabetes education in improving knowledge (Table 9). Of these, 24 studies (9 RCTs, 5 CCTs, 10 uncontrolled before-and-after) examined the general population of children with type 1 diabetes, 3 studies (1 RCT, 2 cohorts focused on children with newly diagnosed diabetes,

and 3 studies (1 RCT, 1 CCT, 1 uncontrolled before-and-after) considered children with poorly controlled diabetes.

General population of children with diabetes. Twenty-four studies (9 RCTs,[9,22,24,31,32,58-60,72] 5 CCTs,[42,45,48,62,74] 10 uncontrolled before-and-after[12,20,27,35,50,61,65,73,75,77]) assessed the effectiveness of diabetes education in improving diabetes-related knowledge among the general population of children with diabetes. Eight studies assessed general diabetes education,[9,24,32,42,45,61,65,77] six examined interventions that used cognitive behavioral therapy techniques,[20,22,31,48,72,74] 7 assessed interventions delivered at diabetes camps,[12,27,35,58-60,62] and two assessed skills training.[50,73] Overall the methodological quality of the studies was low; only 2 RCTs[59,72] and 34 uncontrolled before-and-after studies[20,50,75,77] were rated as being of moderate quality.

Results. The results of the 5 moderate quality studies were inconsistent (Table 9). Sumowski[72] reported increased knowledge levels in both the intervention and control groups, but the difference between groups was not statistically significant. Three uncontrolled before-and-after studies (Greco et al.,[20] Verrotti et al.,[75] and von Sengbusch et al.[77]) reported gains in knowledge following a cognitive behavior therapy and general diabetes intervention, respectively. Monaco et al.[50] reported increases in knowledge levels, but the difference was not statistically significant. In the RCT by Pichert et al.[59] knowledge of nutrition and meal planning improved for both intervention and control groups, but the difference was not statistically significant.

The results of the remaining studies were also mixed. Two RCTs,[22,60] one CCT[74] and two uncontrolled before-and-after studies[35,65] reported statistically significant increases in diabetes-related knowledge following the education interventions. Two studies reported that their interventions were effective in subgroups of the study population.[24,27] Three trials and three uncontrolled before-and-after studies reported knowledge gains but the differences were not statistically significant[9,42,58,61,73] or were not retained over the longer term.[48] In the remaining studies, the education interventions did not have significant effect on knowledge outcomes.[12,31,32,45,62]

Children with newly diagnosed diabetes. Three moderate quality studies (1 RCT by Dougherty et al.,[18] 2 cohorts by Siminerio et al.[66] and Srinivasan et al.[69]) compared groups of children with newly diagnosed diabetes that received general diabetes education programs delivered in an ambulatory setting (e.g., home, outpatient clinic) vs. a hospital inpatient setting (Table 9). In all three studies, the knowledge levels increased for both intervention and comparisons groups; however, the differences were not statistically significant. The setting of the education program does not appear to have an effect on knowledge outcomes.

Children with poorly controlled diabetes. The large high-quality RCT by Nunn et al,[55] reported no significant differences in knowledge between the intervention group that received general diabetes education plus telephone followup and the control group that received diabetes education with no telephone followup (Table 9). The remaining studies that targeted patients with poorly controlled diabetes were of low quality. One uncontrolled before-and-after reported significant increases in knowledge following a diabetes camp;[34] one CCT reported significantly higher knowledge levels over the short-term, but these gains were not sustained over the long-term.[14]

Table 9. Summary of results of studies assessing the effect of diabetes education on knowledge

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Brown[9] 1997	General diabetes education	RCT 59	Low	IG significantly improved knowledge scores compared to CG at 6 mo.; difference was NS
Christensen[12] 2000	Diabetes camp	Before-after 68	Low	No significant change from baseline levels of knowledge
Greco[20] 2001	Cognitive behavioral therapy	Before-after 23	Moderate	Adolescents and their peers achieved significant increases in knowledge
Gross[22] 1985	Cognitive behavioral therapy	RCT 14	Low	IG had significantly higher knowledge scores compared to CG at 6 mo.
Hackett[24] 1989	General diabetes education	RCT (4 arms) 119	Low	Knowledge scores increased significantly for children, mothers and fathers in IG; gains not sustained by fathers over 8 mo.
Harkavy[27] 1983	Diabetes camp	Before-after 93	Low	Significant improvement in knowledge for 12–13 and 14–15-yr. olds; no significant difference for 10–11-yr. olds

CG = control group; IG = intervention group; NR = not reported; NS = not significant

Table 9. Summary of results of studies assessing the effect of diabetes education on knowledge (continued)

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes (continued)				
Horan[31] 1990	Cognitive behavioral therapy	RCT 20	Low	No significant difference between groups post-intervention
Howe[32] 2005	General diabetes education	RCT (3 arms) 89	Low	No significant differences among groups at 6 mo.
Kemp[35] 1986	Diabetes camp	Before-after 42	Low	Knowledge scores improved significantly from baseline to post-intervention
Lucey[42] 1985	General diabetes education	CCT 49	Low	IG performed better on general information questions than CG
Mason[45] 1986	Cognitive behavioral therapy	CCT 93	Low	Both groups significantly improved knowledge scores; difference was NS
Mendez[48] 1997	Cognitive behavioral therapy	CCT 37	Low	IG significantly higher than CG at post-intervention; difference was NS at 13 mo.
Monaco[50] 1996	Skills training	Before-after 58	Moderate	Both groups significantly improved knowledge scores from baseline; difference was NS
Pichert[60] 1993	Diabetes camp	RCT 146	Low	IG knowledge improved significantly more than CG for diabetes-related exercise guidelines and ability to apply knowledge
Pichert[58] 1994a	Diabetes camp	RCT 83	Low	Both groups improved significantly in recall of nutritional meal plans, knowledge of food groups, exchange equivalents, portions; difference was NS at post-camp
Pichert[59] 1994b	Diabetes camp	RCT 84	Moderate	No significant difference between groups at 8 mo.
Povlsen[61] 2005	General diabetes education	Before-after 37	Low	Knowledge increased from baseline; difference was NS
Remley[62] 1999	Diabetes camp	CCT 237	Low	No significant increase in knowledge levels for either group
Shobhana[65] 1997	General diabetes education	Before-after 37	Low	Significant increase in knowledge at 6 mo.

Table 9. Summary of results of studies assessing the effect of diabetes education on knowledge (continued)

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes (continued)				
Szumowski[72] 1990	Cognitive behavioral therapy	RCT 27	Moderate	Parents in IG increased knowledge of behavioral principles compared to CG at 3 mo. Parents in both groups increased knowledge of diabetes at 3 mo.; difference was NS Children in both groups increased knowledge of diabetes at 3 mo.; difference was NS
Templeton[73] 1988	Skills training	Before-after 30	Low	Knowledge increased from baseline; statistical significance NR
Thomas-Dobersen[74] 1993	Cognitive behavioral therapy	CCT 20	Low	IG had significant increase in knowledge compared to CG at 15 mo.
Verrotti[75] 1993	General diabetes education	Before-after 30	Moderate	Significantly higher knowledge scores at 12 mo.
von Sengbusch[77] 2006	General diabetes education	Before-after 107	Moderate	Significant improvement in knowledge scores compared to baseline
Children with newly diagnosed diabetes				
Dougherty[18] 1999	General diabetes education	RCT 63	Moderate	No significant difference between groups at 36 mo.
Siminerio[66] 1999	General diabetes education	Cohort 32	Moderate	No significant difference between groups at 1 mo.
Srinivasan[69] 2004	General diabetes education	Cohort 110	Moderate	No significant difference between groups at 12 mo.
Children with poorly controlled diabetes				
Couper[14] 1999	Cognitive behavioral therapy	CCT 69	Low	IG children had significantly higher knowledge scores than CG at 6 mo.; difference was NS at 12 mo. IG parents had significantly higher knowledge scores than CG at 6 and 12 mo.
Karaguzel[34] 2005	Diabetes camp	Before-after 25	Low	Significant increase in knowledge scores at 12 mo.
Nunn[55] 2006	General diabetes education	RCT 146	High	No significant difference in knowledge scores between groups

Skills

Overall, there were nine studies were assessed the effect of diabetes education on skills. Of these, all studies evaluated the general population of children with diabetes.

Cognitive Behavioral Therapy—Skills

Results

General population of children with diabetes. Anderson et al.[6] randomized 70 adolescents and parents to a group that received standard care (routine clinic visits) or a group that received standard care plus a problem solving intervention that focused on self-monitoring of blood glucose (SMBG). At the 18-month followup the authors found no significant difference between groups in their use of SMBG to modify their diet, insulin or daily exercise. The methodological quality of the study was low (2/5 on the Jadad score; unclear allocation concealment).

In the CCT by Mendez et al.,[48] 37 adolescents and parents were divided into experimental and control groups. The intervention group underwent 12 sessions. The sessions delivered to the adolescents included review, new content (audiovisual and printed material), skill practice and homework assignment. Parents attended two sessions emphasizing reinforcement and adherence behaviors rather than punishing noncompliance. There was no description of the control group. At the 13-month followup the authors found that the intervention group had significantly higher posttest scores than the control group on blood glucose testing skills. The methodological quality of the study was low (1/3 on the modified Jadad score).

Diabetes Camp—Skills

Description of studies. We identified seven studies (2 RCTs,[58,81] 1 CCT,[62] 4 uncontrolled before-and-after[12,27,37,78]) that assessed the effects of diabetes camp on the development of diabetes-related skills. Studies were conducted in the United States,[12,27,37,58,62] Canada,[81] and Europe.[78] The median year of publication was 1996 and ranged from 1983 to 2001.

The number of participants in the studies ranged from 41 to 237 (median = 83, [IQR 63 to 112]). The mean age of participants ranged from 8.4 years to 14.53 years (n = 3 studies).[27,62,78] For one study the mean age of participants was less than 12 years.[78] One study focused on children who demonstrated poor metabolic control.[81]

Three studies reported immediate post-intervention assessment.[12,27,81] The remaining followup times were 2 to 6 days post-intervention,[58] 2 months,[78] and 3 months.[37,62]

Results

General population of children with diabetes. In the RCT by Pichert et al.[58] 83 children were randomized into two groups, where the intervention group received three 45-minute sessions devoted to nutrition-related skills and knowledge through the use of

written material and video. The sessions were based on anchored instruction. The control group also received three 45-minute sessions using flash cards to learn food group/exchange equivalents and meal planning. On an observed test to see if campers could select an appropriate meal, both groups showed improvement, but there was no significant difference. In a challenge to choose meals for an overnight trip no significant difference was observed between groups, although both showed improvement. The methodological quality of the study was low (2/5 on the Jadad score; unclear allocation concealment).

Remley[62] conducted a CCT to compare a social cognitive theory-based program with a standard non-theory based camp education program. The curriculum included assertive communication training, group discussion, role-playing and nutrition education. Eight 1-week camps across the United States delivered either the intervention or control program. The attrition rate, at the 3-month followup, for both groups was high (40 percent). Participants in the theory-based program decreased slightly in the self-management skills, meal planning self-efficacy, from pre- to post-camp measurements. Control group scores increased slightly. The methodological quality of the study was low (1/3 on the modified Jadad score).

In an uncontrolled before-and-after study, Christensen et al.[12] observed 68 children attending a 2-week camp in the United States. Children were grouped by age so that each class could be tailored to developmental needs. Classes used flash cards, a card game, practiced reading labels, and used measuring utensils and scales with real food. Topics included carbohydrate counting, reading labels, and portion sizes and how to adjust for activity level. Immediate followup demonstrated a 24 percent increase in the campers' abilities to write out meal plans and a 19 percent increase in the ability to accurately describe a meal plan. The change in ability to select appropriate portion sizes was not statistically significant. There was a significant correlation with correctly measuring carbohydrates and participant HbA1c. The methodological quality of the study was low based on the Thomas instrument.

In the uncontrolled before-and-after study by Harkavy et al.,[27] 93 children participated in a 2-week camp held in the United States. During the camp there were formal and information sessions, but most teaching was completed informally. Topics included general diabetes knowledge, daily management, diet, exercise, hypoglycemia, the effects of illness/stress, and teen social issues. Two skills were assessed: urine testing and insulin injection. At the end of camp, all campers demonstrated improved urine test skills, although girls performed urine tests more accurately than boys. Improvement was significant for 12- to 13- and 14- to 15-year-olds but not significant for 10- to 11-year-olds. In regard to insulin injection skills, girls performed more accurately than boys and improved their accuracy during the camp; boys demonstrated no significant change. The methodological quality of the study was low based on the Thomas instrument.

Koontz[37] conducted an uncontrolled before-and-after study that involved 112 children at a 1-week camp in the United States. Education sought to increase self-management skills by teaching insulin administration, relationships between diet, exercise and insulin, meal and snack planning, measuring food portions, and how to identify and treat insulin reactions. The camp also aimed to enhance emotional adjustment, improve self-esteem, and develop positive attitudes toward the outdoors. Followup took place 3 months post-intervention. There was no significant difference in self-management scores from pre-to

post-camp. The methodological quality of the study was moderate based on the Thomas instrument.

One study, a RCT[81] assessed the effects of a diabetes camp on the development of diabetes-related skills among children with poorly controlled diabetes. This study took place in Canada and involved 41 children. Participants were randomized to either the control group, or the intervention group, where campers received one to two individualized sessions and participated in small group discussion on self-testing. Children in the control group received no specialized education. Immediate followup revealed no significant differences between groups on absolute systematic errors in SMBG comparing baseline to post-intervention. The methodological quality of the study was low (2/5 on the Jadad score; unclear allocation concealment).

The last uncontrolled before-and-after study was conducted in the United Kingdom by Vyas et al.[78] and involved 63 children separated into two camps. Children 5 to 7 years of age attended a camp for 10 days and children 9 to 14 years of age attended a different camp for 14 days. Activities at each camp were similar and children learned self-management and problem solving skills through daily activities. Additional opportunities for learning occurred through small informal discussions. Significant increases were seen in the ability of campers to self-test at 3 months post-holiday compared to before camp. The ability to independently self-inject also increased significantly at the post-holiday assessment. The methodological quality of the study was low based on the Thomas instrument.

Summary of Results—Skills

General population of children with diabetes. Overall, nine studies (3 RCTs,[6,58,81] 2 CCTs,[48,62] 4 uncontrolled before-and-after[12,27,37,78]) assessed the effects of diabetes education on the development of diabetes-related skills (Table 10). The interventions that were assessed were cognitive behavioral therapy[6,48] and diabetes camps.[12,27,37,58,62,78] In general, the methodological quality of the studies was low; one study was rated as moderate quality (Koontz[37]).

Results. The uncontrolled before-and-after study by Koontz[37] examined a range of self-management skills aimed at improving glycemic control. There were no significant differences in self-management scores at the 3-month followup.The results of the remaining low quality studies were inconsistent. The outcomes of three studies were associated with monitoring blood glucose. One study[6] found no significant difference between intervention and control groups on the use of SMBG to modify diet, insulin or daily exercise, whereas, the other[48] found improved posttest scores on blood glucose testing in the intervention group compared to the control group. The third[81] found no significant difference between intervention and control groups in regard to performing SMBG (Table 10).

Three studies examined nutrition and diet related skills, all of which were tested in a diabetes camp setting. Two studies found no improvement in ability to choose meals or pack for an over-night trip[58] or in meal-planning self-efficacy.[62] Conversely, another study[12] noted increases in the ability to write-out and describe meal plans, but no change in the ability to select appropriate meal sizes.

Skills such as urine and blood testing and insulin injection were assessed in two studies in a camp setting. Both studies found improvements in these skills.[27,78]

Table 10. Summary of results of studies assessing the effect of diabetes education on skills

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes				
Anderson[6] 1989	Cognitive behavioral therapy	RCT 70	Low	No significant difference in self-monitoring skills
Christensen[12] 2000	Diabetes camp	Before-after 68	Low	Create meal plans—24% increase in pre–post values; Describe meal plan—19% increase in pre–post values; Portion sizes—no significant difference; Carbohydrate measuring—significant improvement
Harkavy[27] 1983	Diabetes camp	Before-after 93	Low	Urine testing—both sexes improved significantly, but girls performed more accurately; Significant improvement for 12–13 and 14–15-yr. olds, no significant difference in 10–11-yr. olds; Insulin injection—girls performed more accurately and improved their accuracy during camp
Koontz[37] 2001	Diabetes camp	Before-after 112	Moderate	No significant difference in self-management skills
Mendez[48] 1997	Cognitive behavioral therapy	CCT 37	Low	IG had significantly improved self-management skills than CG at 13 mo.
Pichert[58] 1994a	Diabetes camp	RCT 83	Low	Behavioral measures—no significant difference between groups Meal selection—no significant difference between groups
Remley[62] 1999	Diabetes camp	RCT 237	Low	IG self-management skills decreased slightly, CG increased slightly; difference was NS

CG = control group; IG = intervention group; NS = not significant; SMBG = self-monitoring blood glucose

Table 10. Summary of results of studies assessing the effect of diabetes education on skills (continued)

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes (continued)				
Vyas[78] 1988	Diabetes camp	Before-after 63	Low	Self testing—significant increase in ability; Independent self-injection—significant increase in ability
Wolanski[81] 1996	Diabetes camp	RCT 41	Low	SMBG—no significant difference in absolute or random errors

Self-Management/Adherence

We identified 21 studies that assessed the effect of education on self-management and regimen adherence. Of these, 14 studies targeted the general population of children with diabetes, 2 examined children with newly diagnosed diabetes, and 5 looked a children with poorly controlled diabetes.

General Diabetes Education—Self-Management/Adherence

Description of studies. We identified seven studies (5 RCTs,[9,15,18,24,32] 1 cohort,[66] 1 uncontrolled before-and-after[20]) that assessed the effect of general diabetes education programs on self-management and adherence outcomes. Studies were conducted in the United States,[9,20,32] Canada,[15,18] and Europe.[24] The median year of publication was 1998 and ranged from 1989 to 2005.

The number of participants in the studies ranged from 23 to 119 (median = 48 [IQR 32 to 76]). The mean age of participants ranged from 9.8 to 14.7 years (n = 7 studies). Two studies included participants where the mean age was less than 12 years.[18,24] Two studies focused on children and their families with newly diagnosed diabetes[18,66] and one targeted children with poor metabolic control.[15]

Most interventions were delivered to both children and their parents or the family; in one study the intervention was delivered to children only.[9] The settings for interventions were described as home,[9] clinic,[24] or mixed (e.g., hospital and home).[18,32,66] The setting was not clearly described in two studies.[15,20] Three studies reported post-intervention followup assessments ranging from 1 to 36 months.[15,18,66] The median follow-up period was 13 months. The remaining studies did not report outcomes beyond the end of the education program.[9,24,32,83]

Results

General population of children with diabetes. Brown et al.[9] randomly assigned 59 children and adolescents to a group that played a video game featuring characters that had diabetes, who manage their diabetes by monitoring blood glucose, taking insulin injections and choosing foods, or a group that played a pinball video game with no information about diabetes. Parents rated their child's motivation to manage their diabetes in terms of behaviors such as testing blood sugar, taking insulin, cooperating with parents and doctor, and eating a good diet. At the end of the 6-month study period, the treatment group demonstrated significantly more gains in self-care behavior than the control group (change score 0.28±0.86 vs. -0.38±0.79, respectively [p = 0.003]). The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment).

In the RCT by Hackett et al.,[24] three cohorts of families received educational packages delivered over 8 months that included information on diabetes, diet and concentration of HbA1c. The content was the same for all groups; one group (cohort 1) received a second reinforcement package for an additional 8 months. The comparison group did not receive the education package. Outcomes included self-reported (by diary) fat, carbohydrate, and fiber intake. Children whose families had attended all educational sessions reported lower fat and higher carbohydrate and fiber intake than those who did not attend, however, this effect was not statistically significant. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Howe et al.[32] randomly assigned 75 patients to one of three treatment groups: : standard care (routine quarterly clinic visits), standard care plus one education session on basic diabetes management skills (SC+ED), and standard care plus the education session plus weekly telephone calls to review management techniques (SC+TCM). The authors assessed child and family behaviors related to diabetes safety and control using the Adherence Evaluation scale. At the 6-month followup, adherence improved significantly in the SC+TCM group compared to the standard care group (24 percent vs. 2 percent respectively [p = 0.0003]). Furthermore, children in the SC+TCM group were better able to assume age-appropriate behaviors related to diabetes management, and parents were better able to provide age-appropriate supervision. All outcomes were physician assessed using the TEAM checklist. TEAM scores in the education and telephone case management group improved by 24 percent over a 6-month period, while the standard care group reduced their score by 5.4 percent (p = 0.003). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

The uncontrolled before-and-after study by Greco et al.[20] delivered the intervention in 2-hour sessions over 4 weeks to groups of three to six diabetes patient-peer pairs. The intervention consisted of homework review on etiology, physiology and treatment of diabetes, reflective listening skills, problem solving related to diabetes, stress management, games or exercises to practice concepts and homework assignments. Regimen adherence was measured using the Self-Care Inventory. There was no significant change in adherence scores between baseline and post-intervention. The methodological quality of this study was rated as moderate using the Thomas instrument.

Children with newly diagnosed diabetes. Dougherty et al.[18] randomly assigned 63 newly diagnosed patients to a 24-month home-based diabetes education program or to traditional hospitalization and outpatient followup. Treatment differences between the groups consisted of duration of initial hospital stay, timing of initial teaching, and the nature and extent of subsequent nursing followup. The authors assessed adherence using the Diabetes Regimen Adherence Questionnaire There were no significant differences in adherence scores between the groups at any time during the 2-year followup. Adherence was high in both the hospital- and home-based groups: 85.5 percent vs. 82.5 percent, respectively at 1-month and declining slightly to 74.1 percent vs. 73.9 percent at 24-months post-intervention. The methodological quality of this study was rated as moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Siminerio[66] compared a 3 to 5 day education program delivered on an inpatient vs. outpatient basis. Patients were divided into two cohorts of 16 patients each. The education program included basic education on diabetes, complications, self-management skills, and nutrition and exercise. The authors assessed food regulation, exercise, blood glucose regulation and emergency precautions. At 1-month followup, both groups had a high level of adherence for food regulation and exercise; there were no statistically significant differences between the groups. However, the inpatient group scored significantly higher in blood glucose monitoring than the outpatient group (4.93 vs. 4.47, respectively [$p < 0.01$]). The outpatient group scored higher in adhering to emergency precautions (4.71 vs. 4.44, respectively [$p < 0.001$]). The methodological quality of this study was rated as moderate using the Thomas instrument.

Children with poorly controlled diabetes. In the RCT by Coupland[15] adolescents and their families participated in a family-based intervention to improve adherence (n = 15); the comparison group (n = 14) comprised adolescents who were taught stress management techniques. Adherence behaviors consisted of self-reported regularity of insulin injections, blood glucose testing timeliness and frequency, and diet and exercise levels. At the 3- and 6-month followup, adolescents in the intervention group had a significant increase in mean frequency of daily blood glucose testing compared to the control group; they also had significantly greater adherence for timing of blood glucose testing. Adolescents in the control group showed decreased adherence to correct timing of insulin injections. There was no significant difference between groups in adherence to diet or daily exercise levels. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Cognitive Behavioral Therapy—Self-Management/Adherence

Description of studies. We identified eight studies (7 RCTs,[8,16,31,47,72,80] 1 CCT[48]) that assessed the effect of interventions using cognitive behavioral therapy techniques on self-management and adherence outcomes. One study was conducted in Europe;[48] the remaining studies were conducted in the United States. The median year of publication was 1991 and ranged from 1985 to 1999.

The number of participants in the studies ranged from 13 to 66 (median = 24 [IQR 17 to 29]). The mean age of participants ranged from 6.4 to 15.4 years (n = 6 studies). Four

studies included participants whose mean age was less than 12 years.[22,47,72,80] Two studies examined interventions delivered to children with poor metabolic control.[8,16]

Interventions were delivered to children[8,31] or to parents and children or the entire family.[16,22,47,72,80] The settings for interventions were described as an outpatient clinic,[8,16,72,80] home,[31] diabetes center,[47] or mixed.[48] The setting was not clearly described in one study.[22] All but one study[31] reported post-intervention followup assessments ranging from 6 weeks to 6 months (median = 3 months).

Results

General population of children with diabetes. In the RCT by Gross et al.[22] 14 children and parents were randomly assigned to either behavior modification training or to a group that included discussion and role-playing. The authors assessed adherence using a subjective rating scale in which parent rated child behavior on a 4-point scale. At 6 months parents from the intervention group rated children as improved on all measures while control group parents gave decreased ratings. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Horan et al.[31] conducted an RCT (n = 20) that compared goal setting and problem solving using dynamic computer-assisted teaching modules that focused on self-management training versus conventional education using an education booklet. At the end of the 15-week study, participants were asked if they, rather than parents or doctor, were more active in controlling their diabetes. Sixty percent of intervention group vs. 20 percent of the control group reported they were more active at the end of the study. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

In the study by McNabb et al.[47] 24 children were randomly assigned to either a 6-week self-management education program or to receive standard care (routine clinic visits). Parents were surveyed using the Children's Diabetes Inventory to report the frequency with which self-care behaviors were practiced in the home and the degree of responsibility assumed by the child. At the end of the program, children in the intervention group were assuming significantly more responsibility for self-care than children in the control group (2.9±0.4 vs. 2.3± 0.6, respectively [$p < 0.01$]). There was no difference between the groups in frequency of self-care behaviors (4.5±0.4 vs. 4.2±0.6 for the control group). This supported the hypothesis that children would become more responsible for self-care while continuing to maintain self-care frequency. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

The CCT by Mendez and Belendez[48] used an intervention comprising 12 sessions of content delivery, skill practice and homework assignment, and involved parents for two of the sessions. The emphasis was on reinforcement of adherence behaviors rather than punishing noncompliance. The intervention delivered to the control group care was not described. The authors reported that frequency of self-monitoring of blood glucose improved in the intervention group immediately following the intervention (18.42±10.92 vs. 21.28±9.78 compared to 18.57±11.78 vs. 18.69±11.67 for the control group, $p = 0.016$). However, at 13 months post-intervention, the frequency dropped to baseline levels. The authors also assessed self-reported physical activity and nutritional

management; they found that the program did not have any effect on dietary or exercise adherence. The methodological quality of this study was rated as low (1/3 on the modified Jadad score).

Szumowski[72] randomly assigned 21 young children to an 8-week behavioral intervention that included information on diabetes management plus instruction and practice in the application of behavioral principles and goal setting to reinforce children's regimen adherence. The comparison group received information on diabetes management but no additional instruction. At the 3-month followup, the intervention group reported increased cooperation with diabetes tasks compared to the control group; however, the change from baseline was not statistically significant (2.4±0.8 vs. 2.1±1.0 and 2.4±1.4 vs. 2.9±0.8, respectively [p = 0.09]). There was no significant change for either group in daily average exercise and diet exchange errors (daily average proportion of total recommended exchanges which were added or deleted). There was no significant change in the percent carbohydrate and fat consumed by either group; however, there was a significant decrease in consumption of concentrated sweets in the intervention group vs. no change for the control group. The methodological quality of this study was rated as moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

In the RCT by Webb,[80] 45 families were assigned to a group that received intensive collaborative goal setting training or a group that used a goal setting worksheet with guidance from a therapist. The author used the Goal Attainment Scaling to measure goal attainment in self-care behavior areas such as insulin administration, SMBG, food intake and physical activity. At the 3-month followup, both groups reported significant gains in goal attainment for all four areas. The gains reported by the intervention group were significantly greater than those of the control group. The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

Children with poorly controlled diabetes. In the RCT (n = 19) by Boardway et al.,[8] a 3-month stress management training program for adolescents was compared to standard outpatient care. The authors used a 24-hour recall interview to assess regimen adherence. At the end of the intervention, there were no significant changes in regimen adherence for either group. The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment).

Delamater et al.[16] randomized 13 adolescents to receive a 2-month family-based behavior therapy program with training in parent-teen communication, problem solving and goal setting, with focus on adjusting meals and insulin in response to self-monitoring of blood glucose- or to standard outpatient care. Regimen adherence was measured through using the Diabetes Management Questionnaire. At the 4-month followup, patients in both groups improved their adherence ratings; however, there was no significant difference between the groups. Parent ratings of adherence did not show any significant effects for either group. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Family Therapy—Self-Management/Adherence

General population of children with diabetes. Laffel et al.[38] randomly assigned 105 families to a family-focused teamwork intervention (TW) or to standard care (i.e., routine multidisciplinary clinical care). Measures of parental involvement in management tasks were reported by both parents and children. At the end of the 12-month intervention the TW families maintained or increased family involvement significantly more than families in the control group (30 percent vs. 14 percent, respectively [p = 0.05]). The methodological quality of this study was low (2/5 on the Jadad score; unclear concealment of allocation).

Wysocki et al.[82] randomized 104 families to one of three groups: standard care plus behavioral family systems therapy (BFST), standard care plus family education and support (ES), and standard care (physician directed clinical care). Treatment adherence was assessed using the Diabetes Self-Management Profile (DSMP). At all followup periods up to 12-months post-intervention, the BFST group had significantly better DSMP scores than the standard care group. There were no significant differences between the BFST and the ES groups or between the ES and standard care groups at any followup point. A significantly higher percentage of BFST group members attained moderate or greater improvement (i.e., an increase in score of ≥5 points on the DSMP) in treatment adherence compared with either of the comparison groups. Changes in treatment adherence correlated significantly with change in HbA1c at each time point. The methodological quality of this study was low (2/5 on the Jadad score; unclear concealment of allocation).

Children with poorly controlled diabetes. Wysocki et al.[83] randomly assigned 119 children to 1 of 3 groups: standard care (physician directed clinical therapy), education and support (standard care plus 10 sessions of a diabetes support group), and BFST (standard care plus family problem-solving and communication training and individualized treatment plan). The authors measured adherence with the Self-Care Inventory (SCI). At the end of the 3-month intervention, there were no significant differences in regimen adherence among the three groups. The methodological quality of this study was high (3/5 on the Jadad score; adequate concealment of allocation).

In an uncontrolled before-and-after study, Harris et al.[28] reported 6-month followup data for 18 adolescents and their families who enrolled in a BFST program. The authors used two self-report measures to assess adherence: the SCI (measuring treatment adherence over 2 weeks) and the Diabetes Mismanagement Questionnaire. There was a small improvement in reports from fathers on the SCI at immediate post-intervention. However, there were no significant differences in adherence reports from adolescent, mother or father at the 6-month followup. The methodological quality of this study was low based on the Thomas instrument.

Diabetes Camp—Self-Management/Adherence

General population of children with diabetes. Remley[62] conducted a CCT to compare a social cognitive theory-based program that focused on assertive

communication and nutrition education with a standard non-theory based camp education program. Eight 1-week camps across the United States were designated to deliver either the theory-based intervention or the standard program. At the 3-month followup there were no significant differences in self-reported self-management skills between the groups. The methodological quality of this study was low (1/3 on the modified Jadad score).

Zorumski[84] investigated the effects of self-care training for 49 children. All children received basic self-care training from their physicians; 27 also attended a 1-week day camp that provided additional self-care instruction. At the 4-month followup both groups reported an increase in the number of self-care behaviors that they practiced; however, there was no statistically significant difference between groups. The methodological quality of this study was low (0/3 on the modified Jadad score).

Summary of Results—Self-management/Adherence

Overall, we identify 21 studies that assessed self-management or regimen adherence. Of these, 15 studies examined the general population of children with type 1 diabetes, five examined children with poorly controlled diabetes, and one focused on children with newly diagnosed diabetes(Table 11). We were unable to pool the results of any of the studies due to differences across studies in terms of population, interventions, comparison groups, duration of intervention and followup timepoints.

General population of children with diabetes—self-management and regimen adherence. Fourteen studies (10 RCTs,[9,22,24,31,32,38,47,72,80,82] 3 CCTs,[48,62,84] 1 uncontrolled before-and-after[20]) assessed self-management or regimen adherence in the general population of children with type 1 diabetes. The education interventions that were assessed included general diabetes education,[9,20,24,32,48] cognitive behavioral therapy,[22,31,47,72,80] family therapy,[38,82] and diabetes camp.[62,84] In general, the methodological quality of the studies was low, with only one RCT (Szumowski[72]) and one uncontrolled before-after (Greco et al.[20]) rated as being of moderate quality.

Results. The RCT by Szumowski[72] found that children in the group that received a behavioral intervention were more compliant in performing diabetes tasks and decreased their intake of sweets compared to the control group. Other measures of self-management were unchanged in either group following the intervention. The uncontrolled before-and-after study by Greco et al.[20] assessed an intervention aimed at integrating teenage peers into the diabetes care of a friend with diabetes. There was not significant change in adherence scores following the intervention.

The results of the remaining studies were mixed. Two RCTs reported that groups receiving family therapy interventions[38,82] demonstrated increased levels of self-management or regimen adherence compared to the control group. Studies assessing interventions based cognitive behavioral therapy were inconsistent with two studies[22,31] reporting gains in self-management for the intervention group compared to control group and two studies[47,80] reporting no change following the intervention. Similarly, some studies examining general diabetes education programs reported that self-management skills improved,[9,32] while others found no change following the intervention.[24,48] The two

studies that took place at diabetes camps[62,84] found that self-management/adherence were unchanged following camp.

Children with Newly Diagnosed Diabetes

One RCT (Dougherty et al.[18]) and one cohort study (Siminerio[66]) assessed self-management or regimen adherence in the children with newly diagnosed diabetes (Table 11). The methodological quality of both studies was moderate. Both compared general diabetes education programs that were delivered in inpatient vs. ambulatory settings. Dougherty et al. found that there was no significant difference in adherence between the intervention and control groups. Siminerio reported that the inpatient group scored higher on some elements of adherence (e.g., blood glucose monitoring) but lower on others (e.g., adherence to emergency precautions). For others, there were no significant differences (e.g., adherence to food regulation and exercise).

Children with Poorly Controlled Diabetes

The large high-quality RCT by Wysocki et al.[83] that assessed family therapy reported improved levels of adherence at 3 months post-intervention; the improvements disappeared by 6 months (Table 11). The results of the remaining studies were mixed. One RCT reported improved self-management/adherence compared to the control group;[15] one RCT found improved levels of adherence, but the difference between groups was not significant.[16] Two studies found that adherence was unchanged following the intervention.[9,28]

Table 11. Summary of results of studies assessing the effect of diabetes education on self management/regimen adherence

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes				
Brown[9] 1997	General diabetes education	RCT 59	Low	Self-Management—IG had significant gains in self-care compared to CG at 6 mo.
Greco[20] 2001	General diabetes education	Before-after 23	Moderate	Adherence—No significant change for either group at 4 wk.
Gross[22] 1985	Cognitive behavioral therapy	RCT 14	Low	Adherence—IG showed an increase in compliance compared to CG at 6 mo.
Hackett[24] 1989	General diabetes education	RCT (4 arms) 119	Low	Self-Management—No significant difference for either group in nutritional management
Horan[31] 1990	Cognitive behavioral therapy	RCT 20	Low	Self-Management—IG showed greater behavioral change compared to CG at 15 wk.
Howe[32] 2005	General diabetes education	RCT (3 arms) 89	Low	Self-Management—Significant group x time interaction; significant increase in ED+ group compared to CG for roles/responsibilities
Laffel[38] 2003	Family therapy	RCT 105	Low	Self-Management—IG had significantly more involvement in roles/responsibilities than CG at 12 mo.
McNabb[47] 1994	Cognitive behavioral therapy	RCT 24	Low	Self-Management—No significant difference between groups after 12 wk.
Mendez[48] 1997	General diabetes education	CCT 37	Low	Self-Management—IG significantly higher skills than CG at posttest; IG significantly higher at nutritional management and physical activity than CG at posttest (loses significance at 13 mo.)
Remley[62] 1999	Diabetes camp	CCT 237	Low	Self-Management—No significant difference between groups at 3 mo.
Szumowski[72] 1990	Cognitive behavioral therapy	RCT 27	Low	Self-Management—Significant interaction comparing baseline to 3 mo.; Roles/responsibilities—No significant change in either group at 3 mo.; Physical activity or nutritional management— No significant change in either group at 3 mo.

BG = blood gas; CG = control group; IG = intervention group; NS = not significant

Table 11. Summary of results of studies assessing the effect of diabetes education on self-management/regimen adherence (continued)

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes (continued)				
Webb[80] 1999	Cognitive behavioral therapy	RCT 66	Low	Self-Management—No significant differences between groups at 3 mo.
Wysocki[82] 2007	Family therapy	RCT (3 arms) 104	Low	Adherence—Significantly higher scores for BFST-D compared to SC at each followup (up to 18 mo.); All other group differences NS; Significant main effects for groups
Zorumski[84] 1997	Diabetes camp	CCT 56	Low	Self-Management—No significant difference between groups at 4 mo.
Children with newly diagnosed diabetes				
Dougherty[18] 1999	General diabetes education	RCT 63	Moderate	Adherence—No significant change for either group at 36 mo.
Siminerio[66] 1999	General diabetes education	Cohort 32	Moderate	Self-Management—Inpatient group significantly higher than outpatient group at 1 mo. For BG regulation; Outpatient group significantly higher than inpatient group at 1 mo. For emergency precautions
Children with poorly controlled diabetes				
Boardway[8] 1993	Cognitive behavioral therapy	RCT 31	Low	Adherence—No significant change for either group at 6 mo.
Coupland[15] 1992	General diabetes education	RCT 32	Low	Self-management—IG significantly higher compared to CG at 6 mo. (also at 3 mo. For mean % BG testing); Adherence—IG significantly different than CG at 6 mo.
Delamater[16] 1991	Cognitive behavioral therapy	RCT (3 arms) 13	Low	Adherence—IG higher when compared to CG at 4 mo.; difference between groups was NS
Harris[28] 2005	Family therapy	Before-after 18	Low	Self-Management—No significant change at 6 mo.; Adherence—No significant change at 6 mo.
Wysocki[83] 2000	Family therapy	RCT (3 arms) 119	High	Adherence—Improvement in younger children at 3 mo. NS, effect dissipated by 6 mo.

Psychosocial Outcomes

We identified 40 studies that assessed the effect of education on psychosocial outcomes. Of these studies, 22 examined the general population of children with diabetes, 9 focused on children with newly diagnosed diabetes and 9 considered children with poorly controlled diabetes. The psychosocial outcomes reported on were grouped into the following categories: family or social relationships (16 studies), family or social support (9 studies), social skills (3 studies), coping (14 studies), self-perception (8 studies), self-efficacy (9 studies), stress (2 studies), and anxiety and depression (6 studies).

Family or Social Relationships

General Diabetes Education—Family or Social Relationships

Children with newly diagnosed diabetes. In the prospective cohort study by Srinivasan et al,[69] a 4- to 16-week outpatient day care program was compared with a 4- to 7-day inpatient program for delivering general diabetes education to 110 newly diagnosed patients and their families. Using the Diabetes Responsibility and Conflict Scale, there were no significant differences between the cohorts in the area of diabetes responsibility and conflict or parent-child conflict at the 12-month followup. The methodological quality of the study was moderate based on the Thomas instrument.

Cognitive Behavioral Therapy—Family or Social Relationships

General population of children with diabetes. Anderson et al.[5] assessed the effectiveness of an intervention for families that focused on teamwork and shared parent-teen responsibility for diabetes tasks. It was delivered in the form of 20- to 30-minute sessions every 3 to 4 months for 12 months. Eighty-nine families were randomly assigned to the intervention group or to one of two comparison groups: standard care (routine clinical care from the diabetes team) or standard care plus didactic diabetes education. The two comparison groups were combined to increase the power of the study. Using the Diabetes Family Conflict Scale, at the 12-month followup, the mean level of diabetes-related family conflict in the intervention group decreased significantly compared to the control group (4.8±3.09 vs. 3.8± 2.75 and 3.6± 2.6 to 3.9±2.6, respectively [$p<0.02$]). The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Gross et al.[22] randomly assigned 14 children and parents to either an intervention or control group. The intervention comprised eight weekly 90-minute sessions on self-management training for both parents and children. The control group attended eight weekly 90-minute sessions of open ended discussion for both parents and children. In both groups there were separate sessions for parents and children. The number of family-child conflicts was recorded on worksheets by parents. At 6 months post-intervention, the intervention group reported fewer conflicts than control group (1.6 conflicts vs. 0.1 conflicts per week; the control group remained at 1.1 conflicts per week). The

methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Szumowski[72] randomized 27 children and parents to either an intervention or control group. Parents and children in the control group met for six group sessions over 2 months and were given information on glucose testing, insulin injection and adjustment, diet and exercise. The intervention group received the same intervention as the control group plus they received additional instruction and practice in diabetes behavioral education and goal setting. At each assessment point, parents monitored the occurrence of diabetes-related family conflict. At the 3-month followup there was no significant change in conflict scores for either group. The methodological quality of this study was rated as moderate (2/5 on the Jadad score; unclear allocation concealment; blinding of outcome assessors).

The uncontrolled before-and-after study by Greco et al.[20] examined an intervention targeted at integrating peers into diabetes care. It comprised four 2-hour sessions delivered to three to six diabetes adolescent and peer pairs. Sessions included lectures and games or exercises on diabetes, problem solving, and stress management. Family conflict was assessed using the Diabetes Responsibility and Conflict Scale; information was obtained separately from parents and adolescents. The Peer Interaction Record was used to measure the adolescents' social interactions. Following the intervention, parents reported significantly less diabetes-related conflict (26.5± 8.5 vs. 23.7±6.4, $p<0.05$); however, the adolescents did not report a significant change. On the Peer Interaction Record, peers reported significant improvement following the intervention; however, the adolescents with diabetes did not report a significant change. The methodological quality of the study was rated as moderate based on the Thomas instrument.

Children with poorly controlled diabetes. Delamater et al.[16] randomized 13 patients with poor metabolic control to receive a 2-month family-based behavior therapy program or to standard outpatient care. The intervention comprised six 90-minute group sessions that focused on self-management and psychosocial skills. There were separate parent and teen sessions. Global ratings of parent-teen relationships were made using a 7-point Likert scale. At the end of the intervention, the adolescents from the intervention group showed improvement in the ratings of parent-teen relationships compared to the control group. At the 4-month followup, there was no difference between the groups. Ratings by parents in either group were unchanged over time. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Family Therapy—Family or Social Relationships

General population of children with diabetes. Laffel et al.[38] randomly assigned 105 families to a family-focused teamwork intervention (TW) or to standard care (routine multidisciplinary clinical care). Diabetes-related conflict was measured with the Diabetes Family Conflict Scale. At the end of the 12-month program, there were no significant differences between groups on this measure. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Satin et al.[63] randomized 32 adolescents to one of three groups. The first group participated in a multifamily support group where families met for six weekly sessions of 90-minutes each to discuss diabetes management and feelings about diabetes and to

receive group support. The second group received the same intervention plus parents participated in simulated diabetes management for one week. The third group received no intervention. Family relationships were assessed using the Family Environment Scale (FES). At the 6-month followup, there were no significant changes for any of the groups on the subscales of the FES. The methodological quality of this study was rated as low (1/5 on the Jadad score; unclear allocation concealment).

Wysocki et al.[82] randomized 104 families to one of three groups: standard care plus behavioral family systems therapy (BFST), standard care plus family education and support, and standard care (physician directed clinical care). Family conflict about diabetes was measured using the Diabetes Responsibility and Conflict scale. At the 12-month followup, the BFST group demonstrated a greater reduction in family conflict scores; however, the difference was not statistically significant. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Children with newly diagnosed diabetes. The RCT by Sundelin et al.[70] compared conventional inpatient education (n = 19 families) to a multidisciplinary program delivered in an outpatient setting (n = 19). Families in the intervention group were encouraged to move in to a training apartment for 2 weeks to receive a family-oriented crisis therapy program that developed customized management strategies based on problems and questions formulated by the family. The control group received the established clinic protocol, in which the child was hospitalized with one parent, and families were encouraged to attend information sessions with medical staff. Family and social relationships were evaluated using the Family Relations Scale and the Family Climate test. There were no statistically significant differences between groups over the 24-month followup period. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Kennedy-Iwai[36] randomly assigned 19 families to receive standard care (standard clinical treatment and diabetes education) or standard care plus a couple communication program delivered to parents. The effects of communication training with parents of newly diagnosed diabetic children was examined. Family relationships were measured by two subscales in the Family Environment Scale: cohesion and conflict. In the conflict subscale, mothers from the intervention group had less family conflict than mothers from the control group immediately following the intervention; however, at 3 months post-intervention this difference had disappeared. There were no differences for fathers at either time point. The methodological quality of this study was rated as low (2/5 on the Jadad score; unclear allocation concealment).

Children with poorly controlled diabetes. Wysocki et al.[83] randomly assigned 119 families of adolescents to three groups: standard care (physician directed clinical therapy), education and support (ES) (standard care plus 10 sessions of a diabetes support group), behavioral family systems therapy (BFST) (standard care plus family problem solving and communication training and individualized treatment plans). Family relationships were assessed with the Parent-Adolescent Relationship Questionnaire (PARQ), the Diabetes Responsibility and Conflict Scale (DRC), the Issues Checklist, and a telephone recall interview to collect descriptions of conflict situations from participants. On the PARQ, there were no significant differences between groups on the family structure subscale. On the overt conflict/skill deficits subscale and the extreme beliefs

subscale, at 3-months post-intervention, the BFST group had significantly lower scores (indicating less conflict) than the standard care group, but not the ES group. On the Issues Checklist, at 6- and 12-month followups, negative communication for both adolescents and mothers significantly decreased in the BFST group compared to the other groups. As well, BFST families significantly improved on measures of negative reciprocity and problem resolution. On the DRC, the BFST group showed significantly greater improvement than the comparison groups at 6-month followup; however, this difference was not sustained at the 12-month followup. Finally, there were no significant differences for family conflict reported during recall interviews. The methodological quality of this study was rated as high (3/5 on the Jadad score; adequate allocation concealment).

In an uncontrolled before-and-after study, Harris et al.[28] evaluated 18 adolescents and their families who enrolled in a BFST program. Family relationships were assessed using the Diabetes Family Behavior Checklist. There were no statistically significant differences between baseline and 6-month followup measures. The methodological quality of this study was weak based on the Thomas instrument.

Skills Training—Family or Social Relationships

Children with newly diagnosed diabetes. One RCT by Mitchell[49] assessed the effect of a skill training intervention on family relationships among 32 newly diagnosed patients. The intervention group received standard multidisciplinary education and support plus a booklet targeted at improving compliance with treatment. The booklet identified problems with adherence and offered basic self-management skills. The standard care group received standard education and support. Social relationships were assessed by the externalizing behavior subscale of the Childhood Behaviour Checklist. At the 12-month followup, there were no significant differences between groups. The intervention group showed a decrease in externalizing behaviors; however, the change was not statistically significant. No change was observed for the control group. The methodological quality of the study was low (1/5 on the Jadad score; unclear concealment of allocation).

Diabetes Camp—Family or Social Relationships

General population of children with diabetes. The uncontrolled before-and-after study by Smith et al.[67] examined the effect of an intervention delivered to 120 adolescents during a 5-day diabetes camp. The objective of the intervention was to develop assertive communication and included daily 1-hour sessions that provided information, facilitated sharing, and provided opportunities to practice assertive communication, problem solving and negotiation skills. Family relationships were assessed using the Parent-Adolescent Communication Scale (P-ACS), which yields a total score and two subscale scores that measure open communication and problems in communication. Overall, at the 3-month followup, there were no significant changes in the degree of problems in communicating. However, adolescents reported a significant decrease in open communication with fathers ($p<0.05$). The methodological quality of the study was weak based on the Thomas instrument.

The prospective cohort study by Hill et al.[29] compared two different diabetes camps: one camp (n = 60) offered a program based on self-determination theory and one camp (n = 74) offered a program that had similar types of activities but was not theory-based. Social relationships were assessed using the Basic Psychological Needs Scale. At the 3-month followup, the children who attended the intervention camp reported a stronger sense of relatedness compared with the comparison camp (p = 0.03). The methodological quality of the study was weak based on the Thomas instrument.

Summary of Results—Family or Social Relationships

Overall, we identified 16 studies that assessed the effect of diabetes education on the psychosocial outcome of family and social relationships (Table 12). Of these, nine studies (6 RCTs, 1 cohort, 2 uncontrolled before-and-after) examined the general population of children with type 1 diabetes, four studies (3 RCTs, 1 cohort) focused on children with newly diagnosed diabetes, and three (2 RCTs, 1 uncontrolled before-and-after) examined children with poorly controlled diabetes. Due to substantial differences across studies in terms of population, intervention, comparison groups, duration of intervention and followup timepoints, we were unable to pool the results of any of the studies.

General population of children with diabetes. Nine studies (6 RCTs,[5,38,63,72] 1 cohort,[29] 2 uncontrolled before-and-after[20,67]) assessed the effectiveness of diabetes education on family and social relationships in the general population of children with type 1 diabetes (Table 12). Four studies assessed the effectiveness of cognitive behavioral therapy,[5,20,22,72] three examined family system therapy interventions,[38,63,82] and two assessed the effect of diabetes camps.[29,67] In general, the methodological quality of the studies was low, with only one RCT[72] and one before-and-after study[20] rated as being of moderate quality.

The results of the two moderate quality studies do not suggest that diabetes education has an effect on family or social relationships. The RCT by Szumowski[72] compared a group that received a combination of cognitive behavior therapy and standard diabetes management training with a group that received standard diabetes management training only. There was no significant difference between the groups in diabetes-related conflict. The before-and-after study by Greco et al.[20] assessed an intervention aimed at integrating teenage peers into the diabetes care of a friend with diabetes. Following the intervention, peers reported improved interaction with their friend; however, no change in peer interaction was reported by the adolescents with diabetes. Parents of the adolescent with diabetes reported less diabetes-related conflict.

The results of the remaining studies were inconsistent. Three studies (2 RCTs,[5,22] 1 cohort[29]) found that family or social relationships improved following diabetes education. In contrast, four studies (3 RCTs,[38,63,82] 1 uncontrolled before-and-after[67]) found that the intervention had no effect on the outcome.

Children with newly diagnosed diabetes. Four studies (3 RCTs,[36,49,70] 1 cohort[69]) assessed the effectiveness of diabetes education on family or social relationships among children with newly diagnosed diabetes (Table 12). In general, the methodological quality of the studies was low, with only the cohort study by Srinivasan[69] assessed as being of moderate quality. Three studies found that diabetes education was not effective in improving family or social relationships.[36,49,69] One study[70] compared the setting for

delivery of a family-based education program (ambulatory vs. inpatient) and found no difference between groups on measures of family or social relationships. This was a small study and there may not have been sufficient statistical power to detect a difference between groups.

Children with poorly controlled diabetes. Three studies (2 RCTs,[16,83] 1 uncontrolled before-and-after[28]) assessed the effectiveness of diabetes education on family or social relationships among children with poorly controlled diabetes (Table 12). The large, high-quality RCT by Wysocki et al.[83] assessed a family systems therapy intervention and found that the intervention group demonstrated improved levels of family conflict and communication on several of the measures used by the researchers. The remaining two studies found that the intervention had no effect on the outcome.[16,28]

Table 12. Summary of results of studies assessing the effect of diabetes education on family/social relationships

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Anderson[5] 1999	Cognitive behavioral therapy	RCT 89	Low	IG reported significantly less conflict than CG at 12 mo.
Greco[20] 2001	Cognitive behavioral therapy	Before-after 23	Moderate	Parents reported significantly less diabetes-related conflict following intervention; Adolescents reported no significant change in peer-interaction following intervention; Peers reported significant improvement in peer-interaction following intervention
Gross[22] 1985	Cognitive behavioral therapy	RCT 14	Low	IG reported significantly less conflict; CG remained unchanged at 6 mo.
Hill[29] 2006	Diabetes camp	Cohort 134	Low	IG reported significantly higher sense of relatedness than CG at 3 mo.

CG = control group; IG = intervention group; NS = not significant; PARQ = Parent-Adolescent Relationship Questionnaire

Table 12. Summary of results of studies assessing the effect of diabetes education on family/social relationships (continued)

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes (continued)				
Laffel[38] 2003	Family therapy	RCT 105	Low	No significant difference in diabetes-related conflict between IG and CG (children or parents) at 12 mo.
Satin[63] 1989	Family therapy	RCT 32	Low	No significant change in family environment at 6 mo.
Smith[67] 1993	Diabetes camp	Before-after 120	Low	No significant change in degree of problems in communicating following camp; adolescents reported significant decrease in open communication with fathers following camp
Szumowski[72] 1990	Cognitive behavioral therapy	RCT 27	Moderate	No significant difference between groups in diabetes-related conflict at 3 mo.
Wysocki[82] 2007	Family therapy	RCT (3 arms) 104	Low	IG had lower family conflict scores than either CG; difference NS at 12 mo.
Children with newly diagnosed diabetes				
Kennedy-Iwai[36] 1991	Family therapy	RCT 19	Low	No difference between groups for family environment or conflict at 3 mo.
Mitchell[49] 1996	Skills training	RCT 32	Low	No significant difference between groups at 12 mo.
Srinivasan[69] 2004	General diabetes education	Cohort 110	Moderate	No significant difference between groups for diabetes responsibility and conflict and parent-child conflict at 12 mo.
Sundelin[70] 1996	Family therapy	RCT 38	Low	No significant difference between groups for parent perception of child behavioral disturbances at 24 mo.; No significant difference between groups for family emotional climate at 24 mo.
Children with poorly controlled diabetes				
Delamater[16] 1991	Cognitive behavioral therapy	RCT 13	Low	No significant difference between groups for parent-teen relationship at 4 mo.
Harris[28] 2005	Family therapy	Before-after 18	Moderate	No significant change from baseline to 6 mo.

Table 12. Summary of results of studies assessing the effect of diabetes education on family/social relationships (continued)

Author Year	Intervention	Study design Sample size	Quality	Results
Children with poorly controlled diabetes (continued)				
Wysocki[83] 2000	Family therapy	RCT (3 arms) 119	High	PARQ overt conflict/skill deficits—IG had significantly lower scores compared to CG1 but not CG2 at 3 mo.; PARQ family structure—No significant difference between groups at 12 mo.; Parent-child division of diabetes responsibilities and family conflict—IG had significantly greater improvement than either CG at 6 mo.; difference was NS at 12 mo.; Adolescent negative communication—IG significantly improved compared to either CG at 12 mo.; Mother negative communication—IG significantly improved compared to either CG at 12 mo.; Negative reciprocity—IG showed significant improvement compared to either CG at 12 mo.; Problem resolution—IG showed significant improvement compared to either CG at 12 mo.; PARQ extreme beliefs—IG had significantly lower scores compared to either CG at 3 mo.

Family or Social Support

General Diabetes Education—Family or Social Support

General population of children with diabetes. Brown et al.[9] randomized 59 children to an intervention group that viewed a diabetes-related interactive video game, or to a comparison group that received an entertainment video game with no diabetes-related content. Social support was measured by parent report of how many times in the previous month the child initiated discussions about diabetes care and about their feelings related to having diabetes. At 6-month followup, the intervention group had increased communication significantly compared to the control group (9.8±9.5 vs. 19.3±25.1 instances and 18.9±25.1 vs. 15.0±20.6 instances, respectively [p = 0.025]). The

methodological quality of this study was low (1/5 on the modified Jadad scale; unclear concealment of allocation).

Children with newly diagnosed diabetes. Siminerio et al.[66] compared a 3- to 5-day education program delivered on an inpatient vs. outpatient basis. Patients were divided into two cohorts of 16 patients each. The education program included basic education on diabetes, complications, self-management skills, and nutrition and exercise. Family support was measured by the Coping Health Inventory for Parents, which has three subscales measuring maintenance of family integration, maintaining social support, and understanding the medical situation through consultation with medical support personnel. There were no significant differences between the groups at the 1-month followup. The methodological quality of this study was moderate using the Thomas instrument.

Children with poorly controlled diabetes. In the RCT by Coupland,[15] adolescents and their families participated in a family-based intervention to improve adherence (n = 15); the comparison group (n = 14) consisted of adolescents who were taught stress management techniques. Perceived diabetes-specific family support was assessed with the supportive items of the Diabetes Family Behaviour (DFB) checklist and general family support was assessed with the Family APGAR. At the 6-month followup, the intervention group reported improved general family support ($p < 0.001$). There was no significant difference between the two groups on the DFB checklist. The methodological quality of this study was low (2/5 on the modified Jadad scale; unclear concealment of allocation).

Cognitive Behavioral Therapy—Family or Social Support

General population of children with diabetes. Anderson et al.[5] assessed the effectiveness of an intervention for families that focused on teamwork and shared parent-teen responsibility for diabetes tasks. Eighty-nine families were randomly assigned to the intervention group or to one of two comparison groups—standard care (routine clinical care from the diabetes team) or standard care plus didactic diabetes education. Family support was measured with the Diabetes Family Behavior Checklist (Unsupportive behavior subscale). At 12-month followup, the intervention group showed a significantly greater decrease in unsupportive behavior compared with the comparison groups ($p<0.02$). The methodological quality of this study was low (2/5 on the Jadad score; unclear concealment of allocation).

The CCT by Mendez and Belendez[48] used an intervention comprising 12 sessions of content delivery, skill practice and homework; parents were involved for two of the sessions. The emphasis was on reinforcement of adherence behaviors rather than punishing noncompliance. The intervention delivered to the control group care was not described. Family support was measured using the Diabetes Family Behavior Checklist. There were no significant differences between intervention and control groups for positive or negative family support at 13-month followup. The methodological quality of this study was low (1/3 on the modified Jadad score).

The uncontrolled before-and-after study by Greco et al.[20] delivered the intervention in 2-hour sessions over 4 weeks to groups of three to six diabetes patient-peer pairs. The intervention consisted of a review of the etiology, physiology and treatment of diabetes, reflective listening skills, problem solving related to diabetes, stress management, games

or exercises to practice concepts and homework assignments. Family and peer support were measured using the Diabetes Social Support Inventory. Perceived levels of support did not improve significantly following the intervention. The methodological quality of this study was moderate based on the Thomas instrument.

Children with poorly controlled diabetes. Delamater et al.[16] randomized 13 adolescents to receive a 2-month behavior therapy program or to standard outpatient care. Patient and parent ratings of parental supportiveness and non-supportiveness were compared between the two groups. There were no significant differences between groups at 4-month followup. The methodological quality of this study was low (2/5 on the modified Jadad score; unclear concealment of allocation).

Family Therapy Family or Social Support

Children with poorly controlled diabetes. In an uncontrolled before-and-after study, Harris et al.[28] evaluated 18 adolescents and their families who enrolled in a behavioral family systems therapy (BFST) program. Family supportive and non-supportive behaviors were assessed using the Diabetes Family Behavior Checklist. There were no statistically significant differences between baseline and 6-month followup measures. The methodological quality of this study was weak based on the Thomas instrument.

Diabetes Camp—Family or Social Support

General population of children with diabetes. Remley[62] conducted a CCT (n = 237) to compare a social cognitive theory-based camp program with a standard non-theory based camp education program. Eight 1-week camps across the United States were designated to deliver either the theory-based intervention or the standard program. Social support was measured using the Diabetes Social Support index. At the 3-month followup, there were no significant changes in outcomes for either group. The methodological quality of this study was low (1/3 on the modified Jadad scale).

Summary of Results—Family or Social Support

Overall, we identified nine studies that assessed the effect of diabetes education on the psychosocial outcome of family and social support (Table 13). Of these, five studies (2 RCTs, 2 CCTs, 1 uncontrolled before-and-after) examined the general population of children with type 1 diabetes, one cohort study focused on children with newly diagnosed diabetes, and three (2 RCTs, 1 uncontrolled before-and-after) examined children with poorly controlled diabetes.

General population of children with diabetes. Five studies (2 RCTs,[5,9] 2 CCTs,[48,62] 1 uncontrolled before-and-after[20]) assessed the effectiveness of diabetes education on family and social support in the general population of children with type 1 diabetes (Table 13). Three studies assessed the effectiveness of cognitive behavioral therapy,[5,20,48] one examined general diabetes education,[9] and one assessed the effect of diabetes camps.[120] In general, the methodological quality of the studies was low, with only the before-and-after study by Greco et al.[20] rated as being of moderate quality.

The uncontrolled before-and-after study by Greco et al.[20] assessed an intervention aimed at integrating teenage peers into the diabetes care of a friend with diabetes. There was no change in perceived levels of family support following the intervention. The results of the remaining studies were inconsistent. Two RCTs,[5,9] found that family/social support improved following diabetes education. In contrast, two CCTs[48,62] found that the intervention had no effect on the outcome.

Children with newly diagnosed diabetes. The moderate quality cohort study by Siminerio et al.[66] compared inpatient vs. ambulatory delivery of general diabetes education among children with newly diagnosed diabetes (Table 13). There were no significant differences between groups for the family/social support outcome.

Children with poorly controlled diabetes. Three studies (2 RCTs,[15,16] 1 uncontrolled before-and-after[28]) assessed the effectiveness of diabetes education on family/social support among children with poorly controlled diabetes (Table 13). The methodological quality of the studies was low. None of the studies found that the intervention had an effect on the outcome.

Table 13. Summary of results of studies assessing the effect of diabetes education on family and social support

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Anderson[5] 1999	Cognitive behavioral therapy	RCT 89	Low	IG reported significant decreases in unsupportive behavior compared with CG at 12 mo.
Brown[9] 1997	General diabetes education	RCT 59	Low	IG significantly increased communication skills compared to CG at 6 mo.

CG = control group; IG = intervention group

Table 13. Summary of results of studies assessing the effect of diabetes education on family and social support (continued)

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes (continued)				
Greco[20] 2001	Cognitive behavioral therapy	Before-after 23	Moderate	No significant change following the intervention
Mendez[48] 1997	Cognitive behavioral therapy	CCT 37	Low	No significant difference between groups on any of the social support measures at 13 mo.
Remley[62] 1999	Diabetes camp	CCT 237	Low	No significant difference between groups on any of the social support measures at 3 mo.
Children with newly diagnosed diabetes				
Siminerio[66] 1999	General diabetes education	Cohort 32	Moderate	No significant difference between groups at 1 mo.
Children with poorly controlled diabetes				
Coupland[15] 1992	General diabetes education	RCT 32	Low	No significant difference between groups at 6 mo.
Delamater[16] 1991	Cognitive behavioral therapy	RCT 13	Low	No significant difference between groups on any of the social support measures at 4 mo.
Harris[28] 2005	Family therapy	Before-after 18	Low	No significant change at 6 mo. for diabetes support; No significant change at 6 mo. for diabetes non-support

Social Skills

General Diabetes Education—Social Skills

Children with poorly controlled diabetes. Nunn et al.[55] conducted a RCT to assess the effect of a general diabetes education intervention on social skills. One hundred and twenty-three patients were randomized to either the intervention group, comprising 15- to 30-minute telephone calls on three main topics: current insulin, carbohydrate intake and blood glucose values; events which may impact diabetes management; and delivery of an educational program, or to the standard care group (routine clinical care). Social skills were measured using the Strengths and Difficulties Questionnaire. At the end of the 5- to 8-month program, there were no significant differences between groups for various social skills (emotional, conduct, hyperactive, peer problem, and pro-social scores). The methodological quality of the study was high (3/5 on the Jadad score; unclear concealment of allocation)

In the CCT by Viner et al.[76] a 6-week motivational and solution-focused therapy group program that used systematic questions, a narrative approach and cognitive behavioral therapy was delivered to 21 adolescents and their parents. The control group comprised 20 adolescents who did not receive any intervention. Social skills were

assessed using the Strengths and Difficulties Questionnaire (SDQ). There were no significant changes in mean SDQ scores for either group. The methodological quality of the study was low (2/5 on the Jadad score; unclear concealment of allocation).

Cognitive Behavioral Therapy—Social Skills

General population of children with diabetes. Gross et al.[23] randomized six children to a social skills training intervention and five to a control group. The social skills training consisted of modeling and role-playing exercises and took place in two 45-minute per week sessions for 5 weeks. The control group subjects did not interact with the experimenters except at assessment times (baseline, post training, one and six-week followups). At the 6-week followup, the intervention group demonstrated increased incidence of certain social skills, including percentage eye contact time (from 53 to 95 percent), percentage verbalizations (from 24 to 79 percent), and speech duration (from 1.7 to 6 seconds). There were no changes observed in these behaviors for the control group. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear concealment of allocation; blinding of outcome assessors).

Summary of Results—Social Skills

General population of children with diabetes. One moderate quality RCT (Gross et al.[23]) assessed the effect of cognitive behavioral therapy on social skills in the general population of children with type 1 diabetes (Table 14). They found that the intervention group significantly improved their social skills compared to the control group.

Children with poorly controlled diabetes. The large high quality RCT by Nunn et al,[55] reported no significant differences in social skills between the intervention group that received general diabetes education plus telephone followup and the control group that received diabetes education with no telephone followup (Table 14). Similarly, the CCT that assessed this population did not find any change in social skills.[76]

Table 14. Summary of results of studies assessing the effect of diabetes education on social skills

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Gross[23] 1983	Cognitive behavioral therapy	RCT 11	Moderate	IG improved significantly for increased eye contact, appropriate verbalization, speech duration, affect ratings at 6 wk.; no change for CG
Children with poorly controlled diabetes				
Nunn[55] 2006	General diabetes education	RCT 123	High	No significant change for either group at 5-8 mo. in emotional, conduct, hyperactive, peer problem, and pro-social scores
Viner[76] 2003	Cognitive behavioral therapy	CCT 21	Low	No significant change for either group at 12 mo.

CG = control group; IG = intervention group

Coping

General Diabetes Education—Coping

General population of children with diabetes. In the uncontrolled before-and-after study by Marteau et al.,[44] a multidisciplinary team delivered a weekend program to 97 parents. There were sessions on problem solving, forming self-help groups, and ways to achieve best care. Parents rated themselves as significantly more confident in looking after their child both immediately following the intervention and at the 3-month followup. However, their perception of the difficulty of looking after their child remained unchanged at 3-months post-intervention. The methodological quality of this study was rated as weak based on the Thomas instrument.

Children with newly diagnosed diabetes. Dougherty et al.[18] delivered a general diabetes education intervention to 63 newly diagnosed patients. Thirty-one patients were randomized to receive the education as inpatients; the other 32 received their education at home in the form of home visits. At 24 months following diagnosis, there was no significant difference between groups on the Impact on Family Scale. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear concealment of allocation; blinding of outcome assessors).

Siminerio et al.[66] compared a 3- to 5-day education program delivered on an inpatient vs. outpatient basis. Patients were divided into two cohorts of 16 patients each. The education program included basic education on diabetes, complications, self management skills, and nutrition and exercise. At 1-month post-intervention, there were no significant differences between the groups in coping as measured by the Coping Health Inventory for Parents and the Coping Health Inventory for Children questionnaires. The methodological quality of this study was rated as moderate based on the Thomas instrument.

In a prospective cohort study by Srinivasan et al.,[69] a 4- to 16-week outpatient day care program was compared with a 4- to 7-day inpatient program for delivering general diabetes education to 110 newly diagnosed patients and their families. There was no

difference between groups for the outcome of coping. The methodological quality of this study was rated as moderate based on the Thomas instrument.

Cognitive Behavioral Therapy—Coping

General population of children with diabetes. The RCT by Grey et al.[21] examined a coping skills training intervention in a group of 77 adolescents that received intensive diabetes management as their standard care. Forty-one children were randomized to the coping skills training group and the training was delivered at 6 weekly sessions. Based on the Issues in Coping with IDDM scale, at 12-month followup, both groups reported significantly less upset about coping with diabetes and found it significantly less difficult to cope with their diabetes. The difference between the groups was not statistically significant. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear concealment of allocation; blinding of outcome assessors).

The CCT by Mendez and Belendez[48] used an intervention comprising 12 sessions of content delivery, skill practice and homework assignment; parents were involved for two of the sessions. The emphasis was on reinforcement of adherence behaviors rather than punishing noncompliance. The intervention delivered to the control group care was not described. The questionnaires used were the Diabetic Daily Hassles Scale and the Diabetic Adolescents Social Skills Inventory. The authors reported that the intervention group had a significantly lower incidence of daily diabetes-related hassles and a lower degree of unease and likelihood of response in a social interaction relating to diabetes at post-intervention and 13-month followup. The methodological quality of the study was low (1/3 on the modified Jadad score).

The uncontrolled before-and-after study by Greco et al.[20] delivered the intervention in 2-hour sessions over 4 weeks to groups of three to six diabetes patient-peer pairs. The intervention consisted of homework review on etiology, physiology and treatment of diabetes, reflective listening skills, problem solving related to diabetes, stress management, games or exercises to practice concepts and homework assignments. Using the Teen Adjustment to Diabetes Scale, the authors reported a trend toward improved behavioral, affective, and attitudinal adjustment to diabetes post-intervention; however, the change was not statistically significant. The methodological quality of this study was rated as moderate based on the Thomas instrument.

Children with poorly controlled diabetes. In a three-arm RCT (n = 37) Cigrang[13] investigated the effects of a coping skills program delivered to adolescents with a history of poor metabolic control. There were two comparison groups: conventional diabetes education (8 lectures on diabetes topics including a question and answer session and time for skills practice) and standard care (routine clinical visits). The intervention group received eight sessions that focused on identifying issues that were perceived as difficult and stressful and developing adaptive coping strategies; the group was asked to implement new coping strategies in real life situations during the week. At 3-months followup, there were no significant differences among any of the groups for the outcome of coping using the Acceptance of Illness scale. The methodological quality of the study was low (2/5 on the Jadad score; unclear concealment of allocation).

Boardway et al.[8] randomized 31 children to either a 3-month stress management program or to standard outpatient care. The intervention included group sessions in three

phases of self-monitoring, stress management and regimen adherence. At the 6-month followup, there were no significant differences between the groups on the Ways of Coping questionnaire. The methodological quality of the study was low (1/5 on the Jadad score; unclear concealment of allocation).

Hains et al.[25] randomly assigned 15 adolescents to a 3-phase stress inoculation program or to a control group that received no intervention. At the 1-month followup, there was no difference between groups on the KIDSCOPE questionnaire. The methodological quality of the study was low (2/5 on the Jadad score; unclear concealment of allocation).

Family Therapy—Coping

Children with poorly controlled diabetes. Wysocki et al.[83] randomly assigned 119 families to three groups: standard care (physician directed clinical therapy), education and support (standard care plus 10 sessions of a diabetes support group), and behavioral family systems therapy (BFST) (standard care plus family problem solving and communication training and individualized treatment plans). No significant difference was found among the groups for the outcome of coping at any time point up to 12-months post-intervention. The methodological quality of the study was rated as high (3/5 on the Jadad score; adequate allocation of concealment).

Skills Training

Children with newly diagnosed diabetes. One RCT by Mitchell[49] assessed the effect of a skills training intervention on coping abilities among 32 newly diagnosed patients (mean age 10.7 years). The intervention group received standard multidisciplinary education and support plus a booklet targeted at improving compliance with treatment. The booklet identified problems with adherence and offered basic self-management skills. The standard care group received standard education and support. Using the Problem Situations Questionnaire, at the 12-month followup there were no significant differences in coping outcomes between the groups. The methodological quality of the study was low (1/5 on the Jadad score; unclear concealment of allocation).

Diabetes Camp—Coping

General population of children with diabetes. The uncontrolled before-and-after study by Koontz[37] (n = 112) took place during a 1-week camp. Children were distributed in study groups according to age (grades 2–5, 6–8, and 9–10). The intervention included education on self-management skills, insulin administration, the relationship between diet, exercise and insulin, meal and snack planning, selecting and measuring food portions, SMBG, and identifying and treating insulin reactions, and was aimed to enhance camper's emotional adjustment and improve self-esteem. At the 3-month followup, there was no effect of the intervention on coping strategies. However, the author noted that coping strategies differed as a function of age. The methodological quality of the study was moderate based on the Thomas instrument.

The intervention in the uncontrolled before-and-after study by Smith[68] (n = 108) consisted of daily 1-hour sessions on stress and diabetes in which management techniques were described, modeled and practiced using a variety of techniques. There was no significant change in coping abilities from pre- to post-camp. The methodological quality of the study was weak based on the Thomas instrument.

Summary of Results—Coping

Overall we identified 14 studies that examined the psychosocial outcome of coping (Table 15). Of these, six studies (1 RCT, 1 CCT, 4 uncontrolled before-and-after) examined the general population of children with type 1 diabetes. Four studies (2 RCTs, 2 cohorts,) focused on children with newly diagnosed diabetes. Four RCTs targeted children with poorly controlled diabetes.

General population of children with diabetes. Six studies (1 RCT,[21] 1 CCT,[48] 4 uncontrolled before-and-after[20,37,44,68]) assessed the effect of diabetes education on coping in the general population of children with diabetes (Table 15). Three studies assessed the effectiveness of cognitive behavioral therapy,[20,21,48] one examined general diabetes education,[44] and two assessed the effect of diabetes camps.[37,68] In general the methodological quality of the studies was low, with only one RCT (Grey et al.[21]) and two uncontrolled before-after studies (Greco et al.[20] and Koontz[37]) rated as being of moderate quality.

The results of the three moderate quality studies do not suggest that diabetes education has an effect on coping abilities. The RCT by Grey et al.[21] found that both the intervention and control groups reported improved coping abilities; however, the difference between groups was not statistically significant. Similarly, the before-after studies Koontz[37] and Greco et al.[20] did not find that coping abilities were significantly improved following the education interventions.

The results of the remaining studies were mixed. One uncontrolled before-and-after study found that parents were more confident about their ability to care for their children.[44] One CCT that focused on improving adherence behavior and stress management had a significant impact on coping abilities.[48] One uncontrolled before-and-after studies that assessed the effect of an intervention delivered at diabetes camps found no change in coping behaviors.[68]

Children with newly diagnosed diabetes. Three moderate quality studies (1 RCT[18] and 2 prospective cohort studies[66,69]) examined whether the setting for delivery of general diabetes education (i.e., delivery of education in an inpatient setting vs. an ambulatory setting) had an impact on coping behaviors (Table 15). None of the studies reported significant group differences in coping outcomes. The remaining study assessed a skills training intervention and found no difference between study groups.[49]

Children with poorly controlled diabetes. The large high-quality RCT by Wysocki et al,[83] reported no significant differences in coping behaviors between the intervention group that received behavioral family systems therapy and the control groups that received standard care and education support (Table 15). Similarly, the remaining low quality studies did not report any significant differences between intervention and control groups.[8,13,25]

Table 15. Summary of results of studies assessing the effect of diabetes education on coping

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Greco[20] 1991	Cognitive behavioral therapy	Before-after 23	Moderate	Trend toward improved behavioral, affective, and attitudinal adjustment; difference was NS
Grey[21] 2000	Cognitive behavioral therapy	RCT 77	Moderate	Both groups reported less upset about coping with diabetes and less difficult to cope with diabetes at 12 mo.; difference between groups was NS
Koontz[37] 2002	Diabetes camp	Before-after 112	Moderate	No significant change at 3 mo.
Marteau[44] 1987	General diabetes education	Before-after 97	Low	Parents rated themselves significantly more confident in looking after their child at 3 mo.; Parents perception of difficulty in looking after child did not change at 3 mo.
Mendez[48] 1997	Cognitive behavioral therapy	CCT 37	Low	IG reported significantly fewer daily diabetes-related hassles at 13 mo.; IG reported significantly lower degree of unease and likelihood of response in social situation relating to diabetes at 13 mo.
Smith[68] 1991	Diabetes camp	Before-after 108	Low	No significant change from pre- to post-camp
Children with newly diagnosed diabetes				
Dougherty[18] 1999	General diabetes education	RCT 63	Moderate	No significant difference between groups on family impact at 24 mo.

CCT = controlled clinical trial; IG = intervention group; NS = not significant

Table 15. Summary of results of studies assessing the effect of diabetes education on coping (continued)

Author Year	Intervention	Study design Sample size	Quality	Results
Children with newly diagnosed diabetes (continued)				
Mitchell[49] 1996	Skills	RCT 32	Low	No significant differences between groups in perceived difficulties in diabetes management at 12 mo.; No significant differences between groups in social function and general adjustment at 12 mo.
Siminerio [66] 1999	General diabetes education	Cohort 32	Moderate	No significant difference between groups at 1 mo.
Srinivasan[69] 2004	General diabetes education	Cohort 110	Moderate	No significant difference between groups at 12 mo.
Children with poorly controlled diabetes				
Boardway[8] 1993	Cognitive behavioral therapy	RCT 31	Low	No significant difference between groups at 6 mo.
Cigrang[13] 1992	Cognitive behavioral therapy	RCT 37	Low	No significant difference between groups at 3 mo.
Hains[25] 2000	Cognitive behavioral therapy	RCT 15	Low	No difference between groups at 1 mo.
Wysocki[83] 2000	Family therapy	RCT 119	High	No significant difference between groups at 12 mo.

Self-Perception

Cognitive Behavioral Therapy—Self-Perception

General population of children with diabetes. The uncontrolled before-and-after study by Greco et al.[20] delivered the intervention in 2-hour sessions over 4 weeks to group of three to six diabetes patient-peer pairs. The intervention comprised information about diabetes, reflective listening skills, problem solving, stress management, and games or exercises to practice concepts. Self-perception was assessed using the global self-worth scale of the Self Perception Profile. At the end of the intervention, there was no significant change from baseline in self-perception among adolescents with diabetes. The methodological quality of this study was moderate based on the Thomas instrument.

Thomas-Dobersen et al.[74] conducted a CCT in which 11 obese adolescents participated in the SHAPEDOWN program which included 14 sessions over 3 months addressing various aspects of diabetes management such as diet and knowledge of hypoglycemia. The control group (n = 9) received standard diabetes treatment. Self-esteem was measured using the global self-esteem scale of the Self Perception Profile. At 15 months, more children in the intervention group (4/11) showed clinical improvement

in their self-perception compared to the control group (1/9). The methodological quality of this study was low (1/3 on the modified Jadad score).

Children with poorly controlled diabetes. In a 3-arm RCT, Cigrang[13] investigated the effects of a coping skills program delivered to 37 adolescents with a history of poor metabolic control. There were two comparison groups: conventional diabetes education and standard care. Self-perception was assessed using the Self Perception Profile for Children. At 3-months post-intervention there were no significant differences among the three groups. The methodological quality of this study was low (2/5 on the Jadad score; unclear allocation concealment).

Diabetes Camp—Self-Perception

General population of children with diabetes. In a CCT, Zorumski[84] assigned 56 children to attend either a 1-week camp that used active participation and educational presentations to teach all aspects of diabetic self-management, or to a control group that received standard clinical care but did not attend a camp. At the 4-month followup, the intervention group had a significantly lower score in self-perception (i.e., did not improve) compared to their baseline level (3.52±0.55 vs. 3.41±0.50), whereas the control group improved their score over the same time period (3.27±0.63 to 3.56±0.52). The methodological quality of this study was low (0/3 on the modified Jadad score).

The uncontrolled before-and-after study by Koontz[37] (n = 112) took place during a 1-week camp. Participants were divided into 3 age groups (grades 2–5, 6–8, and 9–10). The intervention included education on self-management skills, insulin administration the relationship between diet, exercise and insulin, meal and snack planning and food portions, SMBG, and identifying and treating insulin reactions. Several subscales of the Self Perception Profile were used: social competence, physical attractiveness, athletic ability and global self-worth. At the 3-month followup, there were no significant differences in social competence and physical attractiveness within or between groups. Campers in the two younger age groups felt more athletically competent than those in the oldest group. Among the older campers, global self-worth decreased over the 3-month followup period; for younger campers, this attribute increased. The methodological quality of this study was moderate based on the Thomas instrument.

In an uncontrolled before-and-after study, Smith et al.[67] used the Adolescent Self Expression scale to measure changes in assertive behavior among adolescents attending a diabetes camp. At the 3-month followup, there was a significant increase in perception of assertive behavior. The methodological quality of this study was weak based on the Thomas instrument.

Family Therapy—Self-Perception

Children with newly diagnosed diabetes. The RCT by Sundelin et al.[70] compared conventional inpatient education (n = 19 families) to a multidisciplinary program for family-oriented crisis intervention delivered in an outpatient setting (n = 19 families). Self-esteem was measured using the "I think I am" test. At 24-month followup, there was no statistically significant difference between groups on this measure. The

methodological quality of this study was low (2/5 on the Jadad score; unclear allocation concealment).

Children with poorly controlled diabetes. In the uncontrolled before-and-after study by Harris et al.[28] reported 6-month followup data for 18 families who enrolled in a BFST program. Self-perception was measured using the Adjustment to Illness Scale which assesses feelings of self-acceptance and acceptance by others despite their illness. There were no significant differences in adjustment scores between baseline and 6-month followup for adolescents, mothers or fathers. The methodological quality of this study was weak based on the Thomas instrument.

Summary of Results—Self-perception

General Population of Children with Diabetes

Five studies (2 CCTs,[74,84] 3 uncontrolled before-and-after[20,37,67]) examined the effect of diabetes education on self-perception in the general population of children with type 1 diabetes (Table 16). Three studies examined interventions based on cognitive behavioral techniques[20,67,74] and two assessed intervention delivered at a diabetes camp.[37,67] Overall the methodological quality of the studies was low, with only two uncontrolled before-and-after studies considered to be of moderate quality (Greco et al.[20]and Koontz[37]).

With the exception of one uncontrolled before-and-after study,[67] none of the studies found that diabetes education had an effect on self-perception.

Children with newly diagnosed diabetes. One study[70] compared the setting for delivery of a family-based education program (ambulatory vs. inpatient) and found no difference between groups on measures of self-perception (Table 16). This was a small study and there may not have been sufficient statistical power to detect a difference between groups.

Children with poorly controlled diabetes. Two studies[13,28] examined the effect of diabetes education on self-perception among children with poorly controlled diabetes. Neither study found that the education intervention had an effect on self-perception (Table 16).

Table 16. Summary of results of studies assessing the effect of diabetes education on self-perception

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Greco[20] 2001	Cognitive behavioral therapy	Before-after 23	Moderate	No significant change in social, academic, job, behavior, athletic competence
Koontz[37] 2002	Diabetes camp	Before-after 112	Moderate	No significant change in social competence and physical attractiveness at 3 mo.; Younger campers felt more athletically competent than older campers at 3 mo.
Smith[67] 1993	Cognitive behavioral therapy	Before-after 120	Low	Significant increase in assertive behavior at 3 mo.
Thomas-Dobersen[74] 1993	Cognitive behavioral therapy	CCT 20	Low	4/11 IG subjects showed improvement at 15 mo. compared to 1/9 in CG; significance NR
Zorumski[84] 1997	Diabetes camp	CCT 56	Low	IG had significantly lower score than CG at 4 mo.
Children with newly diagnosed diabetes				
Sundelin[70] 1996	Family therapy	RCT 38	Low	No significant difference between groups at 24 mo.
Children with poorly controlled diabetes				
Cigrang[13] 1992	Cognitive behavioral therapy	RCT 37	Low	No significant difference between groups at 3 mo.
Harris[28] 2005	Family therapy	Before-after 18	Moderate	No significant change in self acceptance or acceptance by others at 6 mo.

CG = control group; IG = intervention group; NR = not reported

Self-Efficacy

General Diabetes Education—Self-Efficacy

General population of children with diabetes. Brown et al.[9] randomized 59 children to receive either a diabetes related interactive video game (intervention group), or an entertainment video game with no diabetes related content (control group). Perceived self-efficacy was evaluated using a validated yielding a self-efficacy score from 1 to 7. Assessments took place at baseline, 3 and 6 months. The intervention group improved relative to the control group on self-efficacy ratings (0.45±0.60 vs. 0.17±0.57, respectively), but this change was not significant ($p = 0.07$). The methodological quality of the study was low (1/5 on the Jadad score; unclear allocation of concealment).

Children with newly diagnosed diabetes. In the study by Hoff et al.[30] 46 parents of children newly diagnosed with diabetes (mean age = 9.4 years) were randomly assigned to the intervention or control group. The intervention was delivered to parents and

comprised two 2.5-hour group sessions designed to teach skills to manage uncertainty and to decrease parental distress and child behavioral problems. Parents assigned to the control group did not receive an intervention. Self-efficacy regarding dealing with the child's illness was assessed using the Parent Perception of Uncertainty Scale. At the 3- and 6-month followup assessments, there were no significant changes for mothers and fathers in either group. The methodological quality of the study was high (3/5 on the Jadad score; adequate allocation of concealment).

Cognitive Behavioral Therapy—Self-Efficacy

General population of children with diabetes. The RCT by Grey et al.[21] randomized 77 children to either a coping skills training combined with intensive diabetes management or to standard care (intensive management only). Self-efficacy was measured using the Self Efficacy for Diabetes Scale. At 12 months, adolescents in both groups reported significantly improved general, medical, and diabetes self-efficacy. The intervention group had significantly better diabetes and medical self-efficacy compared to the control group. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear allocation of concealment; blinding of outcome assessors).

Children with newly diagnosed diabetes. Boardway et al.[8] randomized 31 children to either a 3-month stress management program or to standard outpatient care. The intervention included group sessions in three phases of self-monitoring, stress management and regimen adherence. Self-efficacy was measured using the Self-Efficacy for Diabetes Scale. At the 3-month followup, there were no significant changes in self-efficacy. The methodological quality of the study was low (1/5 on the Jadad score; unclear allocation of concealment).

Children with poorly controlled diabetes. In the CCT (n = 21), Viner et al.[76] used motivational and solution focused therapy techniques for their intervention group compared to a no treatment control group. Self-efficacy was measured using the Self-Efficacy for Diabetes (SED) Scale. Mean SED scores improved significantly from baseline to the 6-month followup for the intervention group compared to no change in the control group. The methodological quality of the study was low (1/3 on the modified Jadad score).

Skills Training—Self-Efficacy

General population of children with diabetes. In an uncontrolled before-and-after study by Caravalho and Saylor,[11] 56 children and their parents were taught insulin adjustment procedures and received group support and education to improve self-management. Self-efficacy was assessed using the 13-item adapted Self-Efficacy for Diabetes Parent Questionnaire. After the 1-year intervention, self-efficacy scores had increased significantly from 56.2±7.7 to 59.3±6.9 ($p = 0.01$). The methodological quality of the study was weak using the Thomas instrument.

Diabetes Camp—Self-Efficacy

General population of children with diabetes. Remley[62] conducted a CCT (n = 237) to compare a social cognitive theory-based program with a standard non-theory based camp education program. Eight 1-week camps across the United States were designated to deliver either the theory-based intervention or the standard program. At the end of the camp and at the 3-month followup, there was no significant difference in self-efficacy for either group. The methodological quality of the study was low (1/3 on the modified Jadad score).

In an uncontrolled before-and-after study, Schlundt et al.[64] delivered an intervention to 86 campers. The program consisted of two sessions and used a 17-minute video on obstacles faced by adolescents with diabetes. Campers identified, analyzed and proposed solutions and then attempted to apply them to their own lives. Self-efficacy was measured by Self Efficacy for Diabetes (SED) Scale and the Situational Obstacles to Dietary Adherence (SODA) questionnaire. No change in the SED score occurred in either group from baseline to end of the 2-week camp. However, the SODA questionnaire indicated that children had significant increases in confidence to handle dietary obstacles. The methodological quality of the study was weak using the Thomas instrument.

The prospective cohort study by Hill et al.[29] compared two different diabetes camps: one camp (n = 60) offered a program based on self-determination theory and one camp (n = 74) offered a program that had similar types of activities but was not theory-based. Self-efficacy was assessed with a Treatment Self Regulation Scale and a Perceived Confidence scale. At 3-month followup there were no significant differences between the intervention and comparison groups in perceived competence for diabetes management. There was a significant decrease in autonomy for diabetes management in the intervention group vs. and increase in autonomy for the comparison group the intervention group. The methodological quality of the study was weak based on the Thomas instrument.

Summary of Results—Self-Efficacy

General population of children with diabetes. Six studies (2 RCTs,[9,21] 1 CCT,[62] 1 cohort,[29] 2 uncontrolled before-and-after[11,64]) examined the effect of diabetes education on self-efficacy in the general population of children with type 1 diabetes (Table 17). Three studies examined interventions delivered at diabetes camp[29,62,64] and 1 each studied general diabetes education,[9] cognitive behavioral therapy,[21] and skills training.[11] Overall the methodological quality of the studies was low, with only one RCT assessed as being of moderate quality (Grey et al.[21]).

The RCT by Grey et al.[21] reported that the cognitive behavioral intervention had a positive effect on self-efficacy. The results of the remaining studies were mixed. Two studies found self-efficacy improved following the intervention.[11,64] One found that both the intervention and control groups improved, but the difference between groups was not

statistically significant.[9] The remaining studies reported no change in self-esteem measures following the education intervention.[29,62]

Children with newly diagnosed diabetes. The high quality RCT by Hoff et al.[30] assessed an intervention delivered to parents of children with newly diagnosed diabetes to help them manage the uncertainty of how to care for their children (Table 17). There was no significant difference in parental self-efficacy between the intervention and control groups. The remaining study examined the effect of a stress management program on self-efficacy among children with newly diagnosed diabetes and found no difference between the intervention and control groups.[8]

Children with poorly controlled diabetes. One low quality CCT[76] found that an intervention based on cognitive behavior therapy techniques resulted in improved levels of self-efficacy among children with poorly controlled diabetes (Table 17).

Table 17. Summary of results of studies assessing the effect of diabetes education on self-efficacy

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Brown[9] 1997	General diabetes education	RCT 59	Low	Both groups improved; difference was NS at 6 mo.
Caravalho[11] 2000	Skills training	Before-after 56	Low	Significant improvement in scores at 12 mo.
Grey[21] 2000	Cognitive behavioral therapy	RCT 77	Moderate	Both groups showed significant improvement in general self-efficacy at 12 mo.; IG did significantly better for diabetes and medical self-efficacy than CG at 12 mo.
Hill[29] 2006	Diabetes camp	Cohort 134	Low	No significant difference between groups in competence or degree of autonomy at 3 mo.
Remley[62] 1999	Diabetes camp	CCT 237	Low	No significant difference between groups at 3 mo.
Schlundt[64] 1996	Diabetes camp	Before-after 86	Low	Statistically significant increase in confidence to overcome diabetes-related obstacles; No significant change in patient belief in self-care abilities
Children with newly diagnosed diabetes				
Hoff[30] 2005	General diabetes education	RCT 46	High	No significant difference between groups at 6 mo.

CG = control group, IG = intervention group; NS = not significant

Table 17. Summary of results of studies assessing the effect of diabetes education on self-efficacy (continued)

Author Year	Intervention	Study design Sample size	Quality	Results
Children with poorly controlled diabetes				
Boardway[8] 1993	Cognitive behavioral therapy	RCT 31	Low	No significant difference between groups at 3 mo.
Viner[76] 2003	Cognitive behavioral therapy	CCT 21	Low	Significant improvement for IG at 6 mo.; no change for CG intervention

Stress

Cognitive Behavioral Therapy—Stress

Children with poorly controlled diabetes. Boardway et al.[8] randomized 31 adolescents to either a 3-month stress management program or to a control group that received standard outpatient care. Stress was measured using the Diabetes Stress Questionnaire (DSQ). At the 6-month followup, the intervention group reported significantly improved stress levels compared to the control group (93.6±39.0 vs. 56.1±43.7 and 88.4±33.5 vs. 83.4±31.3, respectively). The methodological quality of the study was low (1/5 on the Jadad score; unclear concealment of allocation).

The RCT by Hains et al.[25] randomized 15 middle school children to either a stress inoculation training program delivered over 6 weeks or to a waiting list control group. Stress was measured using the DSQ. At 1-month followup, the intervention group showed improvement in stress levels compared to the control group; however, the difference between the groups was not statistically significant. The methodological quality of the study was low (2/5 on the Jadad score; unclear concealment of allocation).

Summary of Results—Stress

Two RCTs assessed the effect of cognitive behavioral therapy interventions on stress among children with poorly controlled diabetes (Table 18).[8,25] and found that the interventions groups had reduced stress levels compared to the control groups. However, the methodological quality for both studies was low and the results must be interpreted with caution.

Table 18. Summary of results of studies assessing the effect of diabetes education on stress

Author Year	Intervention	Study design Sample size	Quality	Results
Children with poorly controlled diabetes				
Boardway[8] 1993	Cognitive behavioral therapy	RCT 31	Low	IG had significantly reduced stress levels compared to CG at 6 mo.
Hains[25] 2000	Cognitive behavioral therapy	RCT 15	Low	IG had reduced stress levels compared to CG at 1 mo; difference was NS

CG = control group, IG = intervention group; NS = not significant

Anxiety and Depression

General Diabetes Education—Anxiety and Depression

Children with newly diagnosed diabetes. In the study by Hoff et al.[30] 46 parents of children newly diagnosed with diabetes were randomly assigned to the intervention or control group. The intervention was delivered to parents and comprised two 2.5-hour group sessions designed to teach skills to manage uncertainty and to decrease parental distress and child behavioral problems. Parents assigned to the control group did not receive an intervention. Children continued to receive routine clinical care and intensive education. Mothers in the intervention group reported decreased child internalizing problems at the 1- and 6-month followup points; mothers in control group did not report any changes. Conversely, fathers in the intervention group did report changes in child internalizing problems during followup; however, fathers in the control group reported decreased child decreased child internalizing problems at the 1-month followup. This change disappeared at the 6-month followup. The methodological quality of the study was high (3/5 on the Jadad score; adequate concealment of allocation).

Cognitive Behavioral Therapy—Anxiety and Depression

General population of children with diabetes. The RCT by Grey et al.[21] examined a coping skills training intervention in a group of 77 adolescents who received intensive diabetes management as their standard care. Forty-one children were randomized to the coping skills training group and the training was delivered at six weekly sessions. Using the Children's Depression Inventory, at the 12-month followup, both groups reported significantly less depression; however, the difference between the groups was not statistically significant. The methodological quality of the study was moderate (2/5 on the Jadad score; unclear concealment of allocation; blinding of outcome assessors).

Children with poorly controlled diabetes. In a three-arm RCT (n = 37) Cigrang[13] investigated the effects of a coping skills program delivered to adolescents with a history of poor metabolic control. There were two comparison groups: conventional diabetes education (eight lectures on diabetes topics including a question and answer session and time for skills practice) and standard care (routine clinical visits). The intervention group received eight sessions that focused on identifying issues that were perceived as difficult and stressful and developing adaptive coping strategies; the group was asked to implement new coping strategies in real life situations during the week. Immediately following the intervention, there were no significant differences among any of the groups on measures of depression from the Dimensions of Depression Profile. The methodological quality of the study was low (2/5 on the Jadad score; unclear concealment of allocation).

Hains et al.[25] randomly assigned 15 adolescents to a 3-phase stress inoculation program delivered to patients and parents or to a control group that received no intervention. Anxiety was measured using the State-Trait Anxiety Inventory. At 1-month followup, there were no significant decreases in anxiety for either group. The

methodological quality of the study was low (2/5 on the Jadad score; unclear concealment of allocation).

Family Therapy—Anxiety and Depression

Children with newly diagnosed diabetes. Hakimi[26] conducted an RCT to assess effectiveness of a family-based psychosocial intervention designed to ameliorate the negative psychological impact of diabetes. There were 35 patients with a mean age of 11.5 years. The setting was not reported, but followup time was reported to be 6 weeks, and there were no significant differences in levels of depression or anxiety between groups. The methodological quality of the study was low (1/5 on the Jadad score; unclear concealment of allocation; blinding of outcome assessors).

Skills Training—Anxiety and Depression

Children with newly diagnosed diabetes. One RCT by Mitchell[49] assessed the effect of a skills training intervention on coping abilities among 32 newly diagnosed patients (mean age 10.7 years). The intervention group received standard multidisciplinary education and support plus a booklet targeted at improving compliance with treatment. The booklet identified problems with adherence and offered basic self-management skills. The standard care group received standard education and support. At the 12-month followup, the intervention group reported significant improvement in anxiety, depression and withdrawal characteristics as measured with the Child Behaviour Checklists. There was no change for the control group. The methodological quality of the study was low (1/5 on the Jadad score; unclear concealment of allocation). Both the intervention and control groups had substantial dropouts over the study period (47 and 53 percent, respectively).

Summary of Results—Anxiety and Depression

General population of children with diabetes. One moderate quality RCT (Grey et al.[21]) assessed the effect of a cognitive behavioral therapy intervention on depression in the general population of children with type 1 diabetes (Table 19). Both the intervention and control groups reported reduced depression; however, the difference was not statistically significant.

Children with newly diagnosed diabetes. One high-quality RCT (Hoff et al.[30]) reported mixed results of a general diabetes education delivered to parents of children with newly diagnosed diabetes (Table 19). Mothers in the intervention group reported that children had fewer internalizing problems compared to mothers in the control group. Conversely, fathers in the intervention group reported no change in children's internalizing problems. The remaining two studies that focused on children with newly diagnosed diabetes were of low quality. One RCT reported improvement on a composite measure of depression, anxiety and withdrawal for the intervention group;[49] the RCT found no difference in anxiety and depression levels between the intervention and control groups.[26]

Children with poorly controlled diabetes. Two low-quality RCTs found no difference between intervention and control groups on measures of anxiety[25] and depression[13] in the population of children with poorly controlled diabetes (Table 19).

Table 19. Summary of results of studies assessing the effect of diabetes education on anxiety and depression

Author Year	Intervention	Study design Sample size	Quality	Results
General population of children with diabetes				
Grey[21] 2000	Cognitive behavioral therapy	RCT 77	Moderate	Depression—Both groups reported less depression at 12 mo.; difference between groups was NS
Children with newly diagnosed diabetes				
Hakimi[26]	Family therapy	RCT 35	Low	Anxiety—No significant difference between groups at 6 wk. Depression—No significant difference between groups at 6 wk.
Hoff[30] 2005	General diabetes education	RCT 46	High	Child internalizing problems—(maternal report) IG reported decreased levels at 1 and 6 mo.; no change for CG Child internalizing problems—(paternal report) IG reported no change at 1 and 6 mo.; CG reported decreased levels at 1 mo. but no change at 6 mo.
Mitchell[49] 1996	Skills	RCT 32	Low	Depression, anxiety and withdrawal—IG reported significant improvement at 12 mo.; no change for CG
Children with poorly controlled diabetes				
Cigrang[13] 1992	Cognitive behavioral therapy	RCT (3 arms) 37	Low	Depression—No significant difference between groups at 3 mo.
Hains[25] 2000	Cognitive behavioral therapy	RCT 15	Low	Anxiety—No significant difference between groups at 1 mo.

CG = control group; IG = intervention group; NS = not significant

Quality of Life

Overall there were four studies that assessed the effect of diabetes education on quality of life (QOL). All examined the general population of children with diabetes.

General Diabetes Education—Quality of Life

General population of children with diabetes. In an uncontrolled before-and-after study, von Sengbusch et al.[77] assessed the impact of a mobile diabetes education service on a group of 107 children living in rural areas in the United States. At both 6- and 12-month followups there was a statistically significant improvement in QOL using the KINDL® quality of life questionnaire. The methodological quality of this study was moderate based on the Thomas assessment tool.

Cognitive Behavioral Therapy—Quality of Life

General population of children with diabetes. Grey et al.[21] randomly assigned 77 adolescents to receive intensive diabetes management as described in the Diabetes Control and Complications Trial or intensive diabetes management plus a behavioral program of coping-skills training intervention. At 10-months post-intervention, the intervention group experienced less negative impact on QOL as measured by the Diabetes Quality of Life: Youth tool. The methodological quality of this study was moderate (2/5 on the Jadad scale; unclear concealment of allocation; blinding of outcome assessors).

Family Therapy—Quality of Life

General population of children with diabetes. Laffel et al.[38] randomly assigned 105 families to a family-focused teamwork intervention, or to standard care (i.e., routine multidisciplinary clinical care). QOL was assessed using the PedsQL, which was administered to both children and parents. At 12-months post-intervention, there was no difference in the QOL scores between the intervention and standard care groups. The methodological quality of this study was assessed as low (2/5 on the Jadad scale; unclear concealment of allocation).

Skills Training—Quality of Life

General population of children with diabetes. In an uncontrolled before-and-after study by Caravalho and Saylor,[11] 56 children and their parents were taught insulin adjustment procedures and received group support and education to improve self-management. QOL was assessed using the Quality of Life Parent Questionnaire (adapted from the Diabetes Quality of Life instrument). QOL scores improved from pre- to post-intervention (12 months) assessment, but the improvement was not statistically

significant (p = 0.07). The methodological quality of this study was weak based on the Thomas instrument.

Summary of Results—Quality of Life

Overall, there was limited evidence for the QOL outcome and the results were mixed (Table 20). One moderate quality RCT (Grey et al.[21]) found that adolescents who received coping skills training along with intensive diabetes management experienced less negative impact on QOL compared with those who received intensive management only. Similarly, the moderate quality uncontrolled before-and-after study by von Sengbusch et al.[77] reported a statistically significant improvement in QOL scores at 12 months. The RCT by Laffel et al.[38] found no difference in QOL scores between the family therapy group and control group. Caravalho and Saylor[11] reported improved scores for parents of children with diabetes, but the change from baseline was not statistically significant.

Table 20. Summary of results of studies assessing the effect of diabetes education on quality of life

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes				
Caravalho[11] 2000	Skills	Before-after 56	Low	Parents had improved QOL scores at 12 mo.; difference was NS
Grey[21] 2000	Cognitive behavioral therapy	RCT 77	Moderate	IG experienced less negative QOL than CG at 10 mo.
Laffel[38] 2003	Family therapy	RCT 105	Low	No significant differences in QOL between groups at 12 mo.
von Sengbusch[77] 2006	General diabetes education	Before-after 107	Moderate	Significant improvement in QOL scores at 6 mo. and 12 mo.

CG = control group, IG = intervention group; NS = not significant

School Performance

Overall there were two RCTs that assessed the effect of diabetes education on school performance. One examined the general population of children with diabetes and one focused on children with newly diagnosed diabetes (Table 21).

General Diabetes Education—School Performance

Children with newly diagnosed diabetes. Dougherty et al.[18] randomly assigned 63 newly diagnosed patients to a 24-month home-based diabetes education program or to a traditional hospitalization and outpatient followup. Treatment differences between the groups consisted of duration of initial hospital stay, timing of initial teaching, and the nature and extent of subsequent nursing followup. During the course of the 2-year study, there was no difference in absences from school between the groups (28.3±36.4 days for

the hospital-based group and 29.7±28.7 days for the home-based group. The methodological quality of this study was moderate (2/5 on the Jadad scale; unclear allocation of concealment; blinding of outcome assessors).

Diabetes Camp—School Performance

General population of children with diabetes. Pichert et al.[59] randomly assigned 84 patients to either a control group, which participated in two 45-minute sessions where traditional teaching methods were employed to review 9 guidelines for sick-day management; or, to an intervention group, which participated in two 45-minute sessions using a video tape and discussion to review nine guidelines for sick-day management. At 8-month followup there was no significant difference between groups for the number of sick days in the past 10 weeks. The methodological quality of this study was moderate (2/5 on the Jadad scale; unclear allocation of concealment; blinding of outcome assessors).

Summary of Results—School Performance

Overall, there was limited evidence relating to this outcome (Table 21). In the two studies assessing this outcome, diabetes education programs did not have a significant effect on school absence or sick days.

Table 21. Summary of results of studies assessing the effect of diabetes education on school performance

Author Year	Intervention	Study design Sample size	Quality	Conclusion
General population of children with diabetes				
Pichert[59] 1994b	Diabetes camp	RCT 84	Moderate	No significant difference in number of school absences between groups at 8 mo.
Children with newly diagnosed diabetes				
Dougherty[18] 1999	General diabetes education	RCT 63	Moderate	No significant difference in sick days between groups at 24 mo.

Chapter 4. Discussion

Grading the Body of Evidence

We assessed the body of evidence for six key outcomes based on five domains: study design, study quality, consistency of effect estimates across studies, precision of effect estimates, and directness of the link between interventions and outcomes (Table 22). For each outcome, the majority of the studies used an RCT design, which is considered the strongest design; however, the quality of the studies was generally low. There was no consistency of effect estimates across studies for the outcomes. Precision was difficult to evaluate as confidence intervals or exact p values were not reported. The link between interventions and outcomes was often difficult to determine. Most interventions had multiple components and, while there may be a correlation between the entire intervention and the outcome, the association between specific intervention components and the outcomes was not evident. We classified the strength of evidence as low, meaning that there is low confidence in the estimate of effect and further research is likely to change our confidence in the estimate of effect.

Table 22. Grading the strength of evidence

Outcome	Design	Quality	Consistency	Precision	Directness	GRADE
HbA1c (n = 52)	RCT = 33 CCT = 7 Cohort = 4 B-A = 8	Low	No significant effect in 22/52 studies Effect for both IG and CG; change or difference NS in 13/52 IG improved more in 17/52	Unable to evaluate	Uncertainty about directness	Low
Short-term complications (n = 15)	RCT = 6 CCT = 1 Cohort = 2 B-A = 6	Low	No significant effect in 7/15 Effect for both IG and CG; change or difference NS in 1/15 IG improved more in 5/15 Improvement made post intervention in 2/15 (B-A)	Unable to evaluate	Uncertainty about directness	Low
Knowledge (n = 29)	RCT = 10 CCT = 6 Cohort = 2 B-A = 11	Low	No significant effect in 8/29 Intervention group improved more in 4/29 Effect for both IG and CG; change or difference NS in 2/29 Improvements made post intervention in 9/29 (B-A) Results vary between outcome or time point 6/29	Unable to evaluate	Uncertainty about directness	Low
Self-management skills (n = 21)	RCT = 15 CCT = 3 Cohort = 1 B-A = 2	Low	No significant effect in 11/21 Intervention group improved more in 7/21 Results vary between outcome or time point in 3/21	Unable to evaluate	Uncertainty about directness	Low
Coping (n = 14)	RCT = 7 CCT = 1 Cohort = 2 B-A = 4	Low	No significant effect in 10/14 studies Intervention group improved more in 2/14 Results varied between outcomes in 2/14	Unable to evaluate	Uncertainty about directness	Low
Quality of Life (n = 4)	RCT = 2 B-A = 2	Low	No significant effect in 1/4 IG improved more in 1/4 Improvements made post intervention in 2/4 (B-A)	Unable to evaluate	Uncertainty about directness	Low

B-A = uncontrolled before and after study; CG = control group; CCT = controlled clinical trial; IG = intervention group; NS = not significant; RCT = randomized controlled trial

Quality of the Evidence

Although the majority of included studies were RCTs or CCTs, all but four RCTs obtained a low methodological score of 0, 1 or 2 of a possible 5 points on the Jadad scale, or 0 or 1 out of a possible 3 on the modified Jadad scale. These studies were considered of poor quality with serious threats to internal validity. The primary reason for the low scores was the lack of double blinding in these trials. It is important to recognize that it may not be appropriate to evaluate non-pharmacological interventions by the same standards applied to pharmacological interventions. Although there has been some debate as to whether the lack of double blinding is a serious flaw in studies that examine behavioral interventions,[121,122] research has shown that there is a potential for performance bias in outcome assessment and studies that are not double blinded can overestimate treatment effects by 17 percent.[102] Notwithstanding the evidence confirming the importance of double blinding in trials, we conducted a post hoc assessment to identify trials that used single blinding, in particular the blinding of outcome assessors. In 27 percent of the trials, steps had been taken to reduce the potential for measurement bias. While implementing blinding in an RCT of non-pharmacological interventions often requires creative solutions, approaches such as blinding participants to the hypothesis of the study or blinding of outcome assessors have been increasingly adopted. The approaches are ethically justified provided that stringent criteria for protecting research participants are satisfied. Further research in this domain is warranted.

Additionally, 25 percent of included studies were uncontrolled-before-and-after studies, which is not considered to be a rigorous study design because of the difficulty in determining whether any observed effects are solely accounted for by the intervention.

Consistency of the Evidence

Many of the interventions did not have consistent effects across the intervention (for example, all cognitive behavioral therapy studies did not display the same effect) or coherent effects across all outcomes (e.g., all studies that showed a statistically significant effect in HbA1c did not necessarily find an effect in any other outcome).

Types of interventions. Diabetes education is a general term that encompasses a wide variety of interventions. Even within categories of the same type of intervention (e.g., cognitive behavioral therapy) there were many differences among studies in the focus of the intervention (e.g., stress management, coping strategies), the mode of delivery, the intensity of the intervention, whether the program was delivered to parents, children or both, and the times at which endpoints were measured. Although we were able to assign interventions to broad categories, there was still a high level of heterogeneity within categories. For example, the general diabetes education category included interventions delivered in such diverse formats as phone calls, small group sessions, educational leaflets, or video games. In addition to considerable heterogeneity, many of the studies had short study length (1 day to 2 weeks) and/or followup, which may not have been enough time to see significant changes. In some studies that showed positive effects, more intense followup of participants or the presence of an experienced team and an intensive management protocol may have been a factor in their success.

Types of control groups. Most of the trials that used control groups described the comparison intervention as "standard care". Although some studies provided a description of standard care, the content of the education delivered to the control group was rarely detailed. Because the control group would be unlikely to receive "no education", it is important to understand how the intervention and control interventions differed. Only then will we be able to isolate the factors that make education effective. Furthermore, if standard care is the comparison, researchers should be encouraged to change only one or two elements of an education program during their trial in order to better assess which components are effective and which are not. For example, this was successful, in the coping skills training intervention by Grey et al.

Types of populations. We considered three main population groups: the maintenance population of children with diabetes, which was our "general" category; children with newly diagnosed diabetes receiving their first diabetes treatment and education; and children who had problems achieving optimal metabolic control. In the general population, only a small number of interventions were shown to be effective. Many of these studies took place in academic settings where the patient population may be better educated and established educational programs may already exist. It is possible that these studies did not have sufficient statistical power to detect differences. Furthermore, if children entering these studies already had a certain level of education and motivation, there may be a ceiling effect and the additional education intervention may not have a noticeable impact on knowledge, behavior, or metabolic control. It is possible that these interventions may be effective in different study settings.

In the population of children who were newly diagnosed, a small number of studies compared the delivery of education in inpatient and outpatient settings. While this review did not find that the setting of the education program had an impact on outcomes, the number of studies was small, and there were substantial differences in terms of the specific outpatient setting (e.g., training apartment, day care program) and intensity of intervention. Therefore, it is difficult to state that outpatient settings are as effective as inpatient settings for the delivery of education interventions. Further research controlling for these factors is required.

For children with poorly controlled diabetes, we included studies in this category if the researchers specified that the study population was children with poor metabolic control. However, this allowed for some variability in clinical indicators. For example, the mean HbA1c levels in these studies ranged from 8.2 percent to 14.9 percent. Generally, results in this population were inconclusive, with a small number of studies showing improvement in HbA1c, knowledge and adherence and almost none showing changes in psychosocial outcomes. For the studies that reported improvement in outcomes, there were no common factors; the education interventions fell into different categories and the target populations were defined differently.

Types of outcomes. Our main clinical outcome, HbA1c, was standard across studies. However, for knowledge and psychosocial outcomes there was a wide range assessment tools, ranging from self-designed questionnaires to instruments that were developed and validated for people with diabetes. The use of different tools and metrics, even when measuring the same outcome was an additional factor that made it difficult to pool the results of studies or to generalize the effectiveness of interventions. Use of standardized

instruments in studies evaluating outcomes in children with diabetes should alleviate this issue.

Discussion of Key Questions

There were 80 studies included in this review of diabetes education. Although over 65 percent of the studies were RCTs or CCTs, their methodological quality was generally low. There was considerable heterogeneity with regard to the study population, the educational intervention and the outcomes measured. Furthermore, because most control groups also received some level of education, the studies may not have had sufficient power to detect a clinically or statistically significant difference in the various outcomes examined. These factors make it difficult to draw definitive conclusions and recommendations on the benefits of diabetes education. However, the discussion to follow will address the key questions based on the evidence obtained from the available research.

1. What is the evidence that diabetes education on day-to-day management of diabetes improves metabolic control as determined by:

HbA1c. HbA1c is the gold standard for assessing diabetes control. The DCCT clearly showed that lower HbA1c leads to a decreased rate of microvascular complications. Therefore, the goal of all diabetes education interventions is to provide the knowledge, skills, and attitude to achieve the lowest HbA1c possible without frequent hypoglycemia. Unfortunately, the results of this review do not indicate that any specific educational intervention leads to consistent and sustained improvement in HbA1c over that achieved with "standard care" education. Cognitive behavioral and family therapy interventions appear to have a clinically significant benefit in some studies, although this was somewhat inconsistent with some studies showing a benefit while others did not. This can be explained in part by the heterogeneity within the intervention categories. Further research should be conducted to confirm these results and test their robustness in other settings.

Although diabetes camps are frequently touted as venues in which education can occur to positively change practices, the main function of these camps seems to be as a vacation and as a support for children and parents. Studies set in diabetes camps are usually of short duration. While they may be successful in terms of participant satisfaction, the results do not suggest any short- or long-term improvement in metabolic control.

Initial management and education of newly diagnosed patients has moved from an inpatient to an outpatient setting in many centers. The results of studies comparing the same education provided in these settings indicate there is no difference in HbA1c up to 2 years after the diagnosis; however, the settings and the interventions were not consistent across the studies and these results should be interpreted cautiously. There are a few individual studies with newly diagnosed patients that demonstrated that education provided by a multidisciplinary team at the time of diagnosis results in improved HbA1c

compared to education provided by fewer individuals or at a later time. This comparison needs to be replicated to determine if the benefit is significant.

Patients with poorly controlled diabetes can be major consumers of diabetes health care resources. Numerous studies have examined different interventions to improve HbA1c. Unfortunately, only a few have shown a benefit. More intensive general diabetes education, interventions teaching stress management and coping skills, and family therapy have not been shown to improve diabetes control. Frequent (weekly) contact with motivational interviewing and goal-setting, and individual psychotherapy are interventions that have shown benefit but need to be studied further.

It has been hypothesized that changes in HbA1c may be mediated by changes in knowledge, skills, attitudes and/or behavior. In the 16 studies that measured both knowledge and HbA1c, most groups exhibited improved knowledge after the educational intervention. However, improvements in knowledge did not translate into improved diabetes control. This suggests that lack of knowledge in itself is not necessarily a barrier to improving control.

There were only two studies that measured both skills acquisition and HbA1c and neither showed a correlation between the two outcomes. Likewise, studies that measured psychosocial outcomes and HbA1c (n=24) did not show coherence across outcomes. Results spanned the spectrum from one of the outcomes improving but not the other, to neither outcome improving, and to both outcomes improving. In the studies that showed improvement in both outcomes, two were cognitive behavioral therapy interventions that looked at both self-efficacy and HbA1c, one was a family systems therapy intervention that looked at family relationships and HbA1c, and one was a skills training intervention that examined anxiety and HbA1c. In studies that examined both regimen adherence and HbA1c (n=21), there was little correlation between the outcomes. The two studies that showed improvement in both outcomes were family systems therapy trials. Finally, there was no correlation between outcomes in the four studies that measured quality of life and HbA1c. Based on these results, it is difficult to gain any insight into what is mediating metabolic control. It may be that different issues gain precedence in different families, for example adherence may be important for one family and psychosocial issues for another. Therefore, interventions may need to be targeted to more uniform study populations with similar underlying issues in order to assess the effect of the intervention.

Diabetes-related hospitalizations. Diabetes education appears to be effective in decreasing health care utilization (duration of hospital stay after diagnosis, rate of hospitalization, and ED and physician visits). The education interventions used to achieve this were more intensive, were provided by specialists and multidisciplinary teams, and involved some form of psychotherapy or psychosocial focus. The setting of the intervention (inpatient vs. outpatient) did not have an effect on outcome. Intensive, multidisciplinary interventions may be time- and labor-intensive, but their effect on decreasing health care utilization by patients and families may be quite cost-effective. This would be an interesting and worthwhile future research focus.

Frequency of DKA and hypoglycemia. Results were not as clear in the area of diabetes-related short-term complications. Most studies did not have high enough rates of DKA to show significant differences. Studies reporting on hypoglycemia covered the spectrum of possible outcomes. A possible explanation for this may be that hypoglycemia has so many potential causes. For example, an intervention may target nocturnal

hypoglycemia, but not physical activity-related hypoglycemia. It is also possible that standard care and standard diabetes education effectively reduce the incidence of hypoglycemia, making it difficult to demonstrate differences between types of educational interventions.

2. What is the evidence that medical nutrition therapy education in day-to-day management of diabetes improves HbA1c values and results in less variability in blood glucose levels?

There is no clear evidence indicating that nutrition therapy education either improves or does not improve diabetes control. We identified only one uncontrolled before-and-after study[12] that specifically assessed the effect of medical nutrition therapy education on HbA1c. The intervention was delivered to children attending a diabetes camp. The participants' ability to meal-plan and carbohydrate count improved and the improvement in carbohydrate counting correlated with a lower pre-intervention HbA1c. However, none of the other nutrition knowledge scores were correlated with changes in? HbA1c. There were several other studies that described a nutritional education component or module as part of their intervention.[6,9,16,17,24,34,35] Two of these studies found improved nutritional knowledge or behavior after the intervention[24,35] but this did not correlate with a lowering of HbA1c in the intervention group. Three studies found improved metabolic control alone.[6,17,34] The other studies showed no significant changes in HBA1c or regimen adherence.

Studies that reported improvement in HbA1c are disparate in their interventions and designs, and it is difficult to know whether to attribute the improvement to the nutritional therapy component or to the overall change in management[34] or other components of the intervention.[6] Because of this heterogeneity, there is no clear evidence indicating that medical nutrition therapy education either improves or does not improve diabetes control and studies are needed to address this question.

3. What is the evidence that diabetes education results in improved long-term management of diabetes?

In this review, all but three studies followed participants for 2 years or less. The study with the longest followup tracked hospitalizations for 4 years. Long-term followup in diabetes would generally be considered 5 to 10 years. Therefore, there are no data to determine if a particular educational approach improves long-term control and reduces long-term diabetes complications. Since diabetes management has changed over the years covered by this review and will continue to evolve as more research becomes available, it is unlikely that any study will be able to separate the effect of the educational intervention from the change in diabetes management on the rate of complications. It would be possible, however, for a future review to address the question of which diabetes management strategies improve long-term diabetes control and reduce complications.

4. What is the evidence that diabetes education programs improve knowledge about diabetes management?

a. What is the evidence that this knowledge increases the child's self-confidence in his or her ability to handle the disease and has a positive impact on the child's quality of life (QOL) and other psychosocial issues (e.g., school absences, school performance, adherence to a medical regimen)?

In answering this question we have broken the discussion into sections which will discuss interventions for improving knowledge, skills, and adherence separately from those addressing QOL and other psychosocial issues.

In the majority of studies that were controlled and assessed knowledge there was no difference in knowledge scores between those who received the intervention vs. those who received standard care education. In most studies, patients in both the intervention and control groups demonstrated improved knowledge. A minority of studies using either a cognitive behavioral intervention or general diabetes education delivered at diabetes camp showed a significant difference in knowledge scores in favor of the intervention. Only a few studies addressed interventions to improve skills needed for day-to-day diabetes management. Most interventions in this area resulted in an improvement over standard care. However, the number of studies was small and the interventions and specific skills assessed differed. Several studies addressed issues of self-management and adherence behavior; however, the type of interventions and the measured outcomes were not uniform making it difficult to draw conclusions. It appears that cognitive behavioral therapy may be effective in improving self-care behaviors. In patients with poorly controlled diabetes, there was no specific intervention that was consistently effective, but further studies utilizing family based therapy should be considered. In summay, no clear recommendation can be made regarding a specific educational approach, beyond that as part of standard care, to improve knowledge, skills or self-management behavior.

Most research assessing the effect of diabetes education on psychosocial aspects of diabetes has used controlled study designs (75 percent RCTs and CCTs). However, the heterogeneity in study setting, duration and frequency of intervention, followup period, assessment tools, and primary outcomes, makes it impossible to pool the data. The study results mirror this heterogeneity and span the full spectrum of clinical and statistical significance. There is no particular study design or intervention that demonstrates a consistently positive effect of diabetes education on psychosocial outcomes, including QOL and school performance. However, it is likewise impossible to rule out certain intervention types as ineffective. For instance, cognitive behavioral therapy was effective in improving coping skills in two studies, but was not effective in four others. There are very few studies demonstrating negative effects of education on psychosocial outcomes, but this should be interpreted in light of the known low rate of reporting of negative findings. Even among newly diagnosed children, interventions did not result in significantly improved family and social relationships or support, coping, self-perception, or self-efficacy. Similarly, in children with poor metabolic control, only one of two studies showed a significant improvement in self-efficacy, and one more study showed initial, but not sustained improvement in family and social relationships. The education intervention had no significant effect on family or social support, coping or self-perception among this cohort. Although it seems intuitive that working with patients and families through educational interventions is important, the research does not show a clear effect. One possible explanation for this lack of evidence is that standard care and

standard diabetes education used in the control groups may effectively improve psychosocial outcomes, making it difficult to demonstrate differences between groups receiving different types of educational intervention. There are no clear recommendations regarding interventions that are likely to improve psychosocial outcomes.

b. What is the evidence that this knowledge improves long-term metabolic control (i.e., decreases or prevents diabetes-related complications), as shown in the Diabetes Control and Complications Trial (DCCT) (as measured by retinal, renal, cardiovascular, and neurological evaluations), in children of families who receive these diabetes education or medical nutrition therapy program services compared to children of families who do not receive these services?

We did not identify any studies that addressed this question. There are no studies correlating knowledge and/or a specific educational intervention with long-term diabetes complications. In terms of short-term metabolic control, there were 16 studies that measured some aspect of diabetes knowledge as well as changes in metabolic control as on outcome. In five studies[14,22,34,61,75] knowledge increased and HbA1c levels decreased post intervention. However, in two of these studies[61,75] the improvements in metabolic control were not sustained at six and 12 months, respectively. In one study[14] both HbA1c levels and child's knowledge were not sustained at the 12-month followup. In another study[18] the intervention group had superior metabolic control. While knowledge increased in both groups and was stable over time, there was no significant difference between the groups. In five studies[9,24,35,72,77] the significant increase in knowledge did not translate into an improvement in metabolic control. There were five studies[31,32,55,62,69] in which the intervention did not significantly affect either knowledge or metabolic control. From the studies that measured both these outcomes, one can conclude that an increase in knowledge is not sufficient to bring about behavior changes that improve metabolic control.

5. What is the evidence that training in intensive diabetes management (consistent with DCCT, including blood glucose monitoring at least four times a day, three or more daily insulin injections or use of an insulin pump and education on when and how to adjust insulin doses) conducted in the practitioner setting yields:

a. Improved metabolic control, (as determined by HbA1c values, numbers of diabetes-related hospitalizations, frequency of DKA, and numbers of episodes of hypoglycemia)?

Although several studies have reported improved diabetes control in children and adolescents following initiation of intensive diabetes management, only three studies described the educational component or compared different educational interventions among children undergoing intensive diabetes management. Therefore, the majority of intensive diabetes therapy studies in children did not meet the inclusion criteria for this review. All three studies that met our inclusion criteria[21,34,39] reported improved metabolic control after initiation of the intensive treatment which persisted up to 1

year later. Two of the studies compared refinements to the education provided as a component of intensive diabetes management.[21,39] The results of both studies suggest that educational interventions may support the effects of intensive diabetes management in reducing HbA1c.

All three studies reported on frequency of DKA and hypoglycemia. Grey et al.[21] found that the overall rate of severe hypoglycemia was higher than the rate reported in the adolescent cohort of the DCCT of 88/100 patient-years. In the cohort study by Lawson et al.[39] there were two severe hypoglycemic reactions in the individualized education group. In the camp study,[34] intensive diabetes management had no effect on the frequency of mild to moderate hypoglycemia, and there were no severe episodes of hypoglycemia. Among the three studies, there was only one episode of DKA. Therefore, in terms of short-term acute complications, the studies show mixed results with one study reporting an unacceptably high level of severe hypoglycemia suggesting that further educational interventions need to be explored.

b. A decrease in or prevention of diabetes-related complications (as measured by retinal, renal, cardiovascular and neurological evaluations), as demonstrated by DCCT?

No evidence was available to answer this question as none of the studies reported on long-term diabetes complications and all followed patients for less than 2 years. Although the Lawson study included patients who had nephromegaly, the progression of this complication was not monitored and patients were followed for only 15 months.[39]

Limitations

Several limitations of this review need to be discussed. They are associated with weak study designs, potential for publication bias, and heterogeneity in interventions, outcome measurements, and control group definitions.

Although the majority of included studies were RCTs or CCTs, all but four RCTs received a low methodological score of 1 or 2 of a possible 5 points. These studies were considered weak in quality, mainly due to educational interventions not lending themselves to double blinding. Although there has been some debate as to whether this is a serious flaw in studies that examine behavioral outcomes,[121,122] it still indicates that there is a potential for performance bias in outcome assessment. In the majority of the RCTs, the method by which the randomization code was derived, concealed, and allocated was also not reported, thereby leaving the studies open to the question of selection bias. Additionally, 25 percent of included studies were uncontrolled-before-and-after studies, which are not considered a rigorous a design as it is difficult to determine whether any effects are solely accounted for by the intervention.

Potential for publication bias is an issue relevant to all systematic reviews. To minimize publication bias, an experienced research librarian conducted a comprehensive search of the published literature for potentially relevant studies using a systematic strategy. We also searched conference proceedings, theses and dissertations, and grey literature, including professional websites in order to obtain additional relevant studies. In

addition, we handsearched reference lists of reviews and included studies. We restricted the search to English language articles because we felt the majority of relevant research would be published in English language reports. Selection bias was minimized via the use of a priori inclusion criteria which were applied by two reviewers independently. Any discrepancies were resolved with a third party who had clinical expertise in diabetes management.

A particular limitation of this review was the variety of interventions and outcome measures across studies, which meant that we were not able to pool results. Although we combined interventions under broad categories, there was still significant heterogeneity within these categories. Moreover, some interventions were targeted to the child, the parent, or the family or peers, and some interventions were single component while others were multifaceted. Likewise, there were a wide variety of endpoints and outcome measurement instruments. Similarly, control groups were not defined the same way in all studies; some studies specified no intervention, while others specified standard care, which may not be consistent across different regions. Due to lack of time and resources, we did not contact authors directly to determine the breakdown of components in control groups.

Conclusions

Overall, the studies included in this review did not show consistent and coherent effects over the examined outcomes. Therefore, we have limited confidence in our ability to identify one particular intervention above another to improve diabetes control, reduce short-term acute complications, or improve quality of life.

Although we had a number of higher quality trials, disparate interventions, populations, and outcomes made it difficult to determine whether one form of diabetes education was more effective than another. Furthermore, because most control groups also received some level of education, the studies may not have had sufficient power to detect a clinically or statistically significant difference in the various outcomes examined. It is also important to remember that trials often take place in tertiary settings where the patient population may be better educated, and where established educational programs may exist; the studies may not have had power to find differences between study groups. Further testing using strong study designs (e.g., cluster RCTs), clearly defined study populations and interventions, and standard and validated measurement instruments may help to elucidate this.

Future Research Opportunities

To date, research in diabetes education is characterized by a great deal of heterogeneity and few long-term studies.

- Data from this review suggest there is a need for appropriately powered RCTs assessing cognitive behavioral therapy, family systems therapy, motivational interviewing, and frequency of contact with health care professionals on HbA1c

and short-term complications, particularly in a population with poorly controlled diabetes.

- Future RCTs should specify the components of their "standard care" education and followup. A survey of standard education programs for diabetes so that researchers are aware of the diversity of standard care would be a useful addition to the literature.
- Nutrition therapy is a significant component of diabetes management. This review documents that very few studies have assessed specifically this component of diabetes education, and even fewer have assessed its effect on metabolic control. Additional research is needed in this area. For example, different educational formats for providing nutritional information may be more effective in improving knowledge, practice and metabolic control than others.
- The effect of interventions on quality of life was difficult to assess in this review because of the small number of studies that assessed this outcome and the use of a multitude of outcome tools. Future studies should include quality of life as an outcome measure and researchers in this area should work toward adopting a common validated instrument.
- Since diabetes-related complications develop over many years, longer term cohort studies and trials with longer followup will be essential to assess the effect of education on long-term complications of diabetes.
- Well-designed studies that address the challenges of conducting research on behavioral interventions are needed. Strong study designs such as cluster randomized trials should be used and steps should be taken to minimize the risks of bias. Although blinding may be difficult to achieve with educational and behavioral interventions, it should be possible to perform RCTs with the practice of using blinded outcome assessors. Concealment of allocation is always possible and should be reported.
- The DCCT and several subsequent reports have shown the benefit of intensive diabetes management on HbA1c in children and adolescents. Studies are needed to examine the aspects of education that improve outcomes with this management approach. Followup of the previous DCCT cohort (EDIC study) has found that the HbA1c rises over time. Studies are needed to explore education interventions that might lessen this deterioration in control.

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Appendixes

Appendix A. Technical Expert Panel and Peer Reviewers

Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives are sought. Divergent and conflicting opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design and/or methodologic approaches do not necessarily represent the views of individual technical and content experts.

Technical Expert	Affiliations/Location
Denis Daneman, M.B., B.Ch., F.R.C.P.C.	University of Toronto and Hospital for Sick Children Toronto, ON
Alison B. Evert, M.S., R.D., C.D.E.	Diabetes Care Center, University of Washington Medical Center Seattle, WA
Jeffrey Johnson, B.S.P., M.S., Ph.D.	University of Alberta Edmonton, AB
Richard A. Justman, M.D.	United HealthCare Edina, MN
Lori M. B. Laffel, B.S., M.D., M.P.H.	Joslin Diabetes Center Boston, MA
Gabriela Ramírez-Garnica, Ph.D., M.P.H.	Nemours Children's Clinic Orlando, FL
Janet Silverstein, M.D.	University of Florida Gainesville, FL

Peer Reviewers

Peer reviewer comments on a preliminary draft of this report were considered by the EPC in preparation of this final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers.

Technical Expert	Affiliations/Location
William L. Clarke, M.D., F.A.A.P.	University of Virginia Health System Charlottesville, VA
Nathaniel Clark, M.D., F.A.A.P.	Novo Nordisk, Inc. Princeton, NJ
Debra Counts, M.D., F.A.A.P.	University of Maryland Baltimore, MD
Marion J. Franz, M.S., R.D., L.D., C.D.E.	Nutrition Concepts by Franz, Inc. Minneapolis, MN
Stephen J. Spann, M.D., M.B.A.	Baylor College of Medicine Houston, TX
Randi Streisand, Ph.D., C.D.E.	Children's National Medical Center Washington, DC
Dorothy Becker, M.B., B.Ch.	Children's Hospital of Pittsburgh Pittsburgh, PA

Appendix B. Exact Search Strings

Table B1. MEDLINE®—OVID Version: rel10.4.1

Years/issue searched: **1950 to February Week 3 2007**

Search date: **March 4, 2007**

Results: **study design 4,219**; **no study design 6,615**

1. exp Infant/
2. exp Child/
3. exp Adolescent/
4. exp Parents/
5. exp Family/
6. exp Caregivers/
7. infan$.mp.
8. (baby or babies).mp.
9. child$.mp.
10. toddler$.mp.
11. adolescen$.mp.
12. (young adj3 (person? or people or adult?)).mp.
13. (teen$ or teen ager?).mp.
14. youth?.mp.
15. juvenil$.mp.
16. pube$.mp.
17. parent$.mp.
18. famil$.mp.
19. (caregiv$ or care giv$ or care-giv$ or caretak$ or care tak$ or care-tak$ or carer?).mp.
20. or/1-19
21. Diabetes Mellitus/
22. Diabetes Mellitus, Type 1/
23. exp hypoglycemia/
24. ((type 1 or type I) adj (diabetes mellitus or DM)).mp.
25. ((diabetes mellitus or DM) adj (type 1 or type I)).mp.
26. diabet$.mp.
27. IDDM.mp.
28. DM.mp.
29. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
30. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
31. ((autoimmun$ or auto-immun$ or auto immun$ or sudden onset) adj3 (diabetes mellitus or DM)).mp.
32. (insulin defic$ adj3 absolut$).mp.
33. hypoglyc?emi$.mp.
34. or/21-33
35. exp Diabetes Insipidus/
36. (diabet$ adj3 (insipidus not mellitus)).mp.
37. or/35-36
38. 34 not 37
39. Self Help Groups/
40. Health Education/
41. Patient Education/
42. Patient Care/
43. Adolescent Psychology/
44. Child Psychology/
45. Behavior Therapy/
46. Cognitive Therapy/
47. Family Therapy/
48. Counseling/
49. exp patient care management/ and diabet$.mp.
50. exp Nutrition Therapy/
51. exp Home Care Services/
52. exp School Health Services/
53. (behav$ adj3 (therap$ or modif$)).mp.
54. (family adj3 therap$).mp.
55. ed.fs.
56. (video$ or gam$).mp.
57. (phone or telephon$).mp.
58. program$.mp.
59. interven$.mp.
60. inform$.mp.
61. educat$.mp.
62. teach$.mp.
63. train$.mp.
64. instruct$.mp.
65. ((diet or nutrition$) adj2 therap$).mp.
66. (diabet$ adj diet$).mp.
67. ((education$ or home) adj2 (meeting? or session? or strateg$ or workshop? or visit?)).mp.
68. ((psycho-$ or psycho$) and diabet$).mp.
69. or/39-68
70. Hemoglobin A, Glycosylated/
71. Blood Glucose/
72. Diabetic Ketoacidosis/
73. (ketoacido$ or keto-acido$).mp.
74. DKA.mp.
75. SMBG.mp.
76. (blood glucose or BG).mp.
77. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
78. ((glycosylated or glycated) adj3 (hemoglobin or haemoglobin)).mp.
79. (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c).mp.
80. exp Self Care/
81. Self efficacy/
82. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
83. "Outcome Assessment (Health Care)"/
84. Program Evaluation/
85. Treatment Outcome/
86. exp Attitude to Health/
87. exp Health Behavior/
88. Problem Solving/
89. ((effect? or impact or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
90. attitud$.mp.
91. behavio?r$.mp.
92. complian$.mp.
93. adheren$.mp.
94. improv$.mp.
95. chang$.mp.
96. (cope or coping).mp.
97. skill?.mp.
98. (knowledge or learn$ or cognition).mp.

99. Quality of Life/
100. "quality of life".mp.

Table B1. MEDLINE®—OVID Version: rel10.4.1 (continued)

101. exp Hospitalization/
102. hospitali?ation?.mp.
103. admission?.mp.
104. service utilization.mp.
105. or/70-104
106. clinical trial.pt.
107. randomi?ed.ti,ab.
108. placebo.ti,ab.
109. dt.fs.
110. randomly.ti,ab.
111. trial.ti,ab.
112. groups.ti,ab.
113. or/106-112
114. animals/
115. humans/
116. 114 not (114 and 115)
117. 113 not 116
118. exp controlled clinical trials/
119. exp cohort studies/
120. Intervention Studies/
121. evaluation studies/ or program evaluation/
122. random allocation/
123. (pre test$ or pretest$ or (post test$ or posttest$)).mp.
124. (observation$ or prospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or case control$ or case-control$ or case referrent or case-referrent or time series or time-series or followup or follow up or follow-up or before-and-after or before-after).mp. and (study or studies or trial$).ti,ab,sh.
125. or/118-124
126. 125 not 116
127. 117 or 126
128. (letter$ or editorial$ or comment$ or lecture$).pt.
129. 127 not 128
130. and/20,38,69,105,129
131. limit 130 to english language
132. limit 131 to yr="1983-2007"

Table B2. Ovid MEDLINE® In-Process and Other Non-Indexed Citations—OVID Version: rel10.4.1

Years/issue searched: **March 02, 2007**

Search date: **March 4, 2007**

Results: **study design 68; no study design 122**

1. infan$.mp.
2. (baby or babies).mp.
3. child$.mp.
4. toddler$.mp.
5. adolescen$.mp.
6. (young adj3 (person? or people or adult?)).mp.
7. (teen$ or teen ager?).mp.
8. youth?.mp.
9. juvenil$.mp.
10. pube$.mp.
11. parent$.mp.
12. famil$.mp.
13. (caregiv$ or care giv$ or care-giv$ or caretak$ or care tak$ or care-tak$ or carer?).mp.
14. or/1-13
15. ((type 1 or type I) adj (diabetes mellitus or DM)).mp.
16. ((diabetes mellitus or DM) adj (type 1 or type I)).mp.
17. diabet$.mp.
18. IDDM.mp.
19. DM.mp.
20. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
21. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
22. ((autoimmun$ or auto-immun$ or auto immun$ or sudden onset) adj3 (diabetes mellitus or DM)).mp.
23. (insulin defic$ adj3 absolut$).mp.
24. hypoglyc?emi$.mp.
25. or/15-24
26. (diabet$ adj3 (insipidus not mellitus)).mp.
27. 25 not 26
28. (patient adj (care or management)).mp.
29. health services.mp.
30. ((child or adolescent) adj3 psychology).mp.
31. counsel?ing.mp.
32. ((behav$ or cognitiv$) adj3 (therap$ or modif$)).mp.
33. (family adj3 therap$).mp.
34. (video$ or gam$).mp.
35. (phone or telephon$).mp.
36. program$.mp.
37. interven$.mp.
38. inform$.mp.
39. educat$.mp.
40. teach$.mp.
41. train$.mp.
42. instruct$.mp.
43. ((diet or nutrition$) adj2 therap$).mp.
44. (diabet$ adj diet$).mp.
45. ((education$ or home) adj2 (meeting? or session? or strateg$ or workshop? or visit?)).mp.
46. ((psycho-$ or psycho$) and diabet$).mp.
47. or/28-46
48. (blood glucose or BG).mp.
49. (ketoacido$ or keto-acido$).mp.
50. DKA.mp.
51. SMBG.mp.
52. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
53. ((glycosylated or glycated) adj3 (hemoglobin or haemoglobin)).mp.
54. (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c).mp.
55. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
56. "Outcome and Assessment (Health Care)".mp.
57. treatment outcome$.mp.
58. problem solving.mp.
59. ((effect? or impact or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
60. attitud$.mp.
61. behavio?r$.mp.
62. complian$.mp.
63. adheren$.mp.
64. improv$.mp.
65. chang$.mp.
66. (cope or coping).mp.
67. skill?.mp.
68. (knowledge or learn$ or cognition).mp.
69. "quality of life".mp.
70. hospitali?ation?.mp.
71. admission?.mp.
72. service utilization.mp.
73. or/48-72
74. clinical trial.pt.
75. randomi?ed.ti,ab.
76. placebo.ti,ab.
77. randomly.ti,ab.
78. trial.ti,ab.
79. groups.ti,ab.
80. (pre test$ or pretest$ or (post test$ or posttest$)).mp.
81. (observation$ or prospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or case control$ or case-control$ or case referrent or case-referrent or time series or time-series or followup or follow up or follow-up or before-and-after or before-after).mp. and (study or studies or trial$).ti,ab,sh.
82. or/74-81
83. (letter$ or editorial$ or comment$ or lecture$).pt.
84. and/14,27,47,73,82
85. 84 not 83
86. limit 85 to (english language and yr="1983 - 2007")

Table B3. EMBASE—OVID Version: rel10.4.1

Years/issues searched: **1988 to 2007 Week 09**

Search date: **March 4, 2007**

Results: **study design 5,824; no study design 7,805**

1. exp child/
2. exp childhood/
3. exp adolescent/
4. exp adolescence/
5. exp family/
6. caregiver/
7. infan$.mp.
8. (baby or babies).mp.
9. child$.mp.
10. toddler$.mp.
11. adolescen$.mp.
12. (young adj3 (person? or people or adult?)).mp.
13. (teen$ or teen ager?).mp.
14. youth?.mp.
15. juvenil$.mp.
16. pube$.mp.
17. parent$.mp.
18. famil$.mp.
19. (caregiv$ or care giv$ or care-giv$ or caretak$ or care tak$ or care-tak$ or carer?).mp.
20. or/1-19
21. diabetes mellitus/
22. exp hypoglycemia/
23. ((type 1 or I) adj (diabetes mellitus or DM)).mp.
24. ((diabetes mellitus or DM) adj (type 1 or type I)).mp.
25. diabet$.mp.
26. IDDM.mp.
27. DM.mp.
28. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
29. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
30. (insulin defic$ adj3 absolut$).mp.
31. hypogly?emi$.mp.
32. ((autoimmun$ or auto-immun$ or auto immun$ or sudden onset) adj3 (diabetes mellitus or DM)).mp.
33. or/21-32
34. exp diabetes insipidus/
35. (diabet$ adj3 (insipidus not mellitus)).mp.
36. or/34-35
37. 33 not 36
38. exp health service/
39. health education/
40. diabetes education/
41. nutrition education/
42. patient education/
43. child psychology/
44. behavior therapy/
45. cognitive therapy/
46. family therapy/
47. exp counseling/
48. exp diet therapy/
49. (behav$ adj3 (therap$ or modif$)).mp.
50. (family adj3 therap$).mp.
51. (video$ or gam$).mp.
52. (phone or telephon$).mp.
53. program$.mp.
54. interven$.mp.
55. inform$.mp.
56. educat$.mp.
57. teach$.mp.
58. train$.mp.
59. instruct$.mp.
60. ((diet or nutrition$) adj2 therap$).mp.
61. (diabet$ adj diet$).mp.
62. ((education$ or home) adj2 (meeting? or session? or strateg$ or workshop? or visit?)).mp.
63. ((psycho-$ or psycho$) and diabet$).mp.
64. or/38-63
65. exp Hemoglobin/
66. glucose blood level/
67. (ketoacido$ or keto-acido$).mp.
68. DKA.mp.
69. SMBG.mp.
70. (blood glucose or BG).mp.
71. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
72. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
73. ((glycosylated or glycated) adj3 (hemoglobin or haemoglobin)).mp.
74. (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c).mp.
75. exp Self Care/
76. exp self concept/
77. exp treatment outcome/
78. attitude to health/
79. exp Health Behavior/
80. Problem Solving/
81. decision making/
82. ((effect? or impact or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
83. attitud$.mp.
84. behavio?r$.mp.
85. complian$.mp.
86. adheren$.mp.
87. improv$.mp.
88. chang$.mp.
89. (cope or coping).mp.
90. skill?.mp.
91. (knowledge or learn$ or cognition).mp.
92. Quality of Life/
93. "quality of life".mp.
94. hospitalization/
95. hospitali?ation?.mp.
96. admission?.mp.
97. service utilization.mp.
98. or/65-97
99. exp clinical trial/
100. randomi?ed.ti,ab.
101. placebo.ti,ab.
102. (ae or dt or to).fs.
103. randomly.ti,ab.
104. trial.ti,ab.

105. groups.ti,ab.
106. cohort analysis/

Table B3. EMBASE—OVID Version: rel10.4.1 (continued)

107. time Series Analysis/
108. (pre test$ or pretest$ or (post test$ or posttest$)).mp.
109. (observation$ or prospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or case control$ or case-control$ or case referrent or case-referrent or time series or time-series or followup or follow up or follow-up or before-and-after or before-after).mp. and (study or studies or trial$).ti,ab,sh.
110. or/99-109
111. ANIMAL/
112. Human/
113. 111 not (111 and 112)
114. 110 not 113
115. and/20,37,64,98,114
116. (letter$ or editorial$ or note$).pt.
117. 115 not 116
118. limit 117 to (english language and yr="1983 - 2007")

Table B4. EBM Reviews—Cochrane Central Register of Controlled Trials

Years/issue searched: **1st Quarter 2007**

Search date: **March 4, 2007**

Results: **741**

1. exp Infant/
2. exp Family/
3. exp Caregiver/
4. infan$.mp.
5. (baby or babies).mp.
6. child$.mp.
7. toddler$.mp.
8. adolescen$.mp.
9. (young adj3 (person? or people or adult?)).mp.
10. (teen$ or teen ager?).mp.
11. youth?.mp.
12. juvenil$.mp.
13. pube$.mp.
14. parent$.mp.
15. famil$.mp.
16. (caregiv$ or care giv$ or care-giv$ or caretak$ or care tak$ or care-tak$ or carer?).mp.
17. or/1-16
18. exp Diabetes Mellitus/
19. exp Hypoglycemia/
20. diabetes mellitus type 1.sh.
21. ((type 1 or type I) adj (diabetes mellitus or DM)).mp.
22. ((diabetes mellitus or DM) adj (type 1 or type I)).mp.
23. diabet$.mp.
24. IDDM.mp.
25. DM.mp.
26. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
27. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
28. ((autoimmun$ or auto-immun$ or auto immun$ or sudden onset) adj3 (diabetes mellitus or DM)).mp.
29. (insulin defic$ adj3 absolut$).mp.
30. hypoglyc?emi$.mp.
31. or/18-30
32. exp Diabetes Insipidus/
33. (diabet$ adj3 (insipidus not mellitus)).mp.
34. or/32-33
35. 31 not 34
36. Self Help Groups/
37. health education/
38. patient education/
39. exp patient care/
40. exp health services/
41. Adolescent Psychology/
42. Child Psychology/
43. Behavior Therapy/
44. Family Therapy/
45. Counseling/
46. exp patient care management/ and diabet$.mp.
47. (behav$ adj3 (therap$ or modif$)).mp.
48. (family adj3 therap$).mp.
49. ed.fs.
50. (video$ or gam$).mp.
51. (phone or telephon$).mp.
52. program$.mp.
53. interven$.mp.
54. inform$.mp.
55. educat$.mp.
56. teach$.mp.
57. train$.mp.
58. instruct$.mp.
59. ((diet or nutrition$) adj2 therap$).mp.
60. (diabet$ adj diet$).mp.
61. ((education$ or home) adj2 (meeting? or session? or strateg$ or workshop? or visit?)).mp.
62. ((psycho-$ or psycho$) and diabet$).mp.
63. or/36-62
64. Hemoglobin A, Glycosylated/
65. Blood Glucose/
66. diabetic ketoacidosis/
67. DKA.mp.
68. SMBG.mp.
69. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
70. ((glycosylated or glycated) adj3 (hemoglobin or haemoglobin)).mp.
71. (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c).mp.
72. exp Self Care/
73. Self efficacy/
74. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
75. exp "Outcome and Process Assessment (Health Care)"/
76. exp Attitude to Health/
77. exp Health Behavior/
78. Problem Solving/
79. ((effect? or impact or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
80. attitud$.mp.
81. behavio?r$.mp.
82. complian$.mp.
83. adheren$.mp.
84. improv$.mp.
85. chang$.mp.
86. (cope or coping).mp.
87. skill?.mp.
88. (knowledge or learn$ or cognition).mp.
89. "quality of life".mp.
90. exp hospitalization/
91. hospitali?ation?.mp.
92. admission?.mp.
93. service utilization.mp.
94. or/64-93
95. Intervention Studies/
96. evaluation studies/ or program evaluation/
97. (pre test$ or pretest$ or (post test$ or posttest$)).mp.
98. (observation$ or prospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or case control$ or case-control$ or case referrent or case-referrent or time series or time-series or followup or follow up or

follow-up or before-and-after or before-after).mp. and
(study or studies or trial$).ti,ab,sh.

Table B4. EBM Reviews—Cochrane Central Register of Controlled Trials (continued)

```
 99. or/95-98
100. animals/
101. 99 not 100
102. and/17,35,63,94,101
103. (letter$ or editorial$ or comment$ or lecture$ or
     note$).pt.
104. 102 not 103
105. limit 104 to yr="1983 - 2006"
```

Table B5. EBM Cochrane Database of Systematic Reviews (CDSR) and EBM Database of Reviews and Abstracts (DARE)—OVID Version: rel10.4.1

Years/issue searched: **1st Quarter 2007**

Search date: **March 4, 2007**

Results: **CDSR 490**; **DARE 106**

1. infan$.mp.
2. (baby or babies).mp.
3. child$.mp.
4. toddler$.mp.
5. adolescen$.mp.
6. (young adj3 (person? or people or adult?)).mp.
7. (teen$ or teen ager?).mp.
8. youth?.mp.
9. juvenil$.mp.
10. pube$.mp.
11. parent$.mp.
12. famil$.mp.
13. (caregiv$ or care giv$ or care-giv$ or caretak$ or care tak$ or care-tak$ or carer?).mp.
14. or/1-13
15. ((type 1 or type I) adj (diabetes mellitus or DM)).mp.
16. ((diabetes mellitus or DM) adj (type 1 or type I)).mp.
17. diabet$.mp.
18. IDDM.mp.
19. DM.mp.
20. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
21. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
22. ((autoimmun$ or auto-immun$ or auto immun$ or sudden onset) adj3 (diabetes mellitus or DM)).mp.
23. (insulin defic$ adj3 absolut$).mp.
24. hypoglyc?emi$.mp.
25. or/15-24
26. (diabet$ adj3 (insipidus not mellitus)).mp.
27. 25 not 26
28. (patient adj (care or management)).mp.
29. health services.mp.
30. ((child or adolescent) adj3 psychology).mp.
31. counsel?ing.mp.
32. ((behav$ or cognitiv$) adj3 (therap$ or modif$)).mp.
33. (family adj3 therap$).mp.
34. (video$ or gam$).mp.
35. (phone or telephon$).mp.
36. program$.mp.
37. interven$.mp.
38. inform$.mp.
39. educat$.mp.
40. teach$.mp.
41. train$.mp.
42. instruct$.mp.
43. ((diet or nutrition$) adj2 therap$).mp.
44. (diabet$ adj diet$).mp.
45. ((education$ or home) adj2 (meeting? or session? or strateg$ or workshop? or visit?)).mp.
46. ((psycho-$ or psycho$) and diabet$).mp.
47. or/28-46
48. (blood glucose or BG).mp.
49. (ketoacido$ or keto-acido$).mp.
50. DKA.mp.
51. SMBG.mp.
52. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
53. ((glycosylated or glycated) adj3 (hemoglobin or haemoglobin)).mp.
54. (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c).mp.
55. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
56. "Outcome and Assessment (Health Care)".mp.
57. treatment outcome$.mp.
58. problem solving.mp.
59. ((effect? or impact or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
60. attitud$.mp.
61. behavio?r$.mp.
62. complian$.mp.
63. adheren$.mp.
64. improv$.mp.
65. chang$.mp.
66. (cope or coping).mp.
67. skill?.mp.
68. (knowledge or learn$ or cognition).mp.
69. "quality of life".mp.
70. hospitali?ation?.mp.
71. admission?.mp.
72. service utilization.mp.
73. or/48-72
74. and/14,27,47

Table B6. OVID Healthstar—OVID Version: rel10.4.1

Years/issues searched: **1966 to January 2007**

Search date: **March 4, 2007**

Results: **study design 3,631**; **no study design 5,591**

1. exp Infant/
2. exp Child/
3. exp Adolescent/
4. exp Parents/
5. exp Family/
6. exp Caregivers/
7. infan$.mp.
8. (baby or babies).mp.
9. child$.mp.
10. toddler$.mp.
11. adolescen$.mp.
12. (young adj3 (person? or people or adult?)).mp.
13. (teen$ or teen ager?).mp.
14. youth?.mp.
15. juvenil$.mp.
16. pube$.mp.
17. parent$.mp.
18. famil$.mp.
19. (caregiv$ or care giv$ or care-giv$ or caretak$ or care tak$ or care-tak$ or carer?).mp.
20. or/1-19
21. Diabetes Mellitus/
22. Diabetes Mellitus, Type 1/
23. exp hypoglycemia/
24. ((type 1 or type I) adj (diabetes mellitus or DM)).mp.
25. ((diabetes mellitus or DM) adj (type 1 or type I)).mp.
26. diabet$.mp.
27. IDDM.mp.
28. DM.mp.
29. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
30. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
31. ((autoimmun$ or auto-immun$ or auto immun$ or sudden onset) adj3 (diabetes mellitus or DM)).mp.
32. (insulin defic$ adj3 absolut$).mp.
33. hypoglyc?emi$.mp.
34. or/21-33
35. exp Diabetes Insipidus/
36. (diabet$ adj3 (insipidus not mellitus)).mp.
37. or/35-36
38. 34 not 37
39. Self Help Groups/
40. Health Education/
41. Patient Education/
42. Patient Care/
43. Adolescent Psychology/
44. Child Psychology/
45. Behavior Therapy/
46. Cognitive Therapy/
47. Family Therapy/
48. Counseling/
49. exp patient care management/ and diabet$.mp.
50. exp Nutrition Therapy/
51. exp Home Care Services/
52. exp School Health Services/
53. (behav$ adj3 (therap$ or modif$)).mp.
54. (family adj3 therap$).mp.
55. ed.fs.
56. (video$ or gam$).mp.
57. (phone or telephon$).mp.
58. program$.mp.
59. interven$.mp.
60. inform$.mp.
61. educat$.mp.
62. teach$.mp.
63. train$.mp.
64. instruct$.mp.
65. ((diet or nutrition$) adj2 therap$).mp.
66. (diabet$ adj diet$).mp.
67. ((education$ or home) adj2 (meeting? or session? or strateg$ or workshop? or visit?)).mp.
68. ((psycho-$ or psycho$) and diabet$).mp.
69. or/39-68
70. Hemoglobin A, Glycosylated/
71. Blood Glucose/
72. Diabetic Ketoacidosis/
73. (ketoacido$ or keto-acido$).mp.
74. DKA.mp.
75. SMBG.mp.
76. (blood glucose or BG).mp.
77. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
78. ((glycosylated or glycated) adj3 (hemoglobin or haemoglobin)).mp.
79. (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c).mp.
80. exp Self Care/
81. Self efficacy/
82. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
83. "Outcome Assessment (Health Care)"/
84. Program Evaluation/
85. Treatment Outcome/
86. exp Attitude to Health/
87. exp Health Behavior/
88. Problem Solving/
89. ((effect? or impact or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
90. attitud$.mp.
91. behavio?r$.mp.
92. complian$.mp.
93. adheren$.mp.
94. improv$.mp.
95. chang$.mp.
96. (cope or coping).mp.
97. skill?.mp.
98. (knowledge or learn$ or cognition).mp.
99. Quality of Life/
100. "quality of life".mp.
101. exp Hospitalization/
102. hospitali?ation?.mp.
103. admission?.mp.
104. service utilization.mp.

105. or/70-104

106. clinical trial.pt.

Table B6. OVID Healthstar—OVID Version: rel10.4.1 (continued)

107. randomi?ed.ti,ab.
108. placebo.ti,ab.
109. dt.fs.
110. randomly.ti,ab.
111. trial.ti,ab.
112. groups.ti,ab.
113. exp controlled clinical trials/
114. exp cohort studies/
115. Intervention Studies/
116. evaluation studies/ or program evaluation/
117. random allocation/
118. (pre test$ or pretest$ or (post test$ or posttest$)).mp.
119. (observation$ or prospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or case control$ or case-control$ or case referrent or case-referrent or time series or time-series or followup or follow up or follow-up or before-and-after or before-after).mp. and (study or studies or trial$).ti,ab,sh.
120. or/106-119
121. animals/ not human/
122. 120 not 121
123. and/20,38,69,105,122
124. (letter$ or editorial$ or comment$ or lecture$).pt.
125. 123 not 124
126. limit 125 to english language
127. limit 126 to yr="1983-2007"

Table B7. ERIC (Educational Resources Information Center)—OVID Version: rel10.4.1

Years/issue searched: **1966 to January 2007**

Search date: **March 4, 2007**

Results: **study design 220**; **no study design 222**

1. infants/
2. Toddlers/
3. exp children/
4. early adolescents/
5. adolescents/
6. late adolescents/
7. preadolescents/
8. exp youth/
9. exp "family (sociological unit)"/
10. exp parents/
11. exp caregivers/
12. infan$.mp.
13. (baby or babies).mp.
14. toddler$.mp.
15. child$.mp.
16. adolescen$.mp.
17. (young adj3 (person? or people or adult?)).mp.
18. (teen$ or teen ager?).mp.
19. youth?.mp.
20. juvenil$.mp.
21. pube$.mp.
22. parent$.mp.
23. famil$.mp.
24. (caregiv$ or care giv$ or care-giv$ or caretak$ or care tak$ or care-tak$ or carer?).mp.
25. or/1-24
26. diabetes/
27. ((type 1 or type I) adj (diabetes mellitus or DM)).mp.
28. ((diabetes mellitus or DM) adj (type 1 or type I)).mp.
29. diabet$.mp.
30. IDDM.mp.
31. DM.mp.
32. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
33. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
34. hypoglyc?emi$.mp.
35. or/26-34
36. (diabet$ adj3 (insipidus not mellitus)).mp.
37. 35 not 36
38. exp health education/
39. Health Behavior/
40. health programs/
41. health promotion/
42. patient education/
43. Nutrition Instruction/
44. exp behavior modification/
45. exp counseling/
46. exp intervention/
47. self help programs/
48. social support groups/
49. cognitive restructuring/
50. exp health services/
51. school health services/
52. exp therapy/ and diabet$.mp.
53. child psychology/
54. exp educational methods/
55. exp instructional methods/
56. (behav$ adj3 (therap$ or modif$)).mp.
57. (family adj3 therap$).mp.
58. (video$ or gam$).mp.
59. (phone or telephon$).mp.
60. program$.mp.
61. interven$.mp.
62. inform$.mp.
63. educat$.mp.
64. teach$.mp.
65. train$.mp.
66. instruct$.mp.
67. ((diet or nutrition$) adj2 therap$).mp.
68. (diabet$ adj diet$).mp.
69. ((education$ or home) adj2 (meeting? or session? or strateg$ or workshop? or visit?)).mp.
70. ((psycho-$ or psycho$) and diabet$).mp.
71. or/38-70
72. (hemoglobin or haemoglobin).mp.
73. (HbA1c or A1c or HbA1 or GHb).mp.
74. (blood glucose or BG).mp.
75. (ketoacido$ or keto-acido$).mp.
76. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
77. self management/
78. self efficacy/
79. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
80. medical care evaluation/
81. program evaluation/
82. "outcomes of treatment"/
83. Behavior Change/
84. problem solving/
85. ((effect? or impact or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
86. attitud$.mp.
87. behavio?r$.mp.
88. complian$.mp.
89. adheren$.mp.
90. improv$.mp.
91. chang$.mp.
92. (cope or coping).mp.
93. skill?.mp.
94. (knowledge or learn$ or cognition).mp.
95. exp "quality of life"/
96. "quality of life".mp.
97. hospitali?ation?.mp.
98. admission?.mp.
99. service utilization.mp.
100. motivation/
101. or/72-100
102. control?ed clinical trial?.mp.
103. randomi?ed.ti,ab.
104. placebo.ti,ab.
105. randomly.ti,ab.
106. trial.ti,ab.
107. groups.ti,ab.

108. Evaluation Methods/ or Program Evaluation/

Table B7. ERIC (Educational Resources Information Center)—OVID Version: rel10.4.1 (continued)

109. (pre test$ or pretest$ or (post test$ or posttest$)).mp.
110. (observation$ or prospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or case control$ or case-control$ or case referrent or case-referrent or time series or time-series or followup or follow up or follow-up or before-and-after or before-after).mp. and (study or studies or trial$).ti,ab,sh.
111. Cohort Analysis/
112. exp longitudinal studies/
113. or/101-112
114. exp animals/
115. 113 not 114
116. and/25,37,71,101,115
117. (letter$ or editorial$ or commentary or lecture$).ti,ab.
118. 116 not 117
119. limit 118 to (english language and yr="1983 - 2007")

Table B8. PsycINFO®—OVID Version: rel10.4.1

Years/issue searched: **1985 to February Week 4 2007**

Search date: **March 4, 2007**

Results: **study design 468**; **no study design 1,141**

1. infan$.mp.
2. (baby or babies).mp.
3. toddler$.mp.
4. child$.mp.
5. adolescen$.mp.
6. (young adj3 (person? or people or adult?)).mp.
7. (teen$ or teen ager?).mp.
8. youth?.mp.
9. juvenil$.mp.
10. pube$.mp.
11. parent$.mp.
12. famil$.mp.
13. (caregiver? or care-taker or care giver$? or caretaker? or care-taker? or care caker? or carer?).mp.
14. infancy 2 23 mo.ag.
15. childhood birth 12 yrs.ag.
16. preschool age 2 5 yrs.ag.
17. school age 6 12 yrs.ag.
18. adolescence 13 17 yrs.ag.
19. exp parents/
20. exp Family/
21. exp Caregivers/
22. or/1-21
23. diabetes/
24. diabetes mellitus/
25. hypoglycemia/
26. ((type 1 or I) adj (diabetes mellitus or DM)).mp.
27. ((diabetes mellitus or DM) adj (type 1 or I)).mp.
28. diabet$.mp.
29. IDDM.mp.
30. DM.mp.
31. ((insulin-dependent or insulindependent) adj3 (diabetes mellitus or DM)).mp.
32. ((earl$ or juvenil$ or child$ or labil$ or keto$) adj3 (diabetes mellitus or DM)).mp.
33. ((autoimmun$ or auto-immun$ or auto immun$ or sudden onset) adj3 (diabetes mellitus or DM)).mp.
34. (insulin defic$ adj3 absolut$).mp.
35. hypoglyc?emi$.mp.
36. or/23-35
37. exp Diabetes Insipidus/
38. (diabet$ adj (insipidus not mellitus)).mp.
39. 36 not 38
40. health education/
41. health promotion/
42. client education/
43. behavior modification/
44. behavior therapy/
45. cognitive therapy/
46. cognitive behavior therapy/
47. exp counseling/
48. interdisciplinary treatment approach/
49. Multimodal Treatment Approach/
50. exp health care delivery/
51. exp Health Care Services/
52. exp case management/
53. support groups/
54. exp intervention/
55. health behavior/
56. exp psychotherapy/ and diabet$.mp.
57. (behav$ adj3 (therap$ or modif$)).mp.
58. (family adj3 therap$).mp.
59. (video$ or gam$).mp.
60. (phone or telephon$).mp.
61. program$.mp.
62. interven$.mp.
63. inform$.mp.
64. educat$.mp.
65. teach$.mp.
66. train$.mp.
67. instruct$.mp.
68. ((diet or nutrition$) adj2 therap$).mp.
69. (diabet$ adj diet$).mp.
70. ((education$ or home) adj2 (meeting? or sesion? or strateg$ or workshop? or visit?)).mp.
71. child psychology/ and diabet$.mp.
72. adolescent psychology/ and diabet$.mp.
73. ((psycho-$ or psycho$) and diabet$).mp.
74. "Psychoanalytic Therapy".cc.
75. "Behavioral & Psychological Treatment of Physical Illness".cc.
76. or/40-75
77. blood sugar/
78. hemoglobin/
79. self monitoring/
80. DKA.mp.
81. (ketoacido$ or keto-acido$).mp.
82. SMBG.mp.
83. (self adj (care or regulat$ or monitor$ or manage$ or efficacy)).mp.
84. (blood glucose or BG).mp.
85. ((metabolic or diabet$ or glyc?emic or glucose) adj control).mp.
86. ((glycosylated or glycated) adj3 (hemoglobin or haemoglobin)).mp.
87. (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c).mp.
88. self efficacy/
89. exp self management/
90. exp treatment outcomes/
91. Treatment Effectiveness Evaluation/
92. exp program evaluation/
93. health attitudes/
94. "physical illness (attitudes toward)"/
95. problem solving/
96. treatment compliance/
97. ((effect? or impact? or evaluat$ or compar$) adj2 (treatment or care) adj program$).mp.
98. attitud$.mp.
99. behavio?r.mp.
100. complian$.mp.
101. adheren$.mp.
102. improv$.mp.

103. chang$.mp.
104. (cope or coping).mp.

Table B8. PsycINFO®—OVID Version: rel10.4.1 (continued)

105. skill?.mp.
106. (knowledge or learn$ or cognition).mp.
107. "quality of life"/
108. "quality of life".mp.
109. exp hospitalization/
110. hospitali?ation?.mp.
111. admission?.mp.
112. health care utilization/
113. service utilization.mp.
114. or/77-113
115. clinical trials/
116. randomi?ed.ti,ab.
117. placebo.ti,ab.
118. randomly.ti,ab.
119. trial.ti,ab.
120. groups.ti,ab.
121. "research design$".mp.
122. cohort analysis/
123. Followup Studies/
124. exp Longitudinal Studies/
125. exp program evaluation/
126. random sampling/
127. (pre test$ or pretest$ or (post test$ or posttest$)).mp.
128. (observation$ or prospectiv$ or cohort$ or control$ or volunteer$ or evaluat$ or compar$ or longitudinal or long term or long-term or longterm or case control$ or case-control$ or case referrent or case-referrent or time series or time-series or followup or follow up or follow-up or before-and-after or before-after).mp. and (study or studies or trial$).ti,ab,sh.
129. or/115-128
130. exp Animals/
131. 129 not 130
132. and/22,39,76,114,131
133. (letter$ or editorial$ or lecture$ or commentary).ti,ab.
134. 132 not 133
135. limit 134 to (english language and yr="1983 - 2007")

Table B9. CINAHL Plus with Full Text—EBSCOhost

Years/issue searched: **1937 to present**

Search date: **March 5, 2007**

Limits: **not applied (not working day searches were run)**

Results: **study design 646**; **no study design 2,383**

1. (MH "Child+" or MH "Adolescence+" or MH "Family+" or MH "Caregivers" or infan* or baby or babies or child* or toddler* or adolescent* or young w3 person? or young w3 adult? or young w3 people or teen* or teen ager? or teen-ager? or youth? or juvenil* or pube* or parent* or family or families or caregiv* or care giv* or care-giv* or caretak* or care tak* or care-tak* or carer?) and (MH "Diabetes Mellitus" or MH "Diabetes Mellitus, Insulin-Dependent" or MH "Hypoglycemia+" or type 1 diabetes or type I diabetes or diabet* or iddm or dm or earl* w3 diabetes or juvenil* w3 diabetes or child* w3 diabetes or labil* w3 diabetes or keto* w3 diabetes or auto immun* w3 diabetes or auto-immun* w3 diabetes or autoimmun* w3 diabetes or sudden onset w3 diabetes or insulin defic* n3 absolut* or hypoglyc?emi*) and (MH "Support Groups" or MH "Health Education+" or MH "Patient Care+" or MH "Child Psychology" or MH "Adolescent Psychology" or MH "Behavior Therapy" or MH "Cognitive Therapy" or MH "Family Therapy" or MH "Counseling" or behav* n3 therap* or behave* n3 modif* or family n3 therap* or family n3 modif* or MW "Education" or video* or game? or gaming or phone or telephon* or program* or interven* or inform* or educat* or teach* or train* or instruct* or psycho* or diet w2 therap* or nutrition w2 therap* or diabet* diet*) and (HbA1c or A1c or HbA1 or GHb or hemoglobin A1c or haemoglobin A1c or MH "Self Care+" or MH "Self-Efficacy" or MH "Outcomes (Health Care)+" or MH "Program Evaluation" or MH "Attitude to Health+" or MH "Health Behavior+" or MH "Problem Solving" or MH "Quality of Life" or MH "Institutionalization+" or self w2 care or self w2 regulat* or self w2 monitor* or self w2 manage* or self w2 efficacy or effect? or impact or evaluat* or compar* n2 treatment or care w1 program* or attitud* or behavio?r* or complian* or adheren* or improv* or cope or coping or skill? or knowledge or learn* or cognition or "quality of life" or hospitali?ation? or admission? or service utilization or MH "Coping+" or MH "Adaptation, Psychological" or MH "Health Resource Utilization" or MH "Health Services+/UT")
2. (MH "Clinical Trials+" or MH "Case Control Studies" or MH "Multiple Time Series" or MH "Time series" or MH "Concurrent Prospective Studies" or MH "Prospective Studies" or MH "Research Methodology" or MH "Pretest-Posttest Design+" or MH "Experimental studies" or MH "Comparative Studies" or MH "Evaluation Research+" or MH "Program Evaluation" or MH "Evaluation" or MH "Random Assignment")
3. #1 and #2

Table B10. LILACS (Latin American and Caribbean Health Science Literature) (via OCLC WorldCat)

Search date: **February 28, 2007**

Limits: **1983-2007; English**

Results: **800**

1. (kw: diabetes w mellitus OR kw: Diabetes w Mellitus, w Type w 1 OR kw: Diabetic w Ketoacidosis OR kw: DM OR kw: IDDM OR ((kw: diabetes w mellitus OR kw: DM) AND (kw: type and kw: 1) OR (kw: type and kw: I))) OR ((kw: insulin-depend* OR kw: insulindepend* OR kw: keto* OR kw: earl* OR kw: juvenil* OR kw: child* OR kw: labil* OR kw: autoimmun* OR kw: auto-immun* OR (kw: sudden and kw: onset)) AND (kw: diabet* OR kw: DM)) OR (((kw: insulin and kw: def*) AND kw: absolut*) OR kw: hypoglycemi*) and yr: 1983-2007 and la= "eng" and li: lilac

Table B11. OCLC ProceedingsFirst—OCLC First Search

Limits: **1983-2007; English**

Search date: **February 28, 2007**

Results: **14**

1. kw: infant+ OR kw: baby OR kw: babies OR kw: toddler+ OR kw: child* OR kw: adolescent+ OR kw: teen* OR kw: teenager+ OR kw: youth+ OR kw: juvenile+ OR kw: parent+ OR kw: family OR kw: families OR kw: caregiver+ OR kw: caretaker+ OR kw: carer+ and yr: 1983-2007 and ln= "english") and ((kw: diabetes w mellitus OR kw: Diabetes w Mellitus, w Type w 1 OR kw: Diabetic w Ketoacidosis OR kw: DM OR kw: IDDM OR ((kw: diabetes w mellitus OR kw: DM) AND (kw: type and kw: 1) OR (kw: type and kw: I))) OR ((kw: insulin-depend* OR kw: insulindepend* OR kw: keto* OR kw: earl* OR kw: juvenil* OR kw: child* OR kw: labil* OR kw: autoimmun* OR kw: auto-immun* OR (kw: sudden and kw: onset)) AND (kw: diabet* OR kw: DM)) OR (((kw: insulin and kw: def*) AND kw: absolut*) OR kw: hypoglycemi*) and yr: 1983-2007 and ln= "english")

Table B12. OCLC PapersFirst—OCLC First Search

Limits: **1983-2007**

Search date: **February 28, 2007**

Results: **10**

1. kw: infant+ OR kw: baby OR kw: babies OR kw: toddler+ OR kw: child* OR kw: adolescent+ OR kw: teen* OR kw: teenager+ OR kw: youth+ OR kw: juvenile+ OR kw: parent+ OR kw: family OR kw: families OR kw: caregiver+ OR kw: caretaker+ OR kw: carer+ and yr: 1983-2007 and ln= "english") and ((kw: diabetes w mellitus OR kw: Diabetes w Mellitus, w Type w 1 OR kw: Diabetic w Ketoacidosis OR kw: DM OR kw: IDDM OR ((kw: diabetes w mellitus OR kw: DM) AND (kw: type and kw: 1) OR (kw: type and kw: I))) OR ((kw: insulin-depend* OR kw: insulindepend* OR kw: keto* OR kw: earl* OR kw: juvenil* OR kw: child* OR kw: labil* OR kw: autoimmun* OR kw: auto-immun* OR (kw: sudden and kw: onset)) AND (kw: diabet* OR kw: DM)) OR (((kw: insulin and kw: def*) AND kw: absolut*) OR kw: hypoglycemi*) and yr: 1983-2007

Table B13. PubMed®—U.S. National Library of Medicine

Search date: **March 6, 2007**

Limits: **articles published and/or entered within last 180 days**

Results: **218**

1. Search infant[MeSH] OR child[MeSH] OR adolescent[MeSH] OR parents[MeSH] OR family[MeSH] OR caregivers[MeSH]) OR (infan* OR baby OR babies OR toddler* OR child* OR adolescen* OR "young person*" OR "young people" OR "young adult*" OR teen* OR "teen-ager*" OR youth* OR juvenil* OR pube* OR parent* OR famil* OR caregiv* OR care-giv* OR caretak* OR "care-tak*" OR carer*)
2. Search ("diabetes mellitus"[MeSH] OR "Diabetes Mellitus, Type 1"[MeSH] OR "Diabetic Ketoacidosis"[MeSH] OR DM OR IDDM OR (("diabetes mellitus" OR DM) AND type 1 OR type I)) OR ((insulin-depend* OR insulindepend* OR keto* OR earl* OR juvenil* OR child* OR labil* OR autoimmun* OR auto-immun* OR sudden onset) AND (diabet* OR DM)) OR ((insulin def* AND absolut*) OR hypoglycemi*)
3. Search diabetes insipidus[MeSH]
4. Search ((#2)) NOT (#3)
5. Search self help groups[MeSH] OR health education[MeSH] OR patient education[MeSH] OR patient care[MeSH] OR adolescent psychology[MeSH] OR child psychology[MeSH] OR behavior therapy[MeSH] OR cognitive therapy[MeSH] OR family therapy[MeSH] OR counseling[MeSH] OR (exp patient care management[MeSH] AND diabet*) OR exp nutrition therapy[MeSH] OR exp home care services[MeSH] OR (behav* AND (therap* OR modif*)) OR (family AND therap*) OR video OR videos OR game OR games OR phone OR telphon* OR program* OR interven* OR inform* OR educat* OR teach* OR train* OR instruct*
6. Search ((Patient AND (Care OR management)) OR "Self-help group*" OR ((Health OR patient) AND education) OR Counsel* OR ((adolescent OR child) AND psychology) OR (behavio* OR cognit* OR psychotherap* OR family OR nutrition* OR diet*) AND (therap* OR (modif*)) OR "Home care service* OR school health service* OR diabet* diet*)
7. Search ((#5)) OR (#6)
8. Search Hemoglobin A, glycosylated[MeSH] OR blood glucose[MeSH] OR diabetic ketoacidosis[MeSH] OR ketoacido* OR keto-acido* OR DKA OR SMBG OR "blood glucose" OR BG OR ((metabolic OR diabet* OR glycemic OR glycaemic OR glucose) AND control) OR (HbA1c OR A1c OR HbA1 OR GHb OR hemoglobin OR haemoglobin)
9. Search Self care[MeSH] OR self efficacy[MeSH] OR (self AND (care OR regulat* OR monitor* OR manage* OR efficacy)) OR (attitud* OR behavior* OR complian* OR adheren* OR improv* OR chang* OR cope OR coping OR skill* OR knowledge OR learn* OR cognition))
10. Search Program evaluation[MeSH] OR treatment outcome[MeSH] OR attitude to health[MeSH] OR health behavior[MeSH] OR problem solving[MeSH] OR ((effect* OR impact OR evaluat* OR compar*) AND (treatment OR care) AND program*) OR "outcome assessment (health care)"[MeSH] OR quality of life[MeSH] OR hospitalization[MeSH] OR admission* OR "service utilization"
11. Search (((#8)) OR (#9)) OR (#10)
12. Search clinical trial[PT] OR randomized[TIAB] OR placebo[TIAB] OR randomly[TIAB] OR trial[TIAB] OR groups[TIAB] OR controlled clinical trials[MeSH] OR cohort studies[MeSH] OR intervention studies[MeSH] OR evaluation studies[MeSH] OR program evaluation[MeSH] OR random allocation[MeSH]
13. Search pre-test* OR pretest* OR post-test* OR posttest*
14. Search (observation*[TIAB] OR prospectiv*[TIAB] OR cohort*[TIAB] OR control*[TIAB] OR volunteer*[TIAB] OR evaluat*[TIAB] OR compar*[TIAB] OR longitudinal[TIAB] OR long-term[TIAB] OR longterm[TIAB] OR case-control*[TIAB] OR case control*[TIAB] OR case referrent*[TIAB] OR case-referrent*[TIAB] OR time series[TIAB] OR time-series[TIAB] OR followup[TIAB] OR follow up[TIAB] OR follow-up[TIAB] OR before-and-after[TIAB] OR before-after[TIAB]) AND (study[TIAB] OR studies[TIAB] OR trial*[TIAB]))
15. Search (((#12)) OR (#13)) OR (#14)
16. Search (((((#1)) AND (#4)) AND (#7)) AND (#11)) AND (#15)

Table B14. Science Citation Index Expanded (via Web of Science®)—ISI Web of Knowledge ver 3.0
Years/issue searched: **1900-present**
Limits: **1983-2007; English**
Search date: **February 22, 2007**
Results: **938**

1. TS=(infan* OR (baby OR babies) OR toddler* OR child* OR adolescen* OR youth* OR juvenil* OR teen* OR (teen SAME ager*) OR (young SAME person*) OR (young SAME people) OR (young SAME adult*)) OR TS=(pube* OR parent* OR famil* OR caregiv* OR (care SAME giv*) OR caretak* OR (care SAME tak*) OR carer*)
2. TS=((Diabetes SAME mellitus) OR DM) AND TS=((Type SAME 1) OR (Type SAME I)) OR TS=(diabet* OR IDDM) OR TS=((insulin SAME dependent) OR insulindependent OR earl* OR juvenil* OR child* OR labil* OR keto* OR autoimmun* OR (auto SAME immun*) OR (sudden SAME onset)) AND TS=((diabetes SAME mellitus) OR DM)
3. #2 NOT TS=(diabetes SAME insipidus)
4. TS=((education* OR home) SAME (meeting* OR session* OR strateg* OR workshop*OR visit*)) OR TS=(video* OR gam* OR phone OR telephon* OR program* OR interven* OR inform* OR educat*OR teach* OR train* OR instruct*)
5. TS=((Home SAME care) OR TS=(school SAME health) SAME TS=Service*) OR TS=(diabet* SAME diet)
6. TS=(Behav* OR cognit* OR psycho*OR family OR nutrition* OR diet*) AND TS=(therap* OR modif*)
7. TS=Counse?ling OR (TS=(Adolescent OR child) AND TS=psychology)
8. TS=(Patient SAME (Care OR management)) OR TS=(Self SAME help SAME group*) OR TS=(Health OR patient) AND TS=education
9. #8 OR #7 OR #6 OR #5 OR #4
10. TS=(ketoacido* OR keto same acido*) OR TS=DKA OR TS=SMBG OR TS=(blood SAME glucose) OR TS=BG OR TS=((metabolic OR diabet* OR glyc?emic OR glucose) SAME control) OR TS=(HbA1c OR A1c OR HbA1 OR GHb OR hemoglobin OR haemoglobin)
11. TS=(self SAME (care OR regulat* OR monitor* OR manage* OR efficacy)) OR TS=(attitud* OR behavior* OR complian* OR adheren* OR improv* OR chang* OR cope OR coping OR skill* OR knowledge OR learn* OR cognition)
12. TS=(Program SAME evaluation) OR TS=(Treatment SAME Outcome) OR TS=(problem SAME solving) OR TS=((effect* OR impact OR evaluat* OR compar*) SAME (treatment OR care) SAME program*) OR TS="quality of life" OR TS=hospitali?ation OR TS=admission* OR TS=(service SAME utilization)
13. #12 OR #11 OR #10
14. TS=(randomized controlled trial* OR controlled clinical trial* OR research design OR placebo* OR random* OR pre test* OR prettest* OR post test* OR posttest*) OR TS=(observation* OR prospectiv* OR cohort* OR control* OR volunteer* OR evaluat* OR compar* OR intervention OR longitudinal OR long term OR long-term OR longterm OR "case control*" OR case-control* OR "time series" OR time-series OR "case referent" OR case-referent OR before-and-after OR before-after OR followup OR "follow up" OR follow-up) AND TS=(study OR studies OR trial*) NOT TS=animal*
15. #9 AND #3 AND #1
16. #15 AND #14 AND #13

Table B15. SSCI-Expanded (Social Science Citation Index) (Expanded via Web of Science®)—ISI Web of Knowledge ver 3.0

Years/issue searched: **1956-present**

Limits: English; 1983-present

Search date: **February 22, 2007**

Results: 250

1. TS=(infan* OR (baby OR babies) OR toddler* OR child* OR adolescen* OR youth* OR juvenil* OR teen* OR (teen SAME ager*) OR (young SAME person*) OR (young SAME people) OR (young SAME adult*)) OR TS=(pube* OR parent* OR famil* OR caregiv* OR (care SAME giv*) OR caretak* OR (care SAME tak*) OR carer*)
2. TS=((Diabetes SAME mellitus) OR DM) AND TS=((Type SAME 1) OR (Type SAME I)) OR TS=(diabet* OR IDDM) OR TS=((insulin SAME dependent) OR insulindependent OR earl* OR juvenil* OR child* OR labil* OR keto* OR autoimmun* OR (auto SAME immun*) OR (sudden SAME onset)) AND TS=((diabetes SAME mellitus) OR DM)
3. #2 NOT TS=(diabetes SAME insipidus)
4. TS=((education* OR home) SAME (meeting* OR session* OR strateg* OR workshop*OR visit*)) OR TS=(video* OR gam* OR phone OR telephon* OR program* OR interven* OR inform* OR educat*OR teach* OR train* OR instruct*)
5. TS=((Home SAME care) OR TS=(school SAME health) SAME TS=Service*) OR TS=(diabet* SAME diet)
6. TS=(Behav* OR cognit* OR psycho*OR family OR nutrition* OR diet*) AND TS=(therap* OR modif*)
7. TS=Counse?ling OR (TS=(Adolescent OR child) AND TS=psychology)
8. TS=(Patient SAME (Care OR management)) OR TS=(Self SAME help SAME group*) OR TS=(Health OR patient) AND TS=education
9. #8 OR #7 OR #6 OR #5 OR #4
10. TS=(ketoacido* OR keto same acido*) OR TS=DKA OR TS=SMBG OR TS=(blood SAME glucose) OR TS=BG OR TS=((metabolic OR diabet* OR glyc?emic OR glucose) SAME control) OR TS=(HbA1c OR A1c OR HbA1 OR GHb OR hemoglobin OR haemoglobin)
11. TS=(self SAME (care OR regulat* OR monitor* OR manage* OR efficacy)) OR TS=(attitud* OR behavior* OR complian* OR adheren* OR improv* OR chang* OR cope OR coping OR skill* OR knowledge OR learn* OR cognition)
12. TS=(Program SAME evaluation) OR TS=(Treatment SAME Outcome) OR TS=(problem SAME solving) OR TS=((effect* OR impact OR evaluat* OR compar*) SAME (treatment OR care) SAME program*) OR TS="quality of life" OR TS=hospitali?ation OR TS=admission* OR TS=(service SAME utilization)
13. #12 OR #11 OR #10
14. TS=(randomized controlled trial* OR controlled clinical trial* OR research design OR placebo* OR random* OR pre test* OR prettest* OR post test* OR posttest*) OR TS=(observation* OR prospectiv* OR cohort* OR control* OR volunteer* OR evaluat* OR compar* OR intervention OR longitudinal OR long term OR long-term OR longterm OR "case control*" OR case-control* OR "time series" OR time-series OR "case referent" OR case-referent OR before-and-after OR before-after OR followup OR "follow up" OR follow-up) AND TS=(study OR studies OR trial*) NOT TS=animal*
15. #9 AND #3 AND #1
16. #15 AND #14 AND #13

Table B16. Dissertations and Theses Full Text ProQuest™

Search date: **March 1, 2007**

Results: **130**

(diabet* AND (type 1 OR type I))) AND (infan* OR child* OR adolescen* OR famil* OR parent* OR caregiv* OR carer) AND NOT (mouse OR mice OR rat* OR cow*)

OVID databases
RCT filter adapted from:
Cochrane Highly Sensitive Search Strategy (2005) Revision from
Glanville JM, Lefebvre C, Miles JNV, Camosso-Stefinovic J. How to identify randomized controlled trials in Medline: ten years on. J Med Libr Assoc 2006; 94(2):130-6

Science Citation Index and Social Science Citation Index databases
RCT filter from Lisa Tjosvold (ARCHE) located at
http://www.ualberta.ca/ARCHE/filters.html#rctwos

At the recommendation of the TEP panel, the searches were rerun without the study design component. Studies found previously (with the study design filter) were then removed from the search before importing into ProCite. The numbers for "no study design" are the raw results from the search, before removing duplicate studies from the study design results.

Gray Literature

Table B17. Diabetes organizations and societies

Website	URL
Alberta (Canada) Foundation for Diabetes Research	http://www.afdr.ab.ca
American Association of Diabetes Educators (AADE)	http://www.aadenet.org
American Diabetes Association	http://www.diabetes.org
American Dietetic Association	http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/index.html
American Public Health Association	http://www.apha.org
Australian Diabetes Educators Association (ADEA)	http://www.adea.com.au/index.aspx
Australian Diabetes Society (ADS)	http://www.racp.edu.au/ads
Barbara Davis Center for Childhood Diabetes	http://www.uchsc.edu/misc/diabetes
British Society for Paediatric Endocrinology and Diabetes	http://www.bsped.org.uk
Canadian Diabetes Association (CDA)	http://www.diabetes.ca
Center for Disease Control and Prevention. Diabetes Public Health Resource	http://www.cdc.gov/diabetes
Children's Diabetes Foundation at Denver	http://www.childrensdiabetesfdn.org
Diabetes Action Research and Education Foundation	http://www.diabetesaction.org
Diabetes Education and Camping Association	http://www.diabetescamps.org
Diabetes Care and Education	http://www.dce.org
Diabetes Australia	http://www.diabetesaustralia.com.au
Diabetes India	http://diabetesindia.com
Diabetes New Zealand	http://www.diabetes.org.nz
Diabetes Technology Society	http://www.clinicaldiabetestechnology.org
Diabetes UK	http://www.diabetes.org.uk
Diabetes Exercise and Sports Association	http://www.diabetes-exercise.org
Diabetes Institutes Foundation	http://www.dif.org
Diabetes Research and Wellness Foundation	http://www.diabeteswellness.net
Diabetes Research Institute	http://www.drinet.org
Diabetes Technology Society	http://www.diabetestechnology.org
Dietitians of Canada	http://www.dietitians.ca
European Association for the Study of Diabetes	http://www.easd.org

Federation of European Nurses in Diabetes	http://www.fend.org
Finnish Diabetes Association	http://www.diabetes.fi
Joslin Diabetes Center	http://www.joslin.harvard.edu
International Diabetes Institute	http://www.idi.org.au
International Diabetes Federation	http://www.idf.org
International Society for Pediatric and Adolescent Diabetes (ISPAD)	http://www.ispad.org
Juvenile Diabetes Research Foundation Australia	http://www.jdrf.org.au
Juvenile Diabetes Research Foundation International	http://www.jdf.org

Table B17. Diabetes organizations and societies (continued)

Website	URL
Juvenile Diabetes Research Foundation Canada	http://www.jdfc.ca
Naomi Berrie Diabetes Center	http://nbdiabetes.org
National Diabetes Education Initiative (NDEI)	http://www.ndei.org
Pediatric Endocrinology Nursing Society	http://www.pens.org/all.php?l=home&w=1280

Table B18. Medical professional websites

Website	URL
American Association of Clinical Endocrinologists	http://www.aace.com
American Medical Association	http://www.ama-assn.org
Canadian Medical Association	http://www.cma.ca/index.cfm/ci_id/121/la_id/1.htm
Diabetes for Professionals	http://www.d4pro.com/HomeDefault.asp
Diabetes Prevention and Control Branch	http://www.ncdiabetes.org
Diabetes Research in Children Network (DirecNet)	http://public.direc.net/index.htm
DiabetesIndia.com	http://www.diabetesindia.com
Endocrineindia.com	http://www.endocrineindia.com
Healthcare Professionals (Canadian Diabetes Association)	http://www.diabetes.ca/Section_Professionals/index.asp
National Diabetes Support Team	http://www.diabetes.nhs.uk/
National Institute for Health and Clinical Excellence (NICE)	http://www.nice.org.uk
National Institute of Diabetes and Digestive and Kidney Diseases	http://www2.niddk.nih.gov
ndei (National Diabetes Education Initiative)	http://www.ndei.org
National Glycohemoglobin Standardization Program (NGSP)	http://www.ngsp.org/ngsp.html
Royal College of Nursing	http://www.rcn.org.uk/resources/improvingcare/diabetes/index.php
SEARCH For Diabetes in Youth	http://www.searchfordiabetes.org/public/provider/index.cfm
The Endocrine Society	http://www.endo-society.org
Type 1 Diabetes TrialNet	http://www.diabetestrialnet.org
U.S. Department of Health and Human Services—National Institutes of Health	http://health.nih.gov
U.S. Food and Drug Administration Diabetes Information	http://www.fda.gov/diabetes/
World Health Organization	http://www.who.org

Table B19. Journal websites

Website	URL
Acta Diabetologia	http://link.springer.de/link/service/journals/00592
Annals of Nutrition and Metabolism	http://www.karger.ch/journal/anm
Annual Review of Nutrition	http://nutr.annualreviews.org
Asia Pacific Journal of Clinical Nutrition	http://www.healthyeatingclub.com/APJCN/index.htm
Australian Journal of Nutrition and Dietetics	http://www.ajnd.org.au
British Journal of Nutrition	http://journals.cambridge.org/action/displayJournal?jid=BJN
Canadian Journal of Diabetes	http://www.diabetes.ca/Section_Professionals/pub_cjd.asp
Canadian Journal of Dietetic Practice and Research	http://dcjournal.metapress.com/home/main.mpx
Clinical Diabetes	http://clinical.diabetesjournals.org
Clinical Nutrition	http://www.harcourt-international.com/journals/clnu
Current Diabetes Reports	http://www.biomedcentral.com/currdiabetesrep
Current Opinion in Clinical Nutrition and Metabolic Care	http://www.co-clinicalnutrition.com
Diabetes	http://diabetes.diabetesjournals.org
Diabetes	http://www.diabetes.org/Diabetes
Diabetes and Primary Care	http://www.sbcommunicationsgroup.com/publications/diabetesprimarycare/archive.htm
Diabetes Care	http://care.diabetesjournals.org
Diabetes Digest	http://www.diabetesdigest.com
Diabetes Forecast	http://www.diabetes.org/DiabetesForecast
Diabetes Metabolism Research and Reviews	http://www3.interscience.wiley.com/cgi-bin/jhome/10009394
Diabetes Research and Clinical Practice	http://www.sciencedirect.com/science/journal/01688227
Diabetes Self-Management Magazine	http://www.diabetes-self-mgmt.com
Diabetes Spectrum	http://www.diabetes.org/DiabetesSpectrum
Diabetes Technology and Therapeutics	http://www.liebertonline.com/dia?cookieSet=1
Diabetes, Obesity and Metabolism	http://www.blackwellpublishing.com/journal.asp
Diabetes/Metabolism Reviews	http://www3.interscience.wiley.com/cgi-bin/jhome/3666?CRETRY=1&SRETRY=0
Diabetic Medicine	http://www.blackwellpublishing.com/journal.asp?ref=0742-3071&site=1
Diabetologia	http://link.springer.de/link/service/journals/00125/index.htm
Disease Management	http://www.liebertonline.com/dis
DOC News	http://docnews.diabetesjournals.org
eCMAJ	http://www.collectionscanada.ca/eppp-archive/100/201/300/cdn_medical_association/cmaj/index.asp

European Journal of Clinical Nutrition	http://www.nature.com/ejcn/index.html
European Journal of Nutrition	http://www.steinkopff.springer.de/journal/394
Indian Journal of Biochemistry and Biophysics	http://www.niscair.res.in/ScienceCommunication/ResearchJournals/rejour/ijbb/ijbb0.asp
Indian Journal of Medical Research	http://www.icmr.nic.in/ijmr/ijmr.htm
Indian Journal of Medical Sciences	http://www.bioline.org.br/ms
International Journal of Diabetes and Metabolism	http://ijod.uaeu.ac.ae
Journal of Diabetes and its Complications	http://www.sciencedirect.com/science/journal/10568727
Journal of Diabetes Science and Technology	http://www.journalofdst.org

Table B19. Journal websites (continued)

Website	URL
Journal of Diabetic Nursing	http://www.sbcommunicationsgroup.com/publications/diabetesnursing/archive.htm
Journal of the American Dietetic Association	http://www.adajournal.org
Journal of the Association of Physicians of India	http://japi.org/index.asp
Pediatric Diabetes	http://www.blackwell-synergy.com/loi/PDI
Public Health Nutrition	http://www.cabi-publishing.org/journals.phn
Review of Diabetic Studies	http://www.soc-bdr.org/content/e4/e887/volRdsVolumes4215/issRdsIssues4216/index_en.html
The American Journal of Clinical Nutrition	http://www.ajcn.org
Tufts University Health and Nutrition Letter	http://healthletter.tufts.edu/

Appendix C. Sample Data Abstraction Forms

Inclusion Criteria Worksheet: Diabetes & Medical Nutrition Therapy Education for Families with Children Who Have Type 1 Diabetes Mellitus

Reviewer: _____ **Date:** _____ **Record ID:** _____

	Yes	No	Unclear/Comments
Population: Patients with type 1 diabetes (If both type 1 and type 2 diabetes patients are included, results for type 1 must be explicit) **Exclude** Type 2 diabetes, gestational diabetes	Yes	No	
Population: Patients ≤ 18 yr. (or <20% of population over 18 yr.) OR families of patients ≤ 18 years	Yes	No	
Study design: RCT, CCT, cohort studies, interrupted time series, before-after study with concurrent controls, case control studies, uncontrolled before and after studies, case series [make a note of those that are <10 participants] **Exclude** secondary research, case reports	Yes	No	
Intervention: Education program that incorporates at least one of the following content areas: 1) Diabetes disease process and treatment options; 2) Nutritional management; 3) Physical activity; 4) Monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control; 5) Utilizing medications; 6) Preventing, detecting, and treating acute complications; 7) Preventing (through risk reduction behavior), detecting, and treating chronic complications; 8) Goal setting to promote health and problem solving for daily living; 9) Psychosocial adjustment.	Yes	No	
Comparator: Education program vs. usual care OR another education program. **NOTE:** do not exclude based on this item; just make note of whether there is or isn't a comparison group.	Yes	No	
Is the description of intervention sufficient to reproduce? Note: Must include topics or content. Other characteristics: provider, length and # sessions, target audience, mode of delivery (e.g., in person or distance), group or individual, didactic/interactive, changes in treatment.	Yes	No	

Inclusion Criteria Worksheet: Diabetes & Medical Nutrition Therapy Education for Families with Children Who Have Type 1 Diabetes Mellitus (continued)

Outcomes: One or more of the following: 1) Metabolic control (as measured by HbA1c); 2) Hospitalization or ED utilization; 3) Complications (short & long term; e.g., diabetic ketoacidosis, episodes of hypoglycemia, retinal, renal, cardiovascular, neurological); 4) Knowledge; 5) Quality of life; 6) School attendance and performance; 7) Self confidence in ability to cope with disease; 8) Psychosocial outcomes **Exclude** life style outcomes (e.g., smoking, use of recreational drugs, participation in extracurricular activities)	Yes	No	
Final decision: Should this study be included?	**Yes**	**No**	**Unclear (Discuss)**
Results of discussion:			

Quality Assessment Form: (Jadad Scale for RCTs)

Study number _____ Initials of assessor: _____

Part 1 (from: Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996;17(1):1-12.)

1. Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)? _____
Yes=1 No=0

2. Was the study described as double-blind? _____
Yes=1 No=0

3. Was there a description of withdrawals and drop-outs? _____
Yes=1 No=0

Add one point if:

Method to generate the sequence of randomization was described, and was appropriate (e.g., table of random numbers, computer-generated, coin-tossing) _____

Method of double-blinding was described, and was appropriate (identical placebo, active placebo, dummy) _____

Subtract one point if:

Method of randomization was described, and was inappropriate (allocated alternately, according to date of birth, hospital number) _____

Method of double-blinding described, but was inappropriate (comparison of tablet versus injection with no double dummy) _____

OVERALL SCORE (maximum 5)

Score _____

Part 2 (from Schulz – JAMA 1995; 273:408-12)

Concealment of treatment allocation:

- ☐ Adequate
- ☐ Inadequate
- ☐ Unclear

Adequate:	e.g., central randomization; numbered/coded containers; drugs prepared by pharmacy; serially numbered, opaque, sealed envelopes
Inadequate:	e.g., alternation, use of case record numbers, dates of birth or day of week; open lists
Unclear:	Allocation concealment approach not reported or fits neither above category

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

Ref ID: _____
Author: _____
Year: _____
Reviewer: _____

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

Very Likely Somewhat Likely Not Likely

(Q2) What percentage of selected individuals agreed to participate?

80 - 100% Agreement 60 – 79% Agreement Less than 60% Agreement Not Reported Not Applicable

Rate this section (see dictionary)	Strong	Moderate	Weak

B) ALLOCATION BIAS

Indicate the study design

RCT (go to i) Quasi-Experimental (go to C) Case-control, Before/After study, No control group, or Other: _____ (Score Weak and go to C)

(i) Is the method of random allocation stated? Yes No

(ii) If the method of random allocation is stated is it appropriate? Yes No

(iii) Was the method of random allocation reported as concealed? Yes No

Rate this section (see dictionary)	Strong	Moderate	Weak

C) CONFOUNDERS

(Q1) Prior to the intervention were there between group differences for important confounders reported in the paper?

Yes No Can't Tell Not Applicable (Score Weak and go to D)

Please refer to your Review Group list of confounders.

Relevant Confounders reported in the study:

_____ _____ _____

_____ _____ _____

_____ _____ _____

(Q2) If there were differences between groups for important confounders, were they adequately managed in the analysis?

Yes No Not Applicable

(Q3) Were there important confounders not reported in the paper?

Yes No

Relevant Confounders NOT reported in the study:

_____ _____ _____

Rate this section (see dictionary)	Strong	Moderate	Weak

Note: Many studies report the results of multiple data collection tools. If you are interested in only one outcome of interest, measured by one tool, at one point in time, rate the components (validity and reliability of tool, blinding, withdrawals and drop-outs) based on that one tool. If you are collecting multiple outcomes of interest, scored by multiple tools (e.g. self-report AND assessor interview, SF-36 AND made-up questionnaire), at multiple points in time (e.g. 6-month follow-up AND 20-year follow-up) copy components of the EPHPP tool so that each data collection tool of interest is scored.

D) BLINDING

(Q1) Was (were) the outcome assessor(s) blinded to the intervention or exposure status of participants?

Yes No Not Reported Not Applicable

Rate this section (see dictionary)	Strong	Weak	Not Applicable

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown or are they known to be valid?

Yes No

(Q2) Were data collection tools shown or are they known to be reliable?

Yes No

Rate this section (see dictionary)	Strong	Moderate	Weak

F) WITHDRAWALS AND DROP-OUTS

(Q1) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

80 -100% 60 - 79% Less than 60% Not Reported Not Applicable

Rate this section (see dictionary)	Strong	Moderate	Weak	Not Applicable

G) **ANALYSIS**

(Q1) Is there a sample size calculation or power calculation?

Yes Partially No

(Q2) Is there a statistically significant difference between groups?

Yes No Not Reported

(Q3) Are the statistical methods appropriate?

Yes No Not Reported

(Q4a) Indicate the unit of allocation (circle one)

Community Organization/ Institution Group Provider Client

(Q4b) Indicate the unit of analysis (circle one)

Community Organization/ Institution Group Provider Client

(Q4c) If 4a and 4b are different, was the cluster analysis done?

Yes No Not Applicable

(Q5) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

Yes No Can't Tell

H) **INTERVENTION INTEGRITY**

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

80 -100% 60 - 79% Less than 60% Not Reported Not Applicable

(Q2) Was the consistency of the intervention measured?

Yes No Not reported Not Applicable

(Q3) Is it likely that subjects received an unintended intervention (contamination or cointervention) that may influence the results?

Yes No Can't tell

SUMMARY OF COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-3 onto this page.

A SELECTION BIAS

Rate this section (see dictionary)	Strong	Moderate	Weak

B STUDY DESIGN

Rate this section (see dictionary)	Strong	Moderate	Weak

C CONFOUNDERS

Rate this section (see dictionary)	Strong	Moderate	Weak

D BLINDING

Rate this section (see dictionary)	Strong	Weak	Not Applicable

E DATA COLLECTION METHODS

Rate this section (see dictionary)	Strong	Moderate	Weak

F WITHDRAWALS AND DROPOUTS

Rate this section (see dictionary)	Strong	Moderate	Weak	Not Applicable

G ANALYSIS
Comments _____

_____

_

_____

_

H INTERVENTION INTEGRITY
Comments

_____

_____

_

_____

_

WITH BOTH REVIEWERS DISCUSSING THE RATINGS:

Is there a discrepancy between the two reviewers with respect to the component ratings?
No Yes

If yes, indicate the reason for the discrepancy

1	2	3
Oversight	Differences in Interpretation of Criteria	Differences in Interpretation of Study

Data Extraction Form: Diabetes Education for Children with Type 1 Diabetes

Description of Study

Reviewer name:
Date entered:
Verifier's name:
Consensus reached:
Data updated:

Procite ID:
Author: Year:

Study ID: **Reviewer Name:** **Date entered:**

Type of publication:

Funding:

Country:

Study setting:

Single-centre	☑
Multi-centre	☑
Urban	☑
Rural	☑
Mixed	☑
Camp	☑
Unclear	☑

Study design:

Objective or hypothesis of study:

Author's primary outcome:

Measure of primary outcome:

Secondary outcomes:

Inclusion criteria for study:

Exclusion criteria for study:

Procite ID:
Author: **Year:**

Number Eligible: **Number of withdrawals:**

Number Enrolled:
Number Completed:

Number Excluded: **Out of how:**

How many excluded were from treatment group (n/N): **How many from treatment group (n/N):**

How many excluded were from control group (n/N): **How many from control group (n/N):**

Reasons for Exclusion: **Reasons Withdrawn:**

From where were subjects recruited?: (Drop down menu)

Hospital
Clinic
Home
Community
Existing support program
Diabetes centre
School

How were they recruited?: (Drop down menu)

Volunteers
Referrals
Existing patients
Poster/flyer
Administrative data
Chart review/Medical records

How was the control group selected?:

Authors' Conclusions:

Reviewer's Comments: **Verifier's Comments:**

Baseline Characteristics

Verifier's name:
Consensus reached:
Data updated:

Population ID:

Procite ID:

Reviewer Initials:

Group Name: Name of Group:

Number in Group:

Age Mean: Standard deviation: Reported ☑
Age- other measure: Other variance: Calculated ☑

Percent Male: Reported ☑
Calculated ☑

Weight or BMI:

BMI Mean: BMI SD:

Weight Mean: Weight SD:

HbA1C Unit of Measurement:

HbA1C Mean: HbA1C SD:

HbA1C Other Measure: HBA1C Other Variance:

Diabetes Duration: Standard deviation:

Percent Newly Diagnosed:

Comments:

Pop categorical	Population ID	Measures	Category	Numerator	Denominator	%	Mean	SD	Comments
(Auto Number)									

Interventions

Verifier's name:
Consensus reached:
Data updated:

Procite ID:

Group Name: Short Name:

Setting

- Hospital ☑
- Doctor's office ☑
- Home ☑
- Community ☑
- Support Program ☑
- School ☑
- Diabetes Center ☑
- Other ☑

Specify other:

Content

- Diabetes disease process and treatment options ☑
- Nutritional management ☑
- Physical activity ☑
- Monitoring (e.g. blood glucose, urine ketones) ☑
- Medication use ☑
- Preventing, detecting, treating acute complications ☑
- Preventing, detecting, treating chronic complications ☑
- Relationship Skills
- Goal setting to promote health and problem solving for daily living ☑
- Psychosocial adjustment ☑

Description of Intervention:

Theoretical Framework:

Enter the page number where this description is located:

Interventions

Procite ID:

Group Name: **Short Name:**

Study Duration:
Recruitment period:
Follow-up period:
Duration of program delivery:

Component 1:
Frequency of intervention component 1 (ie 2x/week):
Duration of component 1 (i.e. length of session):

Frequency of component 2:
Frequency of intervention component 2 (ie 2x/week):
Duration of component 2 (i.e. length of session):

Frequency of component 3:
Frequency of intervention component 3 (ie 2x/week):
Duration of component 3 (i.e. length of session):

Who delivered the intervention?
Primary deliverer (select one)

- Diabetes educator
- Physician
- Pediatric endocrinologist
- Nurse
- Nurse practitioner
- Psychologist
- Social worker
- Exercise physiologist
- Paramedic
- Camp counsellor
- Multidisciplinary team
- Research staff
- Peer group
- Lay person
- Computer game
- Video game
- Dietician
- Other (specify)
- NR
- N/A

Secondary mode(s) of delivery:

If other, please specify:

To whom was the intervention delivered?

- Parents
- Child
- Family
- Other
- Other (specify)
- NR
- N/A

Secondary deliverers:

If other, please specify:

What was the mode of delivery?
Primary mode of delivery (select one)

- Literature
- Meetings
- Clinic visits
- Personal counselling
- Club
- Computer game
- Presentation
- Class
- Support group
- Workbooks
- Phone calls
- Other (specify)
- NR
- N/A

Other recipient:

Specify other:

Outcomes

Verifier's name:

Consensus reached:

Data updated:

Procite ID:
Reviewer Initials:

Category (drop down menu):
- Knowledge
- Metabolic control
- Short-term complications
- Long-term complications
- Health care utilization
- Quality of life
- School attendance and performance
- Self-confidence in ability to cope with disease
- Psychosocial outcomes
- Adherence

Description of outcome:

Instrument used:

Method of Measurement (drop down menu):
- Patient self-report
- Parent self-report
- Observation
- 24 hr food frequency questionnaires
- Pill count
- Skill demonstration
- Laboratory records
- Medical records
- Other

Specify Other:

Frequency of Measurement:

Unit of Measurement (e.g. mg, score):

Outcome group ID	Outcome ID	Group	Time-point	Number	Mean	SD	Other Measure	Other Variance	Page Number	Comments
(Auto number)										

Appendix D. Excluded Studies

After screening the full-text of studies that were potentially relevant to this review, 327 were excluded from this review. The studies are grouped by reason for exclusion. In addition, there were 46 studies that were unavailable for retrieval.

Topic

The purpose of this review was to answer questions regarding the effectiveness of diabetes and medical nutrition therapy education for children with type 1 diabetes mellitus and their families. The following 50 studies were excluded because they addressed different topics.

1. Diabetes Care Centre at Texas Children's Hospital. Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes-mellitus—diabetes control and complications trial. J Pediatr 1994;125(2):177-88.

2. IHS getting healthy returns in statewide diabetes initiative: early emphasis on education produces solid improvement. Dis Manag Advis 2002;8(6):85-9.

3. Aguilar MI, Hart R. Oral anticoagulants for preventing stroke in patients with non-valvular atrial fibrillation and no previous history of stroke or transient ischemic attacks. Cochrane Database of Systematic Reviews. 2005(3):CD001927.

4. Allen HF, Yarnie S, Murray MA, et al. Is telephone care an effective tool for management of children with Type 1 diabetes? [abstract]. Diabetes 2000;49(Suppl 1):A215.

5. Brandt P, Watts G. Bridging science and practice: four collaborative clinical projects: a clinic based protocol for teens with diabetes and their parents. Commun Nurs Res 2006;39:99.

6. Briery BG. Psychosocial sequelae of relaxation training and peer interaction for children with diabetes [dissertation]. Hattiesburg, MS: University of Southern Mississippi; 2000.

7. Campaigne BN, Gilliam TB, Spencer ML, et al. The effects of a physical-activity program on children with insulin dependent diabetes-mellitus [abstract]. Med Sci Sports Exerc 1983;15(2):149.

8. Carson C. Educating adolescents with type 1 diabetes about drug use. Journal of Diabetes Nursing 2002;6(1):6-8.

9. Challener J, Ozen S, Barnes ND. The memory blood glucose reflectance meter: a useful educational tool for the diabetic adolescent? Practical Diabetes 1989;6(5):219-22.

10. Charron Prochownik D, Sereika SM, Hannan MF, et al. Reproductive health education for adolescent girls with diabetes (Ready-Girls): sustaining long-range outcomes [abstract]. Diabetes 2006;55(Suppl 1):A416.

11. Diabetes Control and Complications Trial Research Group. Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes mellitus: Diabetes Control and Complications Trial. J Pediatr 1994;125(2):177-88.

12. Diabetes Control and Complications Trial Research Group. Progression of retinopathy with intensive versus conventional treatment in the Diabetes Control and Complications Trial. Ophthalmology 1995;102(4):647-61.

13. George CK. Video in pediatric patient education: the role of formal features in the relationship of intervention, knowledge, and anxiety [dissertation]. Austin, TX: University of Texas at Austin; 1992.

14. Hanauer D, Wentzell K, Tovar A, et al. Parent and youth assessments of a handheld wireless device to enhance diabetes mellitus management. Arch Pediatr Adolesc Med 2006;160(3):321.

15. Herskowitz RD. Outward bound, diabetes and motivation: experiential education in a wilderness setting. Diabet Med 1990;7(7):633-8.

16. Hillson RM. Diabetes outward bound mountain course, Eskdale, Cumbria. Diabet Med 1984;1(1): 59-63.

17. Huttunen NP, Lankela SL, Knip M, et al. Effect of once-a-week training program on physical fitness and metabolic control in children with IDDM. Diabetes Care 1989;12(10):737-40.

18. Jones EM. The efficacy of intensive individual play therapy for children diagnosed with insulin-dependent diabetes mellitus [dissertation]. Denton, TX: University of North Texas; 2000.

19. Kerr D, Kerr S. Diabetic camps for children—effects on control and hypoglycaemia. Practical Diabetes 1988;5(2):74-6.

20. Kuno T, Tasaki H, Miyazaki S. [Continuous subcutaneous insulin injection for self-care of young patients with insulin-dependent diabetes mellitus]. Acta Paediatr Jpn 1996;38(5):464-9 (Jap).

21. Laffel LM, Brackett J, Ho J, et al. Changing the process of diabetes care improves metabolic outcomes and reduces hospitalizations. Qual Manag Health Care 1998;6(4):53-62.

22. Landt KW, Campaigne BN, James FW, et al. Effects of exercise training on insulin sensitivity in adolescents with type I diabetes. Diabetes Care 1985;8(5):461-5.

23. Lawson ML, Cohen N, Richardson C, et al. A randomized trial of regular standardized telephone contact by a diabetes nurse educator in adolescents with poor diabetes control. Pediatr Diabetes 2005;6(1):32-40.

24. Lee PD. An outpatient-focused program for childhood diabetes: design, implementation, and effectiveness. Tex Med 1992;88(7):64-8.

25. Lieberman D. Management of chronic pediatric diseases with interactive health games: theory and research findings. J Ambulatory Care Manage 2001;24(1):26-38.

26. Mackowiak L. Education record for new-onset pediatric diabetes. Diabetes Educ 1996;22(4):345, 347, 349-50 passim.

27. Mann LH. Effects of biofeedback-assisted deep muscle relaxation training on blood glucose levels in female adolescents with type I diabetes [dissertation]. Amherst, MA: University of Massachusetts; 1991.

28. Marrero DG, Kronz KK, Golden MP, et al. Clinical evaluation of computer-assisted self-monitoring of blood glucose system. Diabetes Care 1989;12(5):345-50.

29. Melchionne FM. Children with diabetes mellitus: health and education teams. Holist Nurs Pract 1993;7(4):11-9.

30. Miller SG. Family therapy for recurrent diabetic ketoacidosis: treatment guidelines. Fam Syst Health 1996;14(3):303-14.

31. Orr PM, McGinnis M, Hudson LR, et al. A focused telephonic nursing intervention delivers improved adherence to A1c testing. Dis Manag 2006;9(5):277-83.

32. Pinosa C, Marchand C, Tubiana Rufi N, et al. The use of concept mapping to enlighten the knowledge networks of diabetic children: a pilot study. Diabetes Metab 2004;30(6):527-34.

33. Price KJ, Lang JD, Eiser C, et al. Prescribed versus unrestricted carbohydrate diets in children with type 1 diabetes. Diabet Med 1993;10(10):962-7.

34. Roberts L, Jones TW, Fournier P. Exercise training and glycemic control in adolescents with poorly controlled type 1 diabetes mellitus. J Pediatr Endocrinol Metab 2002;15(5):621-7.

35. Rogers DG. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. Clin Pediatr (Phila) 1994;33(6):378.

36. Romanian Young Diabetics Study Team (RYDST). Mixtard 30 HM Penfill insulin treatment in selected young insulin-dependent diabetes mellitus patients. Romanian Young Diabetics Study Team (RYDST). Rom J Intern Med 1997;35(1-4):99-113.

37. Rosenfalck AM, Bendtson I. The Diva(TM) system, a computerized diary, used in young type 1 diabetic patients. Diabetes Metab 1993;19(1):25-9.

38. Ryden O, Nevander L, Johnsson P, et al. Family therapy in poorly controlled juvenile IDDM: effects on diabetic control, self-evaluation and behavioural symptoms. Acta Paediatr 1994;83(3):285-91.

39. Sar V, Akyuz G, Kugu N, et al. Axis I dissociative disorder comorbidity in borderline personality disorder and reports of childhood trauma. J Clin Psychiatry 2006;67(10):1583-90.

40. Schafer LC, McCaul KD, Glasgow RE. Supportive and nonsupportive family behaviors: relationships to adherence and metabolic control in persons with type I diabetes. Diabetes Care 1986;9(2):179-85.

41. Siarkowski AK, Pidgeon V. Documentation of discharge teaching before and after use of a discharge teaching tool. J Pediatr Nurs 1991;6(5):296-301.

42. Smith CA, Kennedy DM, Lahoz MR, et al. Creating an academic and rural community network to improve diabetes care. In: Issues Affecting Rural Communities (II). Proceedings of the International Conference [on] Rural Communities & Identities in the Global Millennium; 2000 May 1-5; Nanaimo, BC. Nanaimo (BC): Rural Communities Research and Development Centre, Malaspina University College; 2000.

43. Smith LJ. Type I diabetes mellitus: dependent care agents' participation in decision making compared to their participation in diabetes education [master's thesis]. Columbia, OH: University of Missouri; 1991.

44. The Diabetes Control and Complications Trial. The effect of intensive diabetes treatment on the progression of diabetic retinopathy in insulin-dependent diabetes mellitus. Arch Ophthalmol 1995;113(1):36-51.

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Study Design

The review included studies that had the following study designs: randomized controlled trial (parallel or crossover), clinical controlled trial, cohort study, case-control study, interrupted time series, before-after study with concurrent control group, case series, and uncontrolled before-after study. The following 93 studies were systematic reviews, descriptive studies, or case reports.

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91. The Diabetes Control and Complications Trial Research Group. Effect of intensive therapy on residual beta-cell function in patients with type 1 diabetes in the diabetes control and complications trial. A randomized, controlled trial. Ann Intern Med 1998;128(7):517-23.

92. The Diabetes Control and Complications Trial Research Group. Hypoglycemia in the Diabetes Control and Complications Trial. Diabetes 1997;46(2):271-86.

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98. Verlato G, Muggeo M, Bonora E, et al. Attending the diabetes center is associated with increased 5-year survival probability of diabetic patients: The Verona Diabetes Study. Diabetes Care 1996;19(3):211-3.

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101. Webb KL, Dobson AJ, O'Connell DL, et al. Dietary compliance among insulin-dependent diabetics. J Chronic Dis 1984;37(8):633-43.

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103. Whitlock WL, Brown A, Moore K, et al. Telemedicine improved diabetic management. Mil Med 2000;165(8):579-84.

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105. Wolever TM, Hamad S, Chiasson JL, et al. Day-to-day consistency in amount and source of carbohydrate associated with improved blood glucose control in type 1 diabetes. J Am Coll Nutr 1999;18(3):242-7.

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Intervention

For key questions pertaining to diabetes education programs, at least one of the following topics had to be included in the intervention: 1) diabetes disease process and treatment options; 2) nutritional management; 3) physical activity; 4) monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control; 5) utilizing medications; 6) preventing, detecting, and treating acute complications; 7) preventing (through risk reduction behaviour), detecting, and treating chronic complications; 8) goal setting to promote health and problem solving for daily living; and 9) psychosocial adjustment. The control/comparison group could be no treatment or standard care. The following 13 studies did not meet the inclusion criteria.

1. Achenbach P, Warncke K, Reiter J, et al. Type 1 diabetes risk assessment: improvement by follow-up measurements in young islet autoantibody-positive relatives. Diabetologia 2006;49(12):2969-76.

2. Campaigne BN, Gilliam TB, Spencer ML, et al. Effects of a physical activity program on metabolic control and cardiovascular fitness in children with insulin-dependent diabetes mellitus. Diabetes Care 1984;7(1):57-62.

3. DiMeglio L, Pottorff TM, Boyd SR, et al. A randomized, controlled study of insulin pump therapy in diabetic preschoolers. J Pediatr 2004;145(3):380-4.

4. Eastman BG, Johnson SB, Silverstein J, et al. Understanding of hypo- and hyperglycemia by youngsters with diabetes and their parents. J Pediatr Psychol 1983;8(3):229-43.

5. Lowes L. Specialist nursing. Evaluation of a paediatric diabetes specialist nurse post. Br J Nurs 1997;6(11):625-6, 628-33.

6. Mortweet S, Robinson J, Howard C. What do you know? The impact of information on the management of type-1 diabetes in children [abstract]. Diabetes 2000;49(Suppl 1):A78.

7. Oliver CM, Johnston CC, Winkler SJ. Problem-solving and adjustment to life with diabetes among adolescents with insulin-dependent diabetes mellitus. In: King K, Prodrick E, Bauer B, eds. Proceedings of the 10th National Research Conference: Nursing Research: Science for Quality Care; 1985 April; Toronto, Ontario. Toronto, ON: University of Toronto; 1986. p. 329-32.

8. Rami B, Popow C, Horn W, et al. Telemedical support to improve glycemic control in adolescents with type 1 diabetes mellitus. Eur J Pediatr 2006;165(10):701-5.

9. Stratton R, Wilson DP, Endres RK, et al. Improved glycemic control after supervised 8-wk exercise program in insulin-dependent diabetic adolescents. Diabetes Care 1987;10(5):589-93.

10. Vanelli M, Chiarelli F, Chiari G, et al. Metabolic control in children and adolescents with diabetes: experience of two Italian regional centers. J Pediatr Endocrinol Metab 1999;12(3):403-9.

11. Villagra VG, Ahmed T. Effectiveness of a disease management program for patients with diabetes. Health Aff (Millwood) 2004;23(4):255-66.

12. Whittemore RU, Tamborlane RD, William V, et al. Quality of life in school-aged children with type 1 diabetes on intensive treatment and their parents. Diabetes Educ 2003;29(5):847-54.

13. Wolters C, Yu SL, Hagen JW, et al. Short-term memory and strategy use in children with insulin-dependent diabetes mellitus. J Consult Clin Psychol 1996;64(6):1397-405.

Ongoing

The following three studies were not yet completed and no outcome data were available.

1. Muir AB, Geffken GR, McKnight M, et al. Feasibility of computer assisted training (CAT) in families of newly diagnosed type I diabetes [abstract]. Diabetes 2004;53(Suppl 2):A225.

2. Streisand R, Hilliard M, Mednick L, et al. Preliminary results of an RCT to prevent nonadherence among preadolescents with T1 diabetes [web page]. Available at: http://professional.diabetes.org/Abstracts_Display.aspx?TYP=1&CID=48746. Accessed 2007.

3. Streisand R, Mednick L. Development of the diabetes education, counseling, information delivery and evaluation (DECIDE) program: a health promotion intervention for preadolescents with type 1 diabetes. J Clin Psychol Med Settings 2006;13(2):180-90.

Outcome

Studies were included if they reported the following outcomes: metabolic control (as measured by HbA1c), hospitalization, ED utilization, short term complications (e.g., diabetic ketoacidosis, episodes of hypoglycemia), long term complications (retinal, renal, cardiovascular, neurological), quality of life; school attendance and performance, self confidence in ability to cope with disease, or psychosocial outcomes. The following 14 studies did not report any of the appropriate outcomes or reported lifestyle outcomes (e.g., smoking, use of recreational drugs, participation in extracurricular activities).

1. Aoki N, Ohta S, Okada T, et al. INSULOT: a cellular phone-based edutainment learning tool for children with type 1 diabetes. Diabetes Care 2005;28(3):760.

2. Can G, Okten A, Kaya G. The effects of the local camps on children with type I diabetes mellitus. Annals of Medical Sciences 2001;10(2):68-70.

3. Daley B. The use of activities in the approach to non-compliance in the treatment of juvenile diabetes. Int J Adolesc Med Health 1985;1(3-4):255-63.

4. Deris-Atassi S. A program design for Hispanic caregivers of children with newly diagnosed type 1 diabetes mellitus [dissertation]. Miami, FL: Carlos Albizu University; 2002.

5. Krause ER. Influence of self-monitoring and visual discrimination training on children's accuracy in blood glucose monitoring (diabetes, teaching straegies, error analysis) [dissertation]. Denver, CO: University of Denver; 1984.

6. Lavalle F, De la Garza N, Martinez I, et al. Forgetfulness curve, exposure to an educational program for youths with type 1 diabetes [abstract]. Diabetes 1998;47(Suppl 1):A382.

7. Malasanos TH, Burlingame JB, Youngblade L, et al. Improved access to subspecialist diabetes care by telemedicine: cost savings and care measures in the first two years of the FITE diabetes project. J Telemed Telecare 2005;11(Suppl 1):74-6.

8. Nurick M, Johnson SB. Enhancing blood glucose awareness in adolescents and young adults with IDDM. Diabetes Care 1991;14(1):1-7.

9. Razeghi S, Renner C, Schafer S, et al. Project D: computer-mediated communication as a tool for self-help in children and adolescents with diabetes. Diabetes Educ 1998;24(5):577-80.

10. Salvatoni A, Pompili V, Biasoli R, et al. ["Governare il diabete" ("to steer diabetes"): a new proposal for diabetic camps]. Acta Biomed Ateneo Parmense 2003;74(Suppl 1):29-31. (Ital).

11. Silverstein JH, Bandyopadhyay R. Camping with a friend. Helping adolescents cope with diabetes. J Fla Med Assoc 1995;82(12):817-20.

12. Solowiejczyk J. The family approach to diabetes management: theory into practice toward the development of a new paradigm. Diabetes Spectrum 2004;17(1):31-6.

13. Wangberg SC, Arsand E, Andersson N. Diabetes education via mobile text messaging. J Telemed Telecare 2006;12(Suppl 1):55-6.

14. Waszak LC. The effects of parent education on adherence and metabolic control of children with insulin-dependent diabetes mellitus [dissertation]. Pittsburgh, PA: University of Pittsburgh; 1987.

Reporting

The following 37 studies were excluded because they did not provide a description of the intervention that was sufficient to reproduce it, or they did not provide measurable data for outcomes relevant to this review.

1. Ahern J, Ramchandani N, Cooper J, et al. Using a primary nurse manager to implement DCCT recommendations in a large pediatric program. Diabetes Educ 2000;26(6):990-4.

2. Arraya G, Trave D, Benavent M. [The influence of education for metabolic control in infant-youth diabetes patients]. Revista ROL de Enfermeria 1998;21(235):51-4. (Span).

3. Auslander WF. Brief family interventions to improve family communication and co-operation regarding diabetes management. Diabetes Spectrum 1993;6:330-3.

4. Basso R. A structured-fantasy group experience in a children's diabetic education program. Patient Educ Couns 1991;18(3):243-51.

5. Codner DE, Mericq GV, Garcia BH, et al. Results of a multidisciplinary and intensified treatment program for type 1 diabetes mellitus in a Chilean public hospital. Rev Med Chil 2003;131(8):857-64.

6. Dammacco F, Torelli C, Frezza E, et al. Computer based instruction of diabetic children and adolescents. Techniques and results. J Endocrinol Invest 1989;12(8 suppl 3):141-2.

7. Delamater AM, Smith J, Kurtz SM, et al. Dietary skills and adherence in children with type I diabetes mellitus. Diabetes Educ 1988;14(1):33-6.

8. Follansbee DJ , Lagreca AM, Citrin WS. Coping skills training for adolescents with diabetes [abstract]. Diabetes 1983;32(Suppl 1):A37.

9. Hansson K, Ryden O, Johnsson P. Parent-rated family climate: a concomitant to metabolic control in juvenile IDDM. Fam Syst Med 1994;12(4):405-13.

10. Hardway D, Weatherly KS, Bonheur B. Diabetes education on wheels. J Nurs Staff Dev 1993;9(3):122-6.

11. Hedbrant J, Ludvigsson J. Use of computer simulator training in the education of diabetic teenagers. Practical Diabetes International 1995;12(1):18-21.

12. Heidgerken AD, Adkins J, Storch E, et al. Telehealth intervention for adolescents with type 1 diabetes. J Pediatr 2006;148(5):707-8.

13. Hunter HL, Rosnov DL, Koontz D, et al. Camping programs for children with chronic illness as a modality for recreation, treatment, and evaluation: an example of a mission-based program evaluation of a diabetes camp. J Clin Psychol Med Settings 2006;13(1):67-80.

14. Jones E, Murphy LG. The efficacy of intensive individual play therapy for chronically ill children. International Journal of Play Therapy 2002;11(1):117-40 .

15. Kaufman FR, Costin G, Roe TF, et al. The efficacy of a residential-treatment program (RTP) for childhood diabetes-mellitus (JDM) [abstract]. Diabetes 1986;35(Suppl 1):A79.

16. Keeter EL, Linehan MS. Affecting children's attitudes toward diabetes through camp. Nurse Pract 1993;18 (8):25-6.

17. Kieren DK, Hurlbut NL, Looney T, et al. Designing a family problem solving training program with an adolescent diabetic. Paper presented at the Conference of the National Council on Family Relations; 1987 November 3-7; Atlanta, GA.

18. Knight KM, Bundy C, Morris R, et al. The effects of group motivational interviewing and externalizing conversations for adolescents with type-1 diabetes. Psychol Health Med 2003;8(2):149-57.

19. Koplatadze K, Koplatadze M, Kacharava L, et al. Diabetes camps: an international experience. Mo Med 2003;100(2):145-7.

20. Kurmacheva N, Svinaryov MY, Kireev R, et al. Self-control teaching and its influence on insulin-dependent diabetes mellitus complications incidence in children [abstract]. Diabetes Nutr Metab 1999;12(3):229.

21. Lorini R, Ciriaco O, Salvatoni A, et al. The influence of dietary education in diabetic children. Diabetes Res Clin Pract 1990;9(3):279-85.

22. MacDonald MJ , Kerouz N, Hayek R, et al. Early referral of children with IDDM to a specialized program correlates with better long-term metabolic control. Diabetes Care 1993;16(9):1310-1.

23. Malasanos TH , Patel BD, Stein JM, et al. FITE Diabetes: improved access to sub-specialist care by telemedicine; no detrimental effect on A1c over 3 years [web page]. 2006; Available at: http://scientificsessions.diabetes.org/Abstracts/index.cfm?fuseaction=Locator.SearchAbstracts. Accessed 2007.

24. Maryniuk MD, Kauwell GPA, Thomas RG. A test of instructional approaches designed to influence food selection...children and adolescents with diabetes. Diabetes Educ 1986;12(1):34-6.

25. McKelvey J, Borgersen M. Family development and the use of diabetes groups: experience with a model approach. Patient Educ Couns 1990;16(1):61-7.

26. Misuraca A, Di Gennaro M, Lioniello M, et al. Summer camps for diabetic children: an experience in Campania, Italy. Diabetes Res Clin Pract 1996;32(1-2):91-6.

27. Nordfeldt S, Ludvigsson J. Prevention of severe hypoglycaemia in type 1 diabetes children. A prospective intervention study 1995-98 [abstract]. Diabetologia 1999;42(Suppl 1):A256.

28. Opipari AL, Kichler J, Fredericks E, et al. The Kids Project: medical and psychosocial outcomes of an intervention to kick in diabetes support for economically disadvantaged adolescents with type 1 diabetes mellitus [abstract]. Pediatr Res 2004;55(4):137A.

29. Scharf LS. Efficacy of diabetes camp in improving psychological adjustment of adolescents [dissertation]. Detroit, MI: Wayne State University; 1985.

30. Shaltout A, Qabazard M, Khawari M, et al. Towards improving care for children with diabetes in Kuwait. Int J Health Care Qual Assur 1995;8(7):4-8.

31. Spevack M, Johnson S, Bennett R, et al. The effect of diabetes summer camp on adherence behaviors and glycemic control. In: Johnson JH, Johnson SB, eds. In: Advances in child health psychology. Gainesville, FL: J Hillis Miller Health Science Center; 1991. p. 285-92.

32. Stinchfield PA. Evaluation of an education program for Type I diabetics [dissertation]. Salt Lake City, UT: University of Utah College of Nursing; 1987.

33. Strickland BR. Management of diabetic children by behavior-modification and blood-glucose monitoring [abstract]. Drug Intell Clin Pharm 1983;17(6):438.

34. von Sengbusch S, Wagner V, Muller GE, et al. [Mobile Diabetes Education Programme Schleswig-Holstein (Mdsh). A new training concept and model for diabetes care for children and adolescents with type 1 diabetes and its effects on the family burden]. Kindheit Und Entwicklung 2005;14(2):96-102. (Ger).

35. Weist MD, Finney JW, Barnard MU, et al. Empirical selection of psychosocial treatment targets for children and adolescents with diabetes. J Pediatr Psychol 1993;18(1):11-28.

36. Zhou YH, Lin CL, Zhou M, et al. [Interventional effect of cognitive education on the quality of life in 227 patients with diabetes mellitus from 4 hospitals in Meizhou city.] Chinese Journal of Clinical Rehabilitation [Zhongguo Linchuang Kangfu] 2005;9(24):40-1. (Chinese).

37. Zimmerman E, Carter MC, Sears JH, et al. Diabetic camping: effect on knowledge, attitude, and self-concept. Issues Compr Pediatr Nurs 1987;10(2):99-111.

Small Sample Size (n≤10)

The following nine studies were excluded because there were ≤ 10 participants enrolled in the study.

1. Albrecht SJ. Increasing blood glucose monitoring in adolescents with type 1 diabetes: effects of a prompt [dissertation]. Kalamazoo, MI: Western Michigan University; 2005.

2. Hains A, Davies WH, Parton E, et al. Brief report: a cognitive behavioral intervention for distressed adolescents with type I diabetes. J Pediatr Psychol 2001;26(1):61-6.

3. Hains AA, Davies W, Hobart P, et al. A cognitive behavioral intervention for distressed adolescents with Type I diabetes. J Pediatr Psychol 2001;26(1):61-6.

4. Lasecki KL. Normalizing blood glucose levels in children with type I diabetes: mystery motivators used within the context of behavioral consultation models [dissertation]. Salt Lake City, UT: University of Utah; 2000.

5. Marrero DG, Fremion AS, Golden MP. Improving compliance with exercise in adolescents with insulin-dependent diabetes mellitus: results of a self-motivated home exercise program. Pediatrics 1988;81(4):519-25.

6. Oksol EM. A treatment development study: a preliminary analysis of a new treatment for parents of diabetic children in poor glycemic control [dissertation]. Reno, NV: University of Nevada; 2004.

7. Rose MI, Firestone P, Heick HM, et al. The effects of anxiety management training on the control of juvenile diabetes mellitus. J Behav Med 1983;6(4):381-95.

8. Silverman AH. Increasing regimen adherence in adolescents with type I diabetes [dissertation]. Milwaukee, WI: University of Wisconsin; 2002.

9. Silverman AH, Hains A, Davies WH, et al. A cognitive behavioral adherence intervention for adolescents with type 1 diabetes. J Clin Psychol Med Settings 2003;10(2):119-27.

Studies Unavailable

The following 46 studies were requested through our interlibrary loan service but did not arrive within the 7-month cut-off that we established for article retrieval.

1. Diabetes program teaches kids to be case managers. Dis State Manag 1997;3(11):138-40.

2. Ambrosino J, Fennie K, Hendrickson K, et al. Coping skills training with parents of school-aged youth with type 1 diabetes (T1d) improves family functioning [abstract]. Diabetes 2005;54(Suppl 1):A18.

3. Assaad-Khalil SH, El Siwy F, Kamel KF, et al. Impact of an educational video film: “The Jinn's Party” on the knowledge, practices and attitudes of school children and adolescents with type 1 diabetes and their parents. Diabetologia 2003;46(Suppl 2):A91.

4. Bartus B, Hecker W. Age-adapted hypoglycemia awareness training for children and adolescents with insulin-dependent diabetes-mellitus (Iddm) [abstract]. Diabetologia 1994;37(Suppl 1):A19.

5. Bellando BJ. Changes in short-term and long-term control of diabetes after participation in Blood Glucose Awareness Training [dissertation]. Lubbock, TX: Texas Tech University; 1989.

6. British Diabetic Association. Education and Professional Care Section and Medical and Scientific Section 1995 Oct 4-6; Harrogate. Diabet Med 1995;12(10 Number Sup 2):S1-56.

7. British Diabetic Association. Education and Professional Care section annual conference 1994 Sep 7-9 and Medical and Scientific Section autumn meeting 1994 Sep 8-9; Lancaster. 1994;11(Suppl 2):S1-51.

8. British Dietetic Association. Conference of the Community Nutrition Group and Health Education Authority; 1991 March; London. In: Hurren CA, Black AE, eds. The food network: achieving a healthy diet by the year 2000. London: Smith-Gordon; 1991.

9. Campaigne B. The effects of a physical activity program on children ages 5 to 11 years with insulin-dependent diabetes mellitus [dissertation]. Ann Arbor, MI: University of Michigan; 1982.

10. Charron Prochownik D, Becker D, Sereika S, et al. The impact of a newly developed CD-ROM reproductive health education program on teens with diabetes [abstract]. Diabetes 2001;50(Suppl 2):A25-A26.

11. Clawson E, Kade D, Dickens M. Efficacy of a rehabilitation program for children and adolescents who are chronically noncompliant with diabetes management [abstract]. Diabetes 1996;45(Suppl 2):38.

12. Cook S, McNabb WL. Problem-solving program for adolescents with diabetes: choices [abstract]. Diabetes 1999;48(Suppl 2):A158.

13. Dammacco F, Frezza E, Torelli C, et al. Computerized mastery learning instruction of diabetic children [abstract]. Diabetologia 1984;27(2):A266-A267.

14. Etzwiler DD. Education and participation of patients and their families. Pediatr Ann 1983;12(9):638-40,642.

15. Fekete D, Guare J, Marrero D, et al. Self-management of "off diet" food intake by adolescents and young adults with insulin-dependent diabetes mellitus (Iddm). Diabetes 1997;46(Suppl 1):1016.

16. Follansbee DJ. Coping skills training for adolescents with insulin dependent diabetes mellitus [dissertation]. Miami, FL: University of Miami; 1984.

17. Franzen I, Ludvigsson J. Specific instructions gave reduction of lipomas and improved metabolic control in diabetic children [abstract]. Diabetologia 1997;40(Suppl 1):2421.

18. Furman SG. The effect of assertiveness training on locus of control and metabolic control of adolescents with diabetes mellitus [dissertation]. Ft. Lauderdale, FL: Nova University School of Psychology; 1983.

19. George C. Video in pediatric patient education: the role of formal features in the relationship of intervention, knowledge, and anxiety [dissertation]. Austin, TX: University of Texas at Austin; 1991.

20. Gordeladze MR, Marinashvili N. Differential diabetes education program for children and adolescents its role and results [abstract]. Diabetologia 2002 ;45(Suppl 2):A19-A20.

21. Halvorson M, Kaufman FR, Carpenter S. Evaluation of a comprehensive childhood diabetes program with intensive management [abstract]. Diabetes 1996;45(Suppl 2):532.

22. Halvorson MJ, Kaufman FR, Engilman R. Comparison of a diabetes Cd-Rom program, diabetes video game and diabetes kids class in diabetes management and knowledge acquisiton in children ages 5-10 with type 1 diabetes [abstract]. Diabetes 1999;48(Suppl 1):A73.

23. Harris R. Diabetic teddies help children to learn. ACCNS Journal for Community Nurses 2003;8(2):6.

24. Hayes JR. Controlling glucose levels of adolescents with diabetes through the use of a voice processing system [dissertation]. Columbus, OH: Ohio State University; 1996.

25. Howells L. Telephone support to improve outcomes in young people. Journal of Diabetes Nursing 2001;5(3):94.

26. Huttunen NP, Lankela SL, Knip M, et al. Effect of a once-a-week training-program on physical-fitness and metabolic control of diabetes in children with type-1 diabetes [abstract]. Acta Endocrinol (Copenh) 1987;115(Suppl 282):23.

27. International Society for Pediatric and Adolescent Diabetes. 6th ISPAD Workshop: controversial issues in childhood and adolescent diabetes mellitus; 1997 April; Garda, Italy. In: Journal of Pediatric Endocrinology and Metabolism, Laron Z, Pinelli L. eds.; Tel Aviv, Israel: Freund Publishing House; 1998.

28. Kaufman V. The effect of educational and psychological programs on metabolic management and glycemic control in diabetes mellitus [dissertation]. San Diego, CA: California School of Professional Psychology—San Diego; 1987.

29. Levine BS, Anderson B, Butler D, et al. Care Ambassador (CA) intervention reduces costly adverse outcomes in youth with type 1 diabetes: a randomized, controlled trial [abstract]. Diabetes 2000;49(Suppl 1):A220-A221.

30. Marrero DG. Adjustment to misfortune: an intervention program to improve metabolic stability of insulin dependent diabetes mellitus in adolescents [dissertation]. Irvine, CA: University of California, Irvine; 1983.

31. Morimoto M, Fukumoto H, Kawabata E. Family education program for the hospitalized diabetic patients [abstract]. Diabetologia 1997;40(Suppl 1):2419.

32. Murkin SA, Snyder GM, Pichert JW, et al. Anchored instruction enhances diabetes problem solving. Diabetes Care 1990;39:8.

33. Okoawo IJ. Diabetic education and follow-up program: test of a model [dissertation]. Boston, MA: Boston University; 1984.

34. Opipari AL, Kichler J, Fredericks E, et al. Self-management intervention improves diabetes-related functioning in at-risk adolescents with type 1 diabetes [abstract]. Diabetes 2005;54(Suppl 1):A455.

35. Pyorala E. Interaction strategies in dietary counselling of diabetic children [abstract]. Diabetologia 1997;40(Suppl 1):45.

36. Rajab A, Sadegian HA. The effect of home visiting program on blood glucose control in diabetic children in Iran [abstract]. Diabetologia 1997;40(Suppl 1):2395.

37. Rami B, Schober E, Popow C, et al. Vie-Diab: telemedical support programme for adolescents with type 1 diabetes mellitus [abstract]. Diabetologia 2004;47(Suppl 1):A348.

38. Schiel R, Perenthaler TJ, Kovar F, et al. Metabolic control and interactions with diabetes-related knowledge, motivational problems and technical devices in children and adolescents with type 1 diabetes mellitus—DIDOM, an intervention trial [abstract]. Diabetologia 2005;48:A326-A327.

39. Sharma A. Diabetes prevention, education and treatment. International Journal of Diabetes 1994;2(3).

40. Sheldon AW. Computer-assisted diet and exercise training in the behavioral treatment of Type I diabetes [dissertation]. Miami, FL: University of Miami; 1996.

41. Silverman AH , Opipari ALC, Lang SW, et al. Intensive therapy and self-management training in pediatric medicaid patients with IDDM: perceptions of adolescents, parents and physicians [abstract]. Pediatr Res 2002;51(4):124A.

42. Sperlich SB. A diabetic camp: its implications for coping with juvenile diabetes mellitus [dissertation]. Washington, DC: The Catholic University of America; 1982.

43. Stinchfield PA. Evaluation of an education program for type 1 diabetes [dissertation]. Salt Lake City, Ut: University of Utah College of Nursing; 1987.

44. Szumowski EK. A family-oriented developmental and behavioral intervention to increase adherence by diabetic children to their treatment regimens [dissertation]. Pittsburgh, PA: University of Pittsburgh; 1991.

45. Tomasi F, Miselli V. Continuing and reinforcing patient education and metabolic control after a summer camp for diabetic children [abstract]. Diabetologia 1989;32(7):A548.

46. Wysocki T, Greco P, Harris M, et al. Behavior therapy for families of adolescents with Iddm: maintenance of treatment effects [abstract]. Diabetes 1997;46(Suppl 1):351.

Appendix E. Secondary Studies

Table E1. Description of secondary studies

Primary report: Anderson BJ, Brackett J, Ho J, et al. An office-based intervention to maintain parent-adolescent teamwork in diabetes management. Impact on parent involvement, family conflict, and subsequent glycemic control. Diabetes Care 1999;22(5):713-21. **Associated publications:** Anderson BJ, Brackett J, Ho J, et al. An intervention to promote family teamwork in diabetes management tasks: relationships among parental involvement, adherence to blood glucose monitoring, and glycemic control in young adolescents with type 1 diabetes. In: Drotar D ed. Promoting adherence to medical treatment in chronic childhood illness: concepts, methods, and interventions. Mahwah, NJ: Lawrence Erlbaum Associates Publishers; 2000. p. 347-65.
Primary report: Anderson BJ, Wolf FM, Burkhart MT, et al. Effect of peer-group intervention on metabolic control of adolescents with IDDM. Randomized outpatient study. Diabetes Care 1989;12(3):179-83. **Associated publications:** Anderson BJ, Burkhart M, Tomlin P, et al. Behavioral and metabolic effects of a controlled self-efficacy group intervention with diabetic adolescents. Diabetes 1986;35(Suppl 1):A78.
Primary report: Brown SJ, Lieberman D, Germeny B, et al. Educational video game for juvenile diabetes: results of a controlled trial. Med Inform (Lond) 1997;22(1):77-89. **Associated publications:** Lieberman DA. Health education video games for children and adolescents: theory, design, and research findings. Paper presented at the 48th Annual Meeting of the International Communication Association; 1998 July 20-24; Jerusalem, Israel.
Primary report: Grey M, Boland E, Davidson, et al. Coping skills training for youth with diabetes mellitus has long-lasting effects on metabolic control and quality of life J Pediatr 2000;137:107-03. **Associated publications:** Grey M, Yu C, Boland E, et al. Short-term effects of coping skills training as adjunct to intensive therapy in adolescents. Diabetes Care 1998;21:902-08.
Primary report: Hackett AF, Court S, Matthews JNS, et al. Do education groups help diabetics and their parents. Arch Dis Child 1989;64(7):977-1003. **Associated publications:** Hackett A. Food intake of children with diabetes mellitus before and after a programme of education [dissertation]. United Kingdom: University of Newcastle Upon Tyne; 1987.

Table E1. Description of secondary studies (continued)

Primary report:
Harris M, Harris BS, Mertlich D. Brief report: in-home family therapy for adolescents with poorly controlled diabetes: failure to maintain benefits at 6-month follow-up. J Pediatr Psychol 2005;30(8):683-8.

Associated publications:
Harris M, Mertlich D. Piloting home-based behavioral family systems therapy for adolescents with poorly controlled diabetes. Child Health Care 2003;32(1):65-79.

Primary report:
Hoff AL, Mullins LL, Gillaspy SR, et al. An intervention to decrease uncertainly and distress among parents of children newly diagnosed with diabetes: a pilot study. Fam Syst Health 2005;23(3):329-42.

Associated publications:
Hoff AL. An intervention to decrease illness uncertainty and psychological distress among parents of children newly diagnosed with type 1 diabetes: a randomized clinical trial [dissertation]. Oklahoma: Oklahoma State University; 2003.

Primary report:
Laffel LMB, Vangsness L, Connell A, et al. Impact of ambulatory family-focused teamwork intervention on glycemic control in youth with type 1 diabetes. J Pediatr 2003;142(4):409-16.

Associated publications:
Butler D, Volkening LK, Milaszewski K, et al. Family-focused teamwork intervention for youth with type 1 diabetes (T1DM) positively impacts A1c and quality of life (QoL): results of a 2-year randomized controlled trial. Diabetes 2006;55:A421-A421.

Laffel LMB, Connell AJ, Vangsness LJ, et al. Family-focused ambulatory teamwork (TW) intervention improves a1c compared with standard care (SC) in youth with type 1 diabetes (T1DM): results of a randomized trial. Diabetes 2002;51:A424.

Primary report:
Nordfeldt S Johansson C Carlsson E Hammersjo J. Persistent effects of a pedagogical device targeted at prevention of severe hypoglycaemia: a randomized, controlled study. Acta Paediatrica 2005;94(10):1395-401.

Associated publications:
Nordfeldt S, Johansson C, Carlsson E, et al. Prevention of severe hypoglycaemia in type I diabetes: a randomised controlled population study. Arch Dis Child 2003;88(3):240-5.

Primary report:
Siminerio LM , Charron PD, Banion C, et al. Comparing outpatient and inpatient diabetes education for newly diagnosed pediatric patients. Diabetes Educator 1999;25(6):895-906.

Associated publications:
Siminerio LM. Comparing outpatient to inpatient diabetes education for newly diagnosed pediatric patients: an exploratory study [dissertation]. Pennsylvania: Pennsylvania State University; 1998.

Table E1. Description of secondary studies (continued)

Primary report:
Wysocki T, Harris M, Greco P, et al. Randomized, controlled trial of behavior therapy for families of adolescents with insulin-dependent diabetes mellitus. J Pediatr Psychol 2000;25(1):23-33.

Associated publications:
Harris M, Greco P, Wysocki T, et al. Family therapy with adolescents with diabetes: a litmus test for clinically meaningful change. Fam Syst Health 2001;19:159-68.

Wysocki T, Greco P, Harris M, et al. Behavior therapy for families of adolescents with diabetes: maintenance of treatment effects. Diabetes Care 2001;24:441-6.

Wysocki T, Greco P, Harris MA, et al. Behavioral Family Systems Therapy for adolescents with diabetes. In: Drotar D ed. Promoting adherence to medical treatment in chronic childhood illness: concepts, methods, and interventions. Mahwah, NJ: Lawrence Erlbaum Associates Publishers; 2000. p. 367-81.

Wysocki T, Miller KM, Greco P, et al. Behavior therapy for families of adolescents with diabetes: effects on directly observed family interactions. Behav Ther 1999;30(3):507-25.

Primary report:
Wadham C, Hassler Hurst J, Almond J, et al. Integrating group education into paediatric diabetes care: FACTS. J Diabetes Nurs 2005;9(6):221-5.

Associated publications:
Murphy HR, Wadham C, Rayman G, et al. Integrating pediatric diabetes education into routine clinical care: The Families, Adolescents and Children's Teamwork Study (FACTS). Diabetes Care 2006;29(5):1177.

Primary report:
Sundelin J, Forsander G, Mattson SE. Family-oriented support at the onset of diabetes mellitus: a comparison of two group conditions during 2 years following diagnosis. Acta Paediatrica 1996;85:49-55.

Associated publications:
Forsander G, Malmodin B, Eklund C, et al. Relationship between dietary intake in children with diabetes mellitus type I, their management at diagnosis, social factors, anthropometry and glycaemic control. Scand J Nutrition/Naringsforskning 2003;47(2):75-84.

Forsander G, Persson B, Sundelin J, et al. Metabolic control in children with insulin-dependent diabetes mellitus 5 y after diagnosis. Early detection of patients at risk for poor metabolic control. Acta Paediatrica 1998;87(8):857-64.

Table E1. Description of secondary studies (continued)

Primary report:
Wysocki T, Harris MA, Buckloh LM, et al. Randomized trial of behavioral family systems therapy for diabetes: maintenance of effects on diabetes outcomes in adolescents. Diabetes Care 2007;30(3):555-60.

Associated publications:
Wysocki T, Harris MA, Buckloh LM, et al. Effects of behavioral family systems therapy for diabetes on adolescents' family relationships, treatment adherence, and metabolic control. J Pediatr Psychol 2006;31(9):928-38.

Wysocki T, Harris MA, Buckloh LM, et al. Effects of behavioral family systems therapy on adolescents' diabetes outcomes. Diabetes 2005;54(Suppl 1):A19.

Appendix F. Evidence Tables

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Anderson[5] 1999	89 RCT (parallel) United States	**IG1** 12.7 yr. ±1.40 50% **IG2** 12.7 yr. ±1.40 50% **CG** 12.5 yr. ±1.4 52%	**IG1** 5.3 yr. ±2.56 8.3%±1.10 **IG2** 6.1 yr. ±2.78 8.7%±1.19 **CG** 5.2 yr. ±2.17 8.6%±0.97	Duration of diabetes >1 yr.	**IG1** – Diabetes responsibilities **IG2** – Didactic diabetes education **CG** – Standard care Diabetes center
Anderson[6] 1989	70 RCT (parallel) United States	**IG** 12.9 yr. 46.7% **CG** 12.5 yr. 46.7%	**IG** 4.9 yr. ±3.2 10.47%±2.30 **CG** 5.1 yr. ±3.3 10.42%±1.9	Duration of diabetes >1 yr.	**IG** – Self-management skills, problem solving **CG** – Standard care Clinic
Barglow[7] 1983	42 CCT United States	**IG** 13.4 yr. ±3.3 43% **CG** 12.2 yr. ±2.5 24%	**IG** 4.9 yr. ±3.8 12.2%±2.3 **CG** 3.2 yr. ±3.0 12.1%±3.5		**IG** – Intensive treatment **CG** – Standard care Diabetes center
Boardway[8] 1993	31 RCT (parallel) United States	**IG** 15.44 yr. ±1.19 22.2% **CG** 14.32 yr. ±1.71 60.0%	**IG** 6.92 yr. ±5.79 13.99%±2.41 **CG** 6.34 yr. ±2.61 15.74%±3.57	Noncompliance and/or poor metabolic control	**IG** – Stress management plus self-management skills **CG** – Standard care Outpatient clinic

CG = control group; IG = intervention group; NR = not reported; TG = total group

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Brown[9] 1997	59 RCT (parallel) United States	**IG** NR **CG** NR	**IG** NR 8.47%±1.64 **CG** NR 8.28%±1.89	Duration of diabetes >3 mo.	**IG** – Diabetes video game **CG –** Pinball video game Home
Campaigne[10] 1985	16 RCT (parallel) United States	**IG** 16.0 yr. ±3 33.3% **CG** 15.0 yr. ±0.9 60.0%	**IG** 6.6 yr. ±3.3 12.0%±3.0 **CG** 6.2 yr. ±2.5 12.0%±2.2		**IG** – Exercise sessions **CG** – Standard care NR
Caravalho[11] 2000	56 Uncontrolled before-and-after study United States	**IG** 9.8 yr. 45%	**IG** 3 yr. 9.15%±2.32		**IG** – Self-management skills, telephone assessments Home, diabetes center
Christensen[12] 2000	68 Uncontrolled before-and-after study United States	**IG** NR 47.1%	**IG** 5.04 yr. 9.6%		**IG** – Nutrition and diet Camp
Cigrang[13] 1991	37 RCT (parallel) United States	**IG1** 14.6 yr. ±1.6 46.7% **IG2** 13.5 yr. ±1.7 30.8% **CG** 13.9 yr. ±1.4 55.6%	**IG1** 4.9 yr. ±2.9 9.07%±0.88 **IG2** 4.5 yr. ±2.9 9.92%±2.2 **CG** 6.7 yr. ±3.5 8.91%±1.2	Poor metabolic control	**IG1** – Stress coping strategies **IG2** – Diabetes lectures **CG** – Standard care Hospital

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Couper[14] 1999	69 CCT Australia	**IG** 14.2 yr. ±1.7 48.6% **CG** 14.3 yr. ±1.9 31.3%	**IG** 7.08 yr. ±3.6 11.1%±1.3 **CG** 5.83 yr. ±3.0 10.5%±1.6	Poor metabolic control	**IG** – Goal setting **CG** – Standard care Hospital, home
Coupland[15] 1992	32 RCT (parallel) Canada	**IG** 14.5 yr. ±1.41 53% **CG** 14.7 yr. ±1.75 33%	**IG** 4.80 yr. ±2.59 11.6%±1.4 **CG** 6.64 yr. ±3.02 11.3%±1.22	Noncompliance and/or poor metabolic control	**IG** – General diabetes knowledge and family adherence **CG** – General diabetes knowledge, stress coping NR
Delamater[16] 1991	13 RCT (parallel) United States	**IG1** NR 33% **CG** NR 57% **TG** 14.9 yr. 46%	**IG** NR **CG** NR **TG** 6.5 yr. range: 2.5–15 yr. 10.9%±1.6	Noncompliance and/or poor metabolic control	**IG** – Self-management skills, psychosocial skills **CG** – Standard care Hospital outpatient clinic
Delamater[17] 1990	36 RCT (parallel) United States	**IG1** 9.3 yr. ±3.9 58% **IG2** 8.6 yr. ±4.1 50% **CG** 9.8 yr. ±2.6 50%	**IG1** < 4 mo. 10.4%±3.1 **IG2** < 4mo. 11.1%±2.4 **CG** < 4 mo 12.3%±2.5	Newly diagnosed	**IG1** – Self-management skills and problem solving **IG2** – Psychosocial adjustment **CG** – Standard care Hospital, home

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Dougherty[18] 1999	63 RCT (parallel) Canada	**IG** 10.7 yr. ±3.9 40.6% **CG** 9.8 yr. ±3.9 48.4%	**IG** 0 yr. 10.0%±2.0 **CG** 0 yr. 10.7%±1.3	Newly diagnosed	**IG** – General diabetes knowledge (in home) **CG** – General diabetes knowledge (in hospital) Hospital, home
Golden[19] 1985	19 CCT United States	**IG1** 2.7 yr. 54.54% **IG2** NR 62.5%	**IG1** NR **IG2** NR	Newly diagnosed	**IG1** – Diabetes management in motel-like setting **IG2** – Delayed IG1 Diabetes center, parent care unit, a motel-like setting
Greco[20] 2001	23 Uncontrolled before-and-after study United States	**IG** 13.1 yr. ±1.98 52.38% **IG (Peer)** 13.6 yr. ±2.25 52.38%	**IG** 0.7025 yr. ±0.385 NR **IG (Peer)** NA		**IG** – General diabetes knowledge, listening and problem solving skills, stress management **IG (Peer)** – a "best friend" received the same intervention Outpatient clinic
Grey[21] 2000	77 RCT (parallel) United States	**IG** 14.1 yr. ±1.8 48.8% **CG** 14.6 yr. ±2.2 35.3%	**IG** NR 9.1%±1.4 **CG** NR 9.2%±1.5	Duration of diabetes >1 yr.	**IG** – Coping skills training **CG** – Standard care Hospital, home

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Gross[22] 1985	14 RCT (parallel) United States	**IG** 11.4 yr. 57.14% **CG** 11.5 yr. 28.57% **TG** 11.4 yr. 42.85%	**IG** NR **CG** NR **TG** 4.8 yr.	≥3 deficit social skill behaviors	**IG** – Behavior modification **CG** – Open-ended discussion NR
Gross[23] 1983	11 RCT (parallel) United States	**IG** NR	**IG** NR		**IG –** Social training **CG** – No social training Treatment room
Hackett[24] 1989	119 RCT (parallel) United Kingdom	**IG1** 12.7 yr. ±2.9 62.5% **IG2** 11.4 yr. ±3.3 65.5% **IG3** 12.4 yr. ±3.6 53.1% **CG** 11.7 yr. ±3.3 69.2%	**IG1** 4.6 yr. ±2.9 11.1%±2.7 **IG2** 5.9 yr. ±2.8 11.2%±1.7 **IG3** 5.3 yr. ±3.2 11.0%±2.3 **CG** 5.0 yr. ±3.1 10.8%±2.1		**IG1** – General diabetes knowledge and reinforcement sessions **IG2** – General diabetes knowledge **IG3** – General diabetes knowledge, 10 mo. after IG1 and IG2 **CG** – No intervention Clinic
Hains[25] 2000	15 RCT (parallel) United States	**IG** NR 37.5% **CG** NR 50.0%	**IG** NR 10.06%±1.07 **CG** NR 9.95%±1.42	Poor metabolic control	**IG** – Cognitive behavioral stress training **CG** – No intervention Hospital

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Hakimi[26] 1998	35 RCT (parallel) United States	**IG** 11.4 yr. ±2.5 26.7% **CG** 11.7 yr. ±2.7 55.5% **TG** 11.5 yr. ±2.5 37.5%	**IG** 0 yr. NR **CG** 0 yr. NR **TG** 0 yr. NR	Newly diagnosed	**IG** – General diabetes knowledge plus psychosocial issues **CG** – General diabetes knowledge NR
Harkavy[27] 1983	93 Uncontrolled before-and-after study United States	**IG** 13.2 yr. 48%	**IG** 4.7 yr. NR		**IG** – General diabetes education Camp
Harris[28] 2005	18 Uncontrolled before-and-after study United States	**IG** 67 yr. NR	**IG** 14.7 11.3%±1.5	Noncompliance and/or poor metabolic control	**IG** – Behavioral family systems therapy Home
Hill[29] 2006	134 Prospective cohort with concurrent control United States	**IG** NR **CG** NR 50% **TG** NR 50%	**IG** NR **CG** NR **TG** NR		**IG** – General diabetes knowledge, choice and sense of self-control **CG** – Regular camp Camp

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Hoff[30] 2005	46 RCT (parallel) United States	**IG** 9.3 yr. ±4.7 47% **CG** 9.4 yr. ±3.4 59% **TG** 9.4 yr. ±4.1 53%	**IG** < 6mo. NR **CG** < 6 mo. NR **TG** < 6 mo. NR	Newly diagnosed	**IG –** Construct of illness, uncertainty management **CG** – Standard care Hospital endocrinology clinic
Horan[31] 1990	20 RCT (parallel) United States	**IG** NR 30.0% **CG** NR 30.0%	**IG** NR 10.0% **CG** NR 9.6%	Duration fo diabetes >1 yr.	**IG** – Dynamic and colourful education modules **CG –** Static, black-and-white education modules Home
Howe[32] 2005	89 RCT (parallel) United States	**IG1** 13.6 yr. ±2.0 57.1% **IG2** 12.1 yr. ±4.0 50.0% **CG** 12.2 yr. ±3.7 57.1%	**IG1** NR 10.1%±1.2 **IG2** NR 10.0%±1.4 **CG** NR 10.2%±1.4		**IG1 –** General diabetes knowledge (family session) **IG2** – IG1 plus telephone calls **CG** – Standard care Diabetes center, home
Kaplan[33] 1985	21 RCT (parallel) United States	**IG** 14.9 yr. ±1.6 40% **CG** 14.0 yr. ±1.4 36.4%	**IG** NR 12.6%±2.4 **CG** NR 13.5%±1.6		**IG** – Social skills training **CG** – General diabetes knowledge (lectures) Summer school

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Karaguzel[34] 2005	25 Uncontrolled before-and-after study Turkey	**IG** 13.2 yr. ±2.6 36%	**IG** 5.0 yr. ±4.1 9.28%±2.46	Moderate–poor metabolic control	**IG** – General diabetes education Camp
Kemp[35] 1986	42 Uncontrolled before-and-after study United States	**IG** 10 yr. NR	**IG** NR 8.1%±1.9		**IG** – General diabetes education Camp
Kennedy-Iwai[36] 1991	19 RCT (parallel) United States	**IG** 6.0 yr. ±3.2 NR **CG** 7.1 yr. ±4.4 NR	**IG** 0.75 yr. ±0.41 9.72%±2.73 **CG** 0.78 yr. ±0.43 8.69%±2.40	Newly diagnosed	**IG** – Communication program for parents **CG** – General diabetes education Home
Koontz[37] 2001	112 Uncontrolled before-and-after study United States	**IG1** NR 30.8% **IG2** NR 35.2% **IG3** NR 44.4%	**IG1** 5.85 yr. ±4.26 8.32%±1.60 **IG2** 5.56 yr. ±3.45 8.93%±2.06 **IG3** 4.22 yr. ±2.62 7.99%±1.42		**IG1** – General diabetes knowledge (grades 9–10) **IG2** – General diabetes knowledge (grades 6–8) **IG3** – General diabetes knowledge (grades 2–5) Camp

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Laffel[38] 2003	105 RCT (parallel) United States	**IG** 11.9 yr. ±2.4 54% **CG** 12.2 yr. ±2.2 52%	**IG** 2.7 yr. ±1.6 8.4%±1.3 **CG** 2.7 yr. ±1.6 8.3%±1.0		**IG** – General diabetes education, responsibility sharing **CG** – Standard care Diabetes center, home
Lawson[39] 2000	28 Retrospective cohort Canada	**IG1** 15.8 yr. ±4.0 NR **IG2** 15.0 yr. ±1.8 NR	**IG1** 7.7 yr. ±1.7 9.5%±1.2 **IG2** 6.8 yr. ±2.9 8.2%±1.3	Motivated to improve metabolic control	**IG1** – 6–8 hours, general diabetes knowledge, telephone calls **IG2** – 4 hours, general diabetes knowledge Diabetes center, home
Likitmaskul[40] 2002	52 Prospective cohort with historical control Thailand	**IG** 7.07 yr. ±3.87 45.8% **CG** 8.4 yr. ±3.26 35.7%	**IG** 0 yr. 17.42% **CG** 0 yr. 13.56%	Newly diagnosed	**IG** – Self-management skills, hypoglycemia **CG** – Standard care Hospital
Lipman[41] 1988	30 Retrospective cohort United States	**IG** 7.4 yr. ±4.3 81.8% **IG** 7.4 yr. ±3.5 69.2%	**IG** 0 yr. NR **CG** 0 yr. NR	Newly diagnosed	**IG** – Clinical nurse specialist plus staff nurses deliver education **CG** – Staff nurses deliver education Hospital

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Lucey[42] 1985	49 CCT United Kingdom	**IG** 11.7 yr. 50% **CG** 12.25 yr NR	**IG** NR **CG** NR	Poor theoretical and practical diabetes skills	**IG** – General diabetes knowledge, problem solving **CG** – No intervention NR
Mann[43] 1984	39 RCT (parallel) United Kingdom	**IG1** 11.2 yr. ±2.7 65% **IG2** 12.3 yr. ±2.2 52.6%	**IG1** 5.9 yr. ±3.3 12.7%±2.0 **IG2** 5.6 yr. ±3.2 14.1%±1.3	Poor metabolic control	**IG1** – Home visits, instructional videos, telephone contact **IG2** – IG1 plus graphically tracking of BG data Home, community, outpatient clinic
Marteau[44] 1987	97 Uncontrolled before-and-after study United Kingdom	**IG** 10.7 yr. 27.8%	**IG** NR		**IG** – Problem solving, self-help groups, best care Hotel
Mason[45] 1985	93 CCT United States	**IG** NR **CG** NR	**IG** NR **CG** NR		**IG** – Diabetes board game **CG** – Same as IG (non-diabetic) School, diabetes center

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Massouh[46] 1989	33 RCT (parallel) United States	**IG** 12.6 yr. ±0.712 41.1% **CG** 13.1 yr. ±0.987 50%	**IG** 3.9 yr. ±3.1 11.3%±3.3 **CG** 4.7 yr. ±3.5 11.5%±3.6		**IG –** General diabetes knowledge, plus social learning intervention **CG** – General diabetes knowledge Camp
McNabb[47] 1994	24 RCT (parallel) United States	**IG** 9.7 yr. NR **CG** 10 yr. NR **TG** 9.9 yr. 54%	**IG** NR 10.5%±2.9 **CG** NR 12.9%±3.8 **TG** NR		**IG –** Goal-setting, self-management (youths), parenting skills (parents) **CG** – Standard care Diabetes center
Mendez[48] 1997	37 CCT Spain	**IG** 13.83 yr. ±2.00 50% **CG** 13.36 yr. ±1.89 47%	**IG** 3.73 yr. ±3.93 NR **CG** 4.46 yr. ±3.52 NR		**IG** – Adherence behaviors **CG** – No data Health centre
Mitchell[49] 1996	32 RCT (parallel) Canada	**IG** 10.43 yr. ±2.44 53.3% **CG** 11.0 yr. ±2.35 58.8%	**IG** 0 yr. 7.0% **CG** 0 yr. 8.0%	Newly diagnosed	**IG** – Adherence behaviors **IG** – Standard care Diabetes center
Monaco[50] 1996	58 Uncontrolled before-and-after study United States	**IG** 8.5 yr. 50%	**IG** NR		**IG** – Injection site identification Diabetes center

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Moran[51] 1991	22 CCT United Kingdom	**IG** 13.4 yr. ±3.2 37.4% **CG** 14.0 yr. ±4.3 37.4%	**IG** 6.2 yr. ±4.3 14.3% **CG** 5.6 yr. ±2.3 13.7%	Poor metabolic control	**IG** – Psychotherapy **CG** – Standard care (hospital) Hospital, home
Nordfeldt[52] 2005	332 RCT (parallel) Sweden	**IG** 12.7 yr. ±4.1 45.6% **CG1** 12.5 yr. ±4.2 44.7% **CG2** 12.7 yr. ±3.9 45.6% **TG** 12.2 yr. ±4.1 45.3%	**IG** 4.9 yr. ±3.5 7.8%±1.4 **CG1** 5.6 yr. ±4.2 7.8%±1.3 **CG2** 5.2 yr. ±3.6 8.0%±1.8 **TG** 5.3 yr. ±3.8 7.9%±1.5	Duration of diabetes >0.5 yr.	**IG** – Self-management skills, 2 instructional videos, 2 brochures **CG1** – Standard care, 1 video, 1 brochure **CG2** – Standard care Home
Nordfeldt[53] 2002	130 Prospective cohort with historical controls Sweden	**IG** 12.2 yr. ±4.3 NR	**IG** 4.6 yr. ±3.7 6.6%±1.1		**IG** – Self-management skills, 2 instructional videos, 2 brochures Home
Nordfeldt[54] 1999	139 Prospective cohort with historical controls Sweden	**IG** 12.9 yr. ±4.4 59% **CG** NR	**IG** 5.0 yr. ±3.9 7.0%±1.1 **CG** 7.4 yr. ±4.9 7.4%±1.1		**IG** – Intense, problem-based training **CG** – Children diagnosed between 1971 and 1981 receiving standard care Home, community, school, diabetes center

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Nunn[55] 2006	123 RCT (parallel) Australia	**IG** 11.9 yr. ±3.7 55% **CG** 11.9 yr. ±3.0 57%	**IG** 3.73 yr. ±2.41 8.15%±1.14 **CG** 3.58 yr. ±2.36 8.32%±1.01	Poor metabolic control	**IG** – General diabetes knowledge (telephone calls) **CG** – Standard care Home, diabetes center
Olmsted[56] 2002	85 RCT (parallel) Canada	**TG** 16.0 yr. ±2.0 0%	**TG** 7.0 yr. ±3.4 9.1%±1.5	Eating disorder	**IG** – Eating disorder intervention **CG** – Standard care Diabetes Center
Panagiotopoulos[57] 2003	50 RCT (parallel) Canada	**IG** 14.4 yr. ±1.7 44% **CG** 13.8 yr. ±1.5 36%	**IG** 7.0 yr. ±3.2 9.7%±1.2 **CG** 5.5 yr. ±3.1 9.6%±1.3	Poor metabolic control	**IG** – Self-management skills (telephone calls) **CG** – Standard care Home, diabetes center
Pichert[58] 1994a	83 RCT (parallel) United States	**TG** NR	**IG** 6.1 yr. **CG** 6.5 yr. range: 6 mo.–15 yr. NR		**TG** – Anchored instruction, nutrition education Camp
Pichert[59] 1994b	84 RCT (parallel) United States	**TG** NR 47.6%	**TG** 6.9 yr. range: 3 mo.–14 yr. NR		**TG** – Anchored instruction, sick-day management Camp
Pichert[60] 1993	70 RCT (parallel) United States	**TG** NR 55.7%	**TG** 5 yr. NR		**IG** – Anchored instruction, problem solving skills **CG** – Prepared lecture/ discussion/ rehearsal/ instruction sessions

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Pichert 1993 (continued)					Camp
Povlsen[61] 2005	37 Uncontrolled before-and-after study Denmark	**IG** NR	**IG** NR 9.2%±1.4	Ethnic minority	**IG** – Re-education session, general diabetes knowledge Hospital
Remley[62] 1999	237 CCT United States	**IG** 14.53 yr. 42% **CG** 14.15 yr. 47%	**IG** 5.78 yr. 8.98% **CG** 5.22 yr. 8.76%		**IG** – Assertive communication, nutrition education **CG –** No intervention Camp
Satin[63] 1989	32 RCT (parallel) United States	**IG1** 15.0 yr. ±2.4 36.4% **IG2** 14.9 yr. ±2.8 25% **CG** 13.7 yr. ±2.7 55.6% **TG** 14.6 yr. ±2.6 37.5%	**IG1** 6.3 yr. ±5.1 13.4%±1.3 **IG2** 5.2 yr. ±3.8 12.6%±0.9 **CG** 6.3 yr. ±4.3 12.9%±1.4 **TG** 5.9 yr. ±4.3 NR		**IG1** – Group process and teamwork, adherence **IG2** – IG1, simulated diabetes management (parent) **CG** – No intervention Hospital
Schlundt[64] 1996	86 Uncontrolled before-and-after study United States	**IG** 12.1 yr. ±1.8 47%	**IG** 4.5 yr. ±3.1 NR		**IG** – Anchored instruction Camp

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Shobhana[65] 1997	37 Uncontrolled before-and-after study India	**IG** NR	**IG** NR	Duration of diabetes ≥1 yr.	**IG** – General diabetes knowledge Diabetes center
Siminerio[66] 1999	32 Prospective cohort with concurrent control group United States	**IG1** 10.1 yr. 62.5% **IG2** 10.2 yr. 56.25%	**IG1** NR **IG2** NR	Newly diagnosed	**IG1** – General diabetes knowledge (Hospital) **IG2** – General diabetes knowledge (outpatient clinic) Hospital, outpatient clinic
Smith[67] 1993	120 Uncontrolled before-and-after study United States	**IG** 14.9 yr. ±1.4 43%	**IG** 4.1 yr. ±3.4 NR		**IG** – Assertive communication, problem solving and negotiation skills Camp
Smith[68] 1991	108 Uncontrolled before-and-after study United States	**IG** 14.5 yr. ±1.4 44%	**IG** 4.5 yr. ±3.5 NR		**IG** – Stress and diabetes Camp
Srinivasan[69] 2004	110 Prospective cohort with concurrent control group Australia	**IG1** NR **IG2** NR	**IG1** NR **IG2** NR	Newly diagnosed	**IG1** – "Survival skills" diabetes knowledge (outpatient) **IG2** – Detailed diabetes knowledge progam (hospital) Outpatient day care program, hospital

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Sundelin[70] 1996	38 RCT (parallel) Sweden	**IG1** 8.7 yr. ±3.2 37% **CG** 8.8 yr. ±2.7 37%	**IG1** NR 9.6%±0.14 **CG** NR 9.8%±0.74	Newly diagnosed	**IG1** – General diabetes knowledge (hospital apartment) **CG** – General diabetes knowledge (hosptial) Hospital, apartment
Svoren[71] 2003	301 RCT (parallel) United States	**IG1** 11.8 yr. ±2.4 39% **IG2** 12.1 yr. ±2.4 42% **CG** 11.7 yr. ±2.6 49%	**IG1** 5.1 yr. ±2.9 8.57%±1.35 **IG2** 5.3 yr. ±3.0 8.68%±1.03 **CG** 5.3 yr. ±30. 8.72%±1.17	Duration of diabetes > 6 mo	**IG1** – Care ambassador to assist families **IG2** – IG1, plus psychoeducation **CG** – No intervention Diabetes center
Szumowski[72] 1990	27 RCT (parallel) United States	**IG** 78.1 mo. 45% **CG** 76.4 mo 60%	**IG** 3.24 yr. 9.7%±1.2 **CG** 2.57 yr. 10.0%±1.5	Duration of diabetes ≥ 1 yr.	**IG** – Goal-setting, adherence behaviors **CG** – General diabetes knowledge Outpatient clinic
Templeton[73] 1988	30 Uncontrolled before-and-after study United States	**IG** 12.7 yr. NR	**IG** 4.9 yr. NR		**IG** – Food choices and SMBG Diabetes center
Thomas-Dobersen[74] 1993	20 CCT United States	**IG** NR	**IG** NR		**IG –** Self-management (adolescents), parenting and communication skills (parents) **CG** – Standard treatment NR

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Verrotti[75] 1993	30 Uncontrolled before-and-after Italy	**IG** 15.4 yr. ±0.8 40.0%	**IG** 1.3 yr. ±0.4 12.0%±2.9		**IG** – General Diabetes knowledge NR
Viner[76] 2003	21 CCT United Kingdom	**IG** 13.0 yr. 28.6% **CG** 13.3 yr. 60.0%	**IG** 6.2 yr. 10.2%±1.4 **CG** 5.7 yr. 10.0%±1.3	Poor metabolic control	**IG** – Systematic focused therapy **CG** – No intervention NR
von Sengbusch[77] 2006	107 Uncontrolled before-and-after study Germany	**IG** 11.1 yr. ±2.5 43.9%	**IG** 4.3 yr. ±3.0 7.9%±1.4	Duration of diabetes > 6 mo.	**IG** – Mobile Diabetic Teaching Team, general diabetic knowledge, independence, self-confidence Hospital
Vyas[78] 1988	63 Uncontrolled before-and-after study United Kingdom	**IG** 8.4 yr. ±2.0 47% CG	**IG** 3.9 yr. ±2.0 NR		**IG** – Self-management and problem solving skills Camp
Wadham[79] 2005	67 RCT (parallel) United Kingdom	**IG** 12.9 yr. ±2.1 56%	**IG** 4.9 yr. ±3.25 9.1%±1.25		**IG** – General diabetes knowledge, teamwork, communication, responsibilities **CG** – No intervention Clinic

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Webb[80] 1999	66 RCT (parallel) United States	**IG1** NR **IG2** NR **TG** 10.2 yr. ±1.4 34.8%	**IG1** NR 8.68%±0.75 **IG2** NR 9.52%±1.28 **TG** 5 yr. ±2.6	Duration of diabetes >1 yr.	**IG1** – Goal setting (5 goal-setting guidelines) **IG2** – Goal setting (without guidelines) Outpatient clinic
Wolanski[81] 1996	41 RCT (parallel) Canada	**IG** NR	**IG** 4 mo.–12 yr. NR	Poor self-management skills	**IG –** BGSM skills **CG** – Usual teaching activities Camp
Wysocki[82] 2007	104 RCT (parallel) United States	**IG1** 14.4 yr. ±1.9 56% **IG2** 13.9 yr. ±1.9 58% **CG** 14.2 yr. ±1.9 50%	**IG1** 5.5 yr. ±3.2 9.7%±1.6 **IG2** 5.1 yr. ±3.0 9.6%±1.6 **CG** 5.9 yr. ±4.0 9.5%±1.5	Duration of diabetes >2yr.	**IG1** – Group meetings emphasized education and social support **IG 2** – Behavioral family systems therapy **CG** – Standard care Diabetes center
Wysocki[83] 2000	119 RCT (parallel) United States	**IG1** 14.5 yr. ±1.2 39% **IG2** 14.1 yr. ±1.4 38% **CG** 14.3 yr. ±1.4 49%	**IG1** 5.4 yr. ±3.8 NR **IG2** 4.5 yr. ±3.7 NR **CG** 5.2 yr. ±3.8 NR	Poor metabolic control, moderate levels of parent-adolescent conflict	**IG1** – Behavioral family systems therapy **IG2** – Group meetings, emphasized education, and social support **CG** – Standard care Doctor's office

Table F1. Characteristics of study population and study setting in studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Location	Age, Mean±SD % Male	Duration of Diabetes, Mean±SD HbA1c at Baseline, Mean±SD	Other Characteristics	Intervention Setting
Zorumski[84] 1997	56 CCT United States	**IG** 10.2 yr. ±1.67 55.6% **CG** 10.43 yr. ±1.57 36.4%	**IG** 2.7 yr. ±2.13 9.93%±2.9 **CG** 2.79 yr. ±2.37 10.85%±2.14		**IG** – General diabetes knowledge **CG** – Standard care Day camp, doctor's office

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Anderson[5] 1999	89 RCT (parallel) Diabetes center	**IG1** – 20-30 min. sessions every 3-4 mo. For 12 mo., parent-teen shared responsibility for diabetes tasks and ways to avoid conflict **IG2** – 20-30 min. sessions every 3-4 mo. For 12 mo., didactic diabetes education with no focus on parental involvement **CG** – Standard care	Research staff (IG1 and IG2); NA (CG) 12 mo. 24 mo. (IG1); 12 mo. (IG2, CG)	**HbA1c** – No significant differences at 12 mo. Or 24 mo. **Pyschosocial** (family/social support) – IG reported less deterioration than CG ($p<0.07$) at 12 mo. **Psychosocial** (family/social relationships) – IG reported greater decrease in conflict than CG ($p<0.02$) at 12 mo.
Anderson[6] 1989	70 RCT (parallel) Clinic	**IG** – Five 3-hr sessions every 3-4 mo. For 18 mo., SMBG in relation to practical skills, puberty, problem solving, exercise and use with intensive therapies **CG** – Standard care	Endocrinologist, diabetes nurse educator, dietician, social work (IG and CG); Nutritionist, psychologist (IG) 18 mo. Immediate	**HbA1c** – IG was significantly lower than CG ($p = 0.04$) **Self-monitoring skills** – No significant differences
Barglow[7] 1983	42 CCT Diabetes center	**IG** – Intensive, multi-component treatment individually designed, delivered over 4 mo., initial visit and assessment, clinic visits every 2 wk., daily telephone calls (providing medical care, teaching, clarification and support), and one group session **CG** – Standard care	Multidisciplinary team (IG); NR (CG) 4 mo. 4 mo.	**HbA1c** – No significant differences
Boardway[8] 1993	31 RCT (parallel) Outpatient clinic	**IG** – Group sessions over 6 mo., 3 phases: self-monitoring, stress-management, regimen adherence **CG** – Standard care	NR 3 mo. 6 mo. (IG); NR (CG)	**HbA1c** – No significant treatment effects **Self-management/adherence** – No significant treatment effects **Psychosocial** (stress) – Significant decrease in IG at 12 mo. ($p<0.05$) **Coping** – No significant treatment effects

BG = blood glucose; carb = carbohydrate; CG = comparison group; d = day; DKA = diabetic ketoacidosis; IG = intervention group; NA = not applicable; NR = not reported; NS = not significant; SMBG = self-monitoring of blood glucose; Tx = treatment

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Brown[9] 1997	59 RCT (parallel) Home	**IG** – For 6 mo., children played the video game *Packy & Marlon*, features characters with diabetes that must engage in self-care **CG** – For 6 mo., children played a pinball video game with no health-related content	Research staff 6 mo. Immediate	**HbA1c** – No significant treatment effect (p = 0.67) **Health care utilization** – IG reported fewer urgent physician visits compared to CG in 3 mo. (p = 0.08, n.s.) **Knowledge** – IG reported gains in knowledge compared to CG at 6 mo. (p = 0.64, n.s.) **Psychosocial** (family/social relationships) – IG reported gains in communication compared to CG at 6 mo. (p = 0.025) **Psychosocial** (self-efficacy) – IG reported gains in self-efficacy compared to CG at 6 mo. (p = 0.07, n.s.) **Psychosocial** (self-efficacy) – IG reported gains in self-care compared to CG at 6 mo. (p = 0.003)
Campaigne[10] 1985	16 RCT (parallel) NR	**IG** – 3 45-min. exercise sessions for 12 wk., warm-up and stretching, aerobic movements to music and cool-down **CG** – Subjects continued with their usual exercise routine	Supervised by principal investigator (IG); NA (CG) 12 wk. Immediate	**HbA1c** – No change reported in either group at 3 mo. **Short-term complications** (hypoglycemia) – No increase in occurrence in either group at 3 mo.
Caravalho[11] 2000	56 Uncontrolled before-and-after study Home, diabetes center	**IG** – Children and parents seen in diabetes team clinic, parents taught insulin adjustment procedures, interventions developed and implemented according to child's age, telephone calls assessed families and assisted in improving self-management, daily calls for newly diagnosed children	Nurse, social worker, dietitian 1 yr. Immediate	**HbA1c** – Small improvement from pre to post (12 mo.) was not statistically significant (p = 0.73) **Psychosocial** (self-efficacy) – Higher self-efficacy score pre to post (12 mo.) significant (p = 0.01) **Quality of life** – Improved mean scores pre to post (12 mo.) not significant (p = 0.07)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Christensen[12] 2000	68 Uncontrolled before-and-after study Camp	**IG** – 45-min. sessions during 2-wk. camp, 12-18 children per class, grouped by age, carbohydrate counting, label reading, food proportioning and adjusting for activity level, teaching methods tailored to developmental needs	Camp counsellor, physician, nurse 2 wk. Immediate	**Knowledge** – Correlation not statistically significant (p = 0.09) **Self-management skills** (write out meal plan in specified formats) – 24% increase comparing pre to post intervention values **Self-management skills** (accurately describe meal plan) – 19% increase comparing pre to post intervention values **Self-management skills** (appropriate portion sizes) – Correlation not statistically significant (p = 0.132) **Self-management skills** (correctly measuring carb.) – Statistically significant correlation (p = 0.006)
Cigrang[13] 1991	37 RCT (parallel) Hospital	**IG1** – 8 90-min. group sessions focused on identifying issues perceived as difficult or stressful and developing adaptive strategies for coping, youths asked to implement new coping strategies in real-life situations during the week **IG2** – 8 90-min. group sessions with a speaker who presented diabetic topics, included a question and answer session and practice time for various skills **CG** – Standard care	Diabetes nurse specialist, advanced clinical psychology doctoral student (IG1); diabetes educator, dietitian, endocrinologist, diabetes resource nurse, exercise physiologist (IG2); physician (CG) 8 wk. 3 mo.	**HbA1c** – IG and CG levels decreased, but not significant (p = 0.43) **Coping** – No significant differences between groups at 3 mo. (p = 0.122) **Psychosocial** (self-perception) – No significant difference between groups at 3 mo. (p = 0.493) **Psychosocial** (depression) – No significant differences between groups at 3 mo. (p = 0.197)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Couper[14] 1999	69 CCT Hospital, home	**IG** – Standard care, plus 6 monthly home visits for 45-60 min. and weekly telephone contact for 5-10 min. to educate and support adolescents in setting goals for insulin adjustment, BGSM, and target blood glucose range, parents not formally involved in home visits, 24-hour phone access for acute problems **CG** – Standard care, plus 24-hour phone access for acute problems	Nurse educator (IG); pediatric endocrinologist, diabetes educator, dietitian (IG and CG) 6 mo. 12 mo.	**HbA1c** – IG significantly lower than CG at 6 mo. ($p = 0.0001$), no significant difference between groups at 12 mo. **Knowledge** (child) – IG significantly higher than CG at 6 mo. ($p = 0.001$), no sig. diff. at 12 mo. **Knowledge** (parent) – IG significantly higher than CG at 6 mo. ($p = 0.001$) and 12 mo. ($p = 0.005$)
Coupland[15] 1992	32 RCT (parallel) NR	**IG** – 3-5 sessions over 2-2.5 mo. Attended by parents, patient, and siblings closest in age to patient, 1 diabetes skills review and update session, 2-4 family adherence counseling sessions **CG** – 3-5 sessions over 2-2.5 mo., 1 diabetes skills review (1 parent and patient) and update session, 2-4 stress coping strategy sessions (patient only)	Ph.D. candidate (IG); diabetes educator (IG and CG) 2.5 mo. 3.5 mo.	**HbA1c** – No significant difference between groups at 6 mo., both groups improved **Self-management/adherence** – IG significantly different compared to CG at 6 mo. ($p<0.05$) **Self-management/adherence** (mean freq. of BG testing) – IG significantly increased compared to CG at 6 mo. ($p<0.001$) **Self-management/adherence** (mean percent of BG testing) – IG significantly higher than CG at 3 and 6 mo. ($p<0.0005$) **Psychosocial** (family/social support) – No significant difference between groups at 6 mo.

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Delamater[16] 1991	13 RCT (parallel) Hospital outpatient clinic	**IG** – Six 90-min. group sessions held over 2 mo. With a booster session 4 wk. after the last session, self-management and psychosocial skills, separate parent and teen discussions **CG** – Standard care	Multidisciplinary team (IG); NR (CG) 2 mo., plus 1 booster session 4wk. later (IG); NA (CG) 4 mo.	**HbA1c** – No significant changes between groups at 4 mo. **Self-management/adherence** – IG rated themselves as adhering more than CG at 4 mo. ($p<0.09$) **Psychosocial** (diabetes specific patient-report) – No significant effects between groups at 4 mo. ($p>0.05$) **Psychosocial** (diabetes specific parent-report) – No significant effects between groups at 4 mo. ($p>0.05$) **Psychosocial** (general patient report) – No significant effects between groups at 4 mo. ($p>0.05$) **Psychosocial** (general parent report) – No significant effects between groups at 4 mo. ($p>0.05$) **Psychosocial** (diabetes-specific non-supportive parent behaviors, patient self-report) – No significant effects between groups at 4 mo. ($p>0.05$) **Psychosocial** (diabetes-specific non-supportive parent behaviors, parent self-report) – No significant effects between groups at 4 mo. ($p>0.05$) **Psychosocial** (diabetes-specific supportive parent behaviors, patient self-report) – No significant effects between groups at 4 mo. ($p>0.05$) **Psychosocial** (diabetes-specific supportive parent behaviors, parent self-report) – No significant effects between groups at 4 mo. ($p>0.05$)
Delamater[17] 1990	36 RCT (parallel) Hospital, home	**IG1** – 7 sessions held in the 4 mo. After discharge, additional sessions at 6 and 12 mo., SMBG, self-management skills aimed at developing and reinforcing problem solving strategies **IG2** – 7 sessions held in the 4 mo. After	Social worker with diabetes expertise (IG1); social worker (IG2); physician, dietitian (CG) 12 mo.	**HbA1c** – Self-management training significantly lower than CG at 2 yr. ($p<0.05$)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Delamater 1990 (continued)		discharge, additional sessions at 6 and 12 mo. Focused on psychosocial adjustment issues, patients encouraged to keep accurate BMBG records **CG** – Standard care	12 mo.	
Dougherty[18] 1999	63 RCT (parallel) Hospital, home	**IG** – Home visits 1-2 times a day for the first 2-3 days, instruction and supervision of treatment, problem solving encouraged during followup, diabetologist and dietitian teaching offered 2 wk. after diagnosis, patient hospitalized if necessary **CG** – Patient hospitalized for metabolic stabilization, initial insulin therapy, and teaching sessions provided	Multidisciplinary team 2 wk. 36 mo.	**HbA1c** – Home-based group had significantly lower values compared to hospital group at 24-36 mo. ($p<0.02$) **Short-term complications** (adverse events) – No significant differences between groups **Short-term complications** (chronic hyperglycemia) – No significant differences between groups **Short-term complications** (DKA) – No significant differences between groups **Short-term complications** (hyperglycemia and ketosis) – No significant differences between groups **Short-term complications** (severe hypoglycemia) – No significant differences between groups **Knowledge** – No significant differences between groups **Self-management/adherence** – No

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Dougherty 1999 (continued)				significant differences between groups **Psychosocial** (stress) – Hospital group significantly lower at 1 mo. Compared to home-based group ($p<0.05$) **Coping** – No significant differences between groups **School Performance** – 28.3±36.4 days of absence for the CG and 29.7±28.7 days for the IG
Golden[19] 1985	19 CCT Diabetes center, parent care unit, a motel-like setting	**IG** – Teaching occurred in a motel-like setting where entire family stayed and was responsible for care, learned diabetes management skills and dietary guidelines, initial crisis intervention offered to families, psychosocial support occurred at 3-mo. Intervals preceded by a 1-hr session with 5-6 other families **CG** – Delayed treatment, intervention began an average of 14.9 mo. After initial treatment group	Psychiatric social worker (IG and CG) NR 6-24 mo. (at least partially concurrent with treatment)	**HbA1c** – Overall CG mean HbA1c > IG mean HbA1c ($p<0.10$), at equivalent durations of illness **Health care utilization** – IG – 1 hospitalization after diagnosis and education, CG – 11 hospitalizations before intervention **Short-term complications** (hypoglycemia) – Significant decrease in CG children and IG relative to both groups ($p<0.01$)
Greco[20] 2001	23 Uncontrolled before-and-after study Outpatient clinic	**IG** – Four 2-hr sessions, composed of 3-6 pairs (diabetes patient and peer), reviewed homework, focused on etiology, physiology and treatment of diabetes, reflective listening skills, problem solving related to diabetes, stress management, game or exercise to practice concepts and homework assignment	Psychologist 4 wk. Immediate	**Knowledge** – At post-intervention, adolescents with DM experienced significant increase ($p<0.0001$) as did their peers ($p<0.0001$) compared to baseline **Self-management/adherence** – No significant change reported **Psychosocial** (family/social support) – Peers provided greater proportion of support relative to family members following intervention ($p<0.05$) **Psychosocial** (family/social relationships) – Parents reported significantly less DM-related conflict following intervention ($p<0.05$)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Greco2001 (continued)				**Psychosocial** (peer interaction record) – Peers reported significant improvement following intervention ($p<0.01$), adolescents reported no significant change **Pyschosocial** (behavior, affective, and attitudinal adjustment to type 1 DM) – Trend towards improved adjustment, though not significant **Psychosocial** (social, academic, job, behavior, athletic competence) –No significant change reported
Grey[21] 2000	77 RCT (parallel) Hospital, home	**IG** – Standard care, plus 6 weekly coping skills training sessions, retrained inappropriate or nonconstructive coping styles, modeled appropriate behaviors, emphasis on social problem solving, skills training, cognitive behavior modification and conflict resolution **CG** – Standard care, monthly outpatient visits, plus interim telephone contact	Multidisciplinary team (IG and CG) 4 to 8 wk. 12 mo.	**HbA1c** – IG subjects had significantly lower HbA1c than CG ($p = 0.001$) after 12 mo. **Short-term complications** (severe hypoglycemia, male) – 48 episodes, 27 in IG, 21 in CG ($p = 0.24$) **Short-term complications** (severe hypoglycemia, female) – 40 episodes, 18 in IG, 22 in CG ($p = 0.03$) **Short-term complications** (DKA) – 1 episode (male, IG), ($p = 0.16$) **Pyschosocial** (self-efficacy) – IG significantly better self-efficacy ($p = 0.002$) after 12 mo. Of, both groups statistically significant at 12 mo. **Pyschosocial** (self-efficacy) – IG significantly better medical self-efficacy ($p = 0.04$) after 12 mo. Both groups statistically significant at 6 mo. **Quality of life** – IG experienced less negative ($p = 0.005$) after 10 mo.

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Grey[21] 2000 (continued)				**Coping** – IG less upset about coping with diabetes **Coping** – IG less hard to cope with diabetes
Gross[22] 1985	14 RCT (parallel) NR	**IG** – 8 weekly 90-min. sessions, separate parent and child groups, children read and completed 1-2 lessons a week from a text on behavior modification, parents discussed similar topics and were required to conduct a behavior modification project on self-identified, problematic components of their child's diabetes **CG** – 8 weekly 90-min. sessions, separate parent and child groups, children participated in open ended discussion, parents discussed problems with having a diabetic child	Psychologist (IG and CG) 8 wk. 6 mo.	**HbA1c** – Significant decrease in HbA1c (both groups) ($p<0.01$), no significant difference between groups ($p>0.05$) **Knowledge** – IG scored significantly higher compared to CG ($p<0.01$) **Self-management/adherence** – IG demonstrated an increase in compliance **Psychosocial** (family/social relationships) – IG dropped from 1.6 conflicts/week to 0.1/week at 2 and 6 mo., CG remained at 1.1 conflicts/week for the entire study period
Gross[23] 1983	11 RCT (parallel) Treatment room	**IG** – Two 45-min. social training sessions per week for 5 wk., modeling behaviors, providing feedback and praise, trained on one behavior until reliably performed **CG** – No intervention	NR 5 wk. 6 wk.	**HbA1c** – No significant difference ($p>0.05$) (both groups) **Pyschosocial** (social skills) – percentage eye contact increased from 53-95% (IG) **Psychosocial** (social skills) – percentage of appropriate verbalization increased from 24-79% (IG) **Psychosocial** (social skills) – speech duration increased from 1.7-6 seconds **Psychosocial** (social skills) – affect ratings increased from 1.5-4
Hackett[24] 1989	119 RCT (parallel)	**IG1** – 4 90-min. education sessions over 8 mo., background and management information, insulin, diet and practical problems, 4 90-min. reinforcement	Research staff (IG) NA (CG) 16 mo. (IG1); 8 mo. (IG2 and	**HbA1c** – No effect for children <11 yr., marginal improvements for children >11 yr. **Knowledge** – Increased mean

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Hackett[24] 1989 (continued)	Clinic	session over 8 mo. (following the first session) **IG2** – 4 90-min. education sessions over 8 mo. **IG3** – 4 90-min. education sessions over 8 mo. Starting 10 mo. After IG1 and IG2 **CG** – No intervention	IG3) Immediate (all IG); 16 mo. (CG)	knowledge scores ($p<0.001$) (all cohorts) **Knowledge** – Mean scores still raised for mothers and children ($p<0.001$), no evidence of this for fathers ($p>0.05$) **Knowledge** (nutritional management) – No significant difference for children (all ages)
Hains[25] 2000	15 RCT (parallel) Hospital	**IG** – 3-phase cognitive behavioral stress inoculation training program, 6 1-hr. sessions: conceptualization phase (1 session), skill acquisition and rehearsal phase (sessions 2-4) and application phase (sessions 5 and 6) **CG** – No intervention	Pyschologist, doctoral student in counseling psychology (IG) 6 wk. 1 mo.	**HbA1c** – No difference between groups **Psychosocial** (anxiety) – No difference between groups **Psychosocial** (stress) – No difference between groups **Coping** (negative) – No difference between groups **Coping** (positive) – No difference between groups **Coping** (behavioral) – No difference between groups
Hakimi[26] 1998	35 RCT (parallel) NR	**IG** – Same as CG, plus additional 2-hr. program, common emotional/behavioral problems, parental reaction to diabetes diagnosis, common sibling problems, mistakes or misconceptions of outsiders, treatment of diabetic child and family interaction to promote positive adaptation **CG** – Standard care, 3-4 d. education program	Psychologist (IG); physician, nurse, dietitian (CG) 3-4 d. 6 wk.	**Psychosocial** (stress) – No significant differences between IG and CG at post-intervention or 6-wk.
Harkavy[27] 1983	93 Uncontrolled before-and-after study Camp	**IG** – 2-wk. camp, informal and formal teaching sessions, diabetes etiology/pathology, self-management skills, effects of diabetes on stress and social issues	Physician, nurse, camp counsellor 2 wk. Immediate	**Knowledge** – Significant improvement for 12-13 and 14-15-yr. olds ($p<0.01$ for each). No significant difference in 10-11-yr. olds over the 2-wk. camp period **Self-management skills** (urine

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Harkavy 1983 (continued)				testing) – Girls performed more accurately than boys, though both sexes improved. Significant improvement for 12-13 and 14-15-yr. olds ($p<0.01$ for each), no significant difference in 10-11-yr. olds **Self-management skills** (insulin injection) – Girls performed more accurately than boys ($p<0.001$), girls improved their accuracy during 2-wk. camp ($p<0.01$) **Knowledge** (problem solving) – Significant improvement for 12-13 and 14-15-yr. olds ($p<0.01$ for each). No significant difference in 10-11-yr. olds over the 2-wk. camp period
Harris[28] 2005	18 Uncontrolled before-and-after study Home	**IG** – 10 90-min. behavioral family systems therapy sessions, 6-8 weeks covering 4 topics: problem solving, communications skills, cognitive restructuring and functional/structural family therapy	Social worker, psychologist 5-8 wk. 6 mo.	**HbA1c** – No significant difference in metabolic control at 6 mo. **Adherence** – No statistically significant differences between baseline and mean 6 mo. Values **Coping** – No statistically significant differences between baseline and mean 6 mo. Values **Self-management/adherence** – No statistically significant differences between baseline and mean 6 mo. Values **Pyschosocial** (family/social relationships) – No statistically significant differences between baseline and mean 6 mo. Values **Pyschosocial** (diabetes support) – No statistically significant differences between baseline and mean 6 mo. Values

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year Study Design Setting	Sample Size (n)	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Harris 2005 (continued)				**Psychosocial** (diabetes non-support) – No statistically significant differences between baseline and mean 6 mo. Values
Hill[29] 2006 Prospective cohort with concurrent controls Camp	134	**IG** – Foundation for Children and Youth with Diabetes 6-day teen camp, knowledge of diabetes management, encouragement to self-monitor and regulate, participated in leisure activities, fostered choice, a sense of self-control and a sense of belonging, on last day campers gathered in small cabin groups to discuss knowledge, questions and comments about camp **CG** – Camp Hodia, regular camp session	Physician, nurse, dietitian, counselor, assistant (IG); camp counselor (CG) 6 d. 3 mo.	**Psychosocial** (self-efficacy, competence) – No significant differences between groups **Psychosocial** (self-efficacy, degree of autonomy) – Greater increase in autonomy in CG versus IG (p = 0,015) **Psychosocial** (family/social relationships) – IG results significantly higher than for CG (p = 0.03) post-intervention
Hoff[30] 2005 RCT (parallel) Hospital, endocrinology clinic	46	**IG** – Standard care, plus 2 weekend sessions, 2.5 hr. long, construct of illness (session 1) and uncertainty management techniques (session 2) **CG** – Standard care	Advanced clinical psychology graduate students (IG); NR (CG) Two 2.5 hr. sessions 6 mo.	**Psychosocial** (depression, maternal report of child internalizing problems) – IG had significantly decreased internalizing behavior at post-int. and 6-mo. Compared to baseline (p = 0.01 and 0.02, respectively) **Psychosocial** (depression, paternal report of child internalizing problems) – CG had significantly decreased internalizing behavior at post-int. compared to baseline (p = 0.001) **Psychosocial** (maternal report of child externalizing problems) – IG had significantly decreased externalizing behavior at post-int. compared to baseline (p = 0.01) **Psychosocial** (paternal report of child externalizing problems) – No significant changes for either group when compared to baseline

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Horan[31] 1990	20 RCT (parallel) Home	**IG** – 7 weeks of diabetes education modules (phase 2), dynamic and colorful, subjects determined when and what modules to read, recorded insulin and blood glucose data daily on computer and mailed data to investigators every 3 wk., 8 wk. of goal setting and problem solving modules (phase 3), subjects focused on self-control and applying information from education sessions **CG** – 7 wk. diabetes education, modules were static and black-and-white, subjects determined when and what modules to read, recorded insulin and blood glucose data and mailed to investigators every 2 wk., 8 wk. of goal setting and problem solving, no additional modules	Commodore computer (IG); printed materials (CG) 15 wk. Immediate	**HbA1c** – No significant changes between groups **Knowledge** (diabetes, applied) – No significant differences between groups at posttest **Knowledge** (diabetes, factual) – More IG subjects showed improvement compared to CG (no stats) **Self-management/adherence** – IG reported more behavioral change as function of what was learned (no stats)
Howe[32] 2005	75 RCT (parallel) Diabetes center (all); home (IG2)	**IG1** – Standard care, plus 1 education session with families, basic diabetes management skills, families given customized written guidelines, parents expected to identify problems and know when to call for assistance **IG2** – Standard care, plus IG1, plus telephone calls from study coordinator, standardized protocol, diabetes management techniques, parental and behavioral management skills discussed with parent **CG** – Standard care	Master's-prepared nurse (IG1, IG2 and CG), pediatric endocrinologist (IG1 and IG2); study coordinator (IG2) 6 mo. Immediate	**HbA1c** – No significant differences between groups at 3 or 6 mo. **Knowledge** – No statistically significant differences were found from baseline–6 mo. Among groups **Psychosocial** (assume age-appropriate behaviors) – Positive significant group x time interaction (p = 0.002), ED+ group significant increase compared to CG (p = 0.0003) **Psychosocial** (diabetes safety/control behaviors) – Positive significant group x time interaction (p = 0.0006), ED+ group significant increase compared to CG (p = 0.0002)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Kaplan[33] 1985	21 RCT (parallel) Summer school	**IG** – 5 social skills training sessions, 3 hr. a day over 1 wk., identified social situations where peer influence might cause variation in diabetes regimen and suggested appropriate responses **CG** – 5 diabetes knowledge lectures and small group discussion, 3 hr. a day over 1 wk., an interactive computer system, educational videos and an assignment identifying important facts for diabetic teens	Pedatric endocrinologist, expert in diabetes care (IG and CG); psychology graduate student (IG) 3 wk. 4 mo.	**HbA1c** – IG had significantly lower levels at 4 mo. ($p<0.05$)
Karaguzel[34] 2005	25 Uncontrolled before-and-after study Camp	**IG** – 1-wk. camp, education in the morning, during meals and spontaneously, self-management skills, recognition of hypoglycemia, DKA, adjustment related to nutrition and activity level, complications, importance of control and new therapies	Multidisciplinary team 1 wk. 12 mo.	**HbA1c** – Post-camp values at 6 and 12 mo. Significantly decreased ($p<0.05$) **Short-term complications** (hypoglycemia) – No significant difference at 6 mo. ($p>0.05$ vs. 3 and 12 mo. Values) or 12 mo. ($p>0.05$ vs. 3 and 6 mo. Values) **Knowledge** – Significant increase post-camp and 6 mo. ($p<0.05$ vs. pre-camp and 3 mo. Values) and 12 mo. ($p<0.01$ vs. pre-camp)
Kemp[35] 1986	42 Uncontrolled before-and-after study Camp	**IG** – 2-wk. camp, 8 hr. of formal diabetes education either as lectures or computer assisted instruction; eye, skin and foot care, treatment of hypo- and hyperglycemia, nutrition, insulin adjustment and exercise	NR 2 wk. 1 yr.	**HbA1c** – No significant long-term change **Knowledge** – Improvement in knowledge scores comparing pre to post intervention were significant ($p<0.0001$)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Kennedy-Iwai[36] 1991	19 RCT (parallel) Home (IG); hospital (CG)	**IG** – Standard care, plus 6-8 sessions of a couple communication program using the text *Couple Communication 1: Talking Together*, explored feelings and intentions, active listening, observing and information checking, communication styles and providing support, program delivered at home **CG** – Standard care, plus education on self-management skills, could also receive information on stress management, child-rearing and handling emotions surrounding diagnosis	Research staff, counseling psychologist (IG); NR (CG) 8-10 hr. (IG), NR (CG) 3 mo. (IG), NR (CG)	**HbA1c** – Levels increased from pre to posttest in both groups **Psychosocial** (family environment, cohesion) – Scores returned to pretest values at 3 mo. **Psychosocial** (family environment, conflict) – IG mothers had lower scores than CG mothers at posttest; no differences for fathers, at 3 mo. Treatment gains disappeared
Koontz[37] 2001	112 Uncontrolled before-and-after study Camp	**IG1** (grades 9-10) – 1-wk. camp, self-management skills, insulin administration, the relationship between diet, exercise and insulin, meal and snack planning, selecting and measuring food portions, SMBG, identifying and treating insulin reactions, aimed to enhance camper's emotional adjustment and improve self-esteem **IG2** (grades 6-8) – same as IG1 **IG3** (grades 2-5) – same as IG1	Camp counsellor 1 wk. 3 mo.	**HbA1c** – Not extracted as high losses to followup **Health care utilization** – No hospitalizations in 29 who completed medical followup form **Health care utilization** – 3 campers visited physician for other than regular check-up **Self-management skills** – No significant difference between pre and post camp but older campers better than younger campers, though younger competence increased over time **Psychosocial** (self-perception) – Differences at 3 mo. In perceived athletic competence **Coping** – Campers differed in their coping strategies as a function of age

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Laffel[38] 2003	105 RCT (parallel) Diabetes center (both); home (CG)	**IG** – Written material and family discussion on 4 module topics: communication, meaning of HbA1c and need for teamwork during adolescent period, response to blood sugar tests and sharing the burden of diabetes tasks, at the end of each session a responsibility-sharing plan was negotiated **CG** – Standard care, plus written material from IG at the end of the study	Research staff 1 yr. Immediate	**HbA1c** – IG reported significantly lower levels ($p<0.05$) at 12 mo. **Psychosocial** (roles/responsibilities) – IG had significantly more involvement than CG ($p = 0.05$) at 12 mo. **Psychosocial** (diabetes-related conflict, patient self-report) – No significant differences between groups at 12 mo. **Psychosocial** (diabetes-related conflict, parent self-report) – No significant differences between groups at 12 mo. **Quality of life** – No significant differences between groups at 12 mo.
Lawson[39] 2000	28 Retrospective cohort Diabetes center (both); home (IG)	**IG** – 6-8 hr of education (comparable to the DCCT), over 3-4 sessions on an outpatient basis, weekly phone contact reviewed insulin dose adjustments and provided ongoing support, diabetes clinic visits **CG** – Two 2-hr. group education sessions attended by patient and their parents, one 1-2 hr individualized session, meal plans and insulin dose adjustment, small group problem solving sessions, weekly physician contact encouraged	Nurse, dietitian (IG and CG); research fellow (IG); diabetologist (CG) 3 mo. 12 mo.	**HbA1c** – Both groups had a significant decrease in levels at 3 mo.; over the following 12 mo. Levels increased in both groups; IG mean HbA1c remained significantly lower than baseline levels ($p = 0.001$), CG mean HbA1c did not differ significantly from baseline **Short-term complications** (hypoglycemia) – 2 patients in IG group had severe hypoglycemic reactions at 12 mo.

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Likitmaskul[40] 2002	52 Cohort with historical comparison Hospital (IG); NR (CG)	**IG** – Hospital admission, 10-12 d., or until family felt comfortable, patient and at least 1 family member attended program, self-management skills, how to manage abnormal blood and urine sugar levels and how to detect and correct hypoglycemia, followup visits to education clinic once a month for 3 mo., then every 3 mo. Thereafter **CG** – Standard care (historical control)	Multidisciplinary team (IG); NA (CG) 10–12 days (IG); NR (CG) Average follow up: 43.5 ±13.1 mo. (IG); 39.9 ±26.8mo. (CG)	**HbA1c** – IG had lower HbA1c levels than CG **Health care utilization** – Average length of first admission in IG was much shorter than CG **Health care utilization** – Readmission rate for CG was 10 times more than IG in second yr.
Lipman[41] 1988	30 Retrospective cohort Hospital	**IG** – Group instruction coordinated and education provided by a clinical nurse specialist with help from staff nurses, daily education plan delineated responsibilities, diabetes care plan revised and expanded to include child/family assessment tool, reading material and discharge criteria same as CG **CG** – Staff nurses provided instruction according to diabetes education flowsheet and standardized diabetes care plan, education booklet provided, tasks depended upon age, discharged when child and/or parent could perform diabetes tasks and answer questions	Nurse (both); clinical nurse specialist (IG) NR None	**Health care utilization** – IG had significantly shorter length of hospitalization than CG ($p<0.01$)
Lucey[42] 1985	49 CCT NR	**IG** – Two 6-hr. small group sessions using demonstration, drama and a video camera, video facilitated discussion, problem solving alternatives discussed, a canteen-style lunch provided and video taken of food choices used for nutrition discussion, second session provided evening tea and observation of insulin injection **CG** – No intervention	Layperson, adult leader (IG); N/A (CG) Two 6-hr. sessions 4–22 wk.	**Knowledge** – IG children performed better on general information questions than CG children ($p<0.05$) **Pyschosocial** (problem solving) – Difference between IG and CG on problem solving questions not statistically significant

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Mann[43] 1984	39 RCT (parallel) Home, outpatient clinic	**IG1** – Teaching during home visits, injection sites inspected, videos on procedures available in waiting area of clinic, group discussion or practical dietary demonstrations, telephone contact encouraged to discuss problems in diabetes management, glucose measurements recorded **IG2** – Same as IG1, plus glucose measurements recorded graphically, patients given dose-regulation algorithms, attempted to achieve specified glucose levels	Physician, diabetes educator, dietitian NR 18 mo.	**HbA1c** – A1c levels had seasonal fluctuation, but values at beginning and end of study were nearly identical in both groups **Health care utilization** – SMBG group showed reduction in number of hospitalizations for stabilization of control and ketoacidosis ($p<0.04$)
Marteau[44] 1987	97 Uncontrolled before-and-after study Hotel	**IG** – Weekend program, parents divided into groups, sessions on problem solving, forming self-help groups, health care for diabetics, ways to achieve best care	Multidisciplinary team 1.5 d. 3 mo.	**Coping** – Perceived difficulty of looking after child remained unchanged at 3 mo. **Coping** – Parents rated themselves significantly more confident in looking after their child post treatment and at 3 mo.
Mason[45] 1985	93 CCT School, diabetes center	**IG** – 2-4 player board game designed to support the role of the health care team, alert individuals to possible complications of diabetes, provide opportunities for discussion and decision making and the ability to control diabetes, players collected tools (cards) for management to ensure continued control, player with the most tools wins	Diabetes educator NR NR	**Knowledge** – Both CG and IG significantly improved knowledge scores from baseline, but there was no significant difference between the two groups

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Massouh[46] 1989	33 RCT (parallel) Camp	**IG** – 1-hr. program presented on self-management and the physiology of diabetes, 40-min. social learning intervention session, role modeling used to enact behaviors used to deal with peer pressure **CG** – 1-hr. program presented on self-management and the physiology of diabetes, 40-min. session developing questions for a game show	Diabetes expert (IG and CG); psychologist (IG) 8 d. 3 ½ mo.	**HbA1c** – No significant differences between IG and CG at 3 mo., paired t-test states significant increase in HbA1c after Tx in the IG
McNabb[47] 1994	24 RCT (parallel) Diabetes center	**IG** – 6 1-hr sessions, children learned and practiced relevant self-care behaviors, parents learned parenting skills, at the end of the session children set self-care goals and practiced the behaviour with their parents, modified goal to a less demanding one if necessary **CG** – Standard care	NR (IG); Physician, nurse, dietitian (CG) 6 wk. (IG); 0 wk. (CG) 6 wk. (IG); 12 wk. (CG)	**HbA1c** – Mean HbA1c was significantly lower in IG than CG ($p<0.04$) but not significant so when compared to baseline levels **Self-management/adherence** – Difference between IG and CG was not statistically significant **Pyschosocial** (family/social support) – Children in IG had mean overall responsibility score that was significantly higher than children in CG
Mendez[48] 1997	37 CCT Health center (IC); NR (CG)	**IG** – 12 sessions, review, new content (audiovisual and printed material), skill practice and homework assignment, parents attended 2 sessions, emphasizing reinforcement of adherence behaviors rather than punishing noncompliance **CG** – NR	The authors of the paper, psychologist (IG); NR (CG) January-April 1993 13 mo.	**Knowledge** – IG significantly higher than CG at posttest ($p = 0.000$) but not sig. diff. at 13 mo. ($p = 0.087$) **Knowledge** (self-management, nutritional management, physical activity) – IG significantly higher than CG at posttest ($p = 0.016$), but loses significance at 13 mo. **Self-management skills** – IG significantly higher than CG at posttest ($p = 0.002$) **Pyschosocial** (roles/responsibilities) – No significant differences between groups for positive or negative family support at posttest or 13 mo.

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Mendez 1997 (continued)				**Coping** (specific daily diabetes-related hassles) – IG significantly lower than CG at posttest (p = 0.000) and at 13 mo. (p = 0.006) **Coping** (degree unease and likelihood of response relating to diabetes) – IG significantly lower than CG at posttest (p = 0.040) and at 13 mo. (p = 0.000)
Mitchell[49] 1996	32 RCT (parallel) Diabetes center	**IG** – Standard care, plus booklet *Improving Compliance with Treatment for Diabetes*, identifies problems with adherence and offers basic self-management skills, contents reviewed with patient **CG** – Standard care	Multidisciplinary team (IG and CG) NR 12 mo.	**HbA1c** – IG significantly lower compared to CG (p<0.01) at 10-13 mo. **Pyschosocial** (depression) – No significant differences between groups. IG significant comparing 1-3 mo. (p<0.05) and 3-12 mo. (p<0.01) **Psychosocial** (family/social relationships) – No significant differences between groups, IG significant comparing 1–12 mo. (p<0.05) **Coping** (perceived difficulties, diabetes management) – No significant differences between groups **Coping** (social function, general adjustment) – No significant differences between groups
Monaco[50] 1996	58 Uncontrolled before-and-after study Diabetes center	**IG** – 1 session, children instructed in the use of injection site charts (before) and injection site bears (after)	Research staff Single event Immediate	**Knowledge** (6-8 yr. olds) – Using the bear there were significantly fewer injection site identification errors compared to using the chart (p = 0.0005) **Knowledge** (9-11yr. olds) – Using the bear there were significantly fewer injection site identification errors compared to using the chart (p = 0.0001)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention Duration of Intervention Followup Interval	Interventionist	Authors' Conclusions
Moran[51] 1991	22 CCT Hospital, home	**IG** – 45-minute psychotherapy sessions, probable cause of child's psychological disturbance determined during initial meeting, interviews unstructured and focused on child's interest and emotional concerns **CG** – Standard care, possible therapy for emotional problems	Psychologist, nurse 45-minute sessions 3–5 meetings/week for 5–28 weeks (IG); 1–12 weeks (CG) 12 mo.	**HbA1c** – IG had significant improvement at 12 mo. (14.3 vs. 11.5 percent), CG no change (13.7 vs. 13.5 percent) **Health care utilization** – At 12 mo. No significant difference in overall hospitalizations, IG had significantly fewer diabetes-related hospitalizations than CG
Nordfeldt[52] 2005	332 RCT (parallel) Home	**IG1** – 2 video programs (17 and 18 min.) received at baseline, reviewed practical self-management skills aimed at preventing hypoglycemia, FAQ brochure (32 pp., 5,200 words), received 1 mo. Later, information on symptoms and prevention of hypog;ycemia and maintenance of normoglycemia **IG2** – Standard care, plus video (13-min.) and brochure (16 pp., 800 words) with general diabetes information **CG** – Standard care	Videotape, brochure (IG and IG2), NA (CG) NA (expected to use tools as needed) 24 mo.	**Short-term complications** (hypoglycemic events) – Significant reduction after 24 mo. In IG (p = 0.0241), no such reduction in either of other two groups
Nordfeldt[53] 2002	130 Prospective cohort with historical controls Home	**IG** – 2 self-study brochures, prevention of severe hypoglycemia (16 pp., 1,800 words) and self-management skills (12 pp., 1,500 words), 2 video programs (17 and 18 min.) with content related to brochures mailed later, outpatient clinic visits	Videotape, brochure NA 3 yr.	**HbA1c** – Significant decrease from 1996-7 (p = 0.042) and from 1996-8 (p = 0.006) **Short-term complications** (severe hypoglycemia with unconsciousness events/pt. yr.) – Both groups decreased, but difference was not significant **Short-term complications** (yearly percent patient hypoglycemia with unconsciousness) – Both groups decrease, but difference was not significant

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention Duration of Intervention Followup Interval	Interventionist	Authors' Conclusions
Nordfeldt[54] 1999	139 Prospective cohort with historical controls Home, community, school, diabetes center	**IG** – Scheduled visits to individual families, intense problem-based training, supplemented by training at camps and evening lectures, continuous individual psychosocial support provided	Multidisciplinary team Median: 4 visits/yr. (range 3-8) 248 patient yr.	**HbA1c** – Mean HbA1c in 1994-5 different from 1980-1 (p = 0.004) **Health care utilization** – Decrease from 3 incidents in 2 patients in 1994 to 0 incidents in 1995 (significance not calculated) **Short-term complications** (hypoglycemia) – Decrease from 0.23 events/patient yr. in 1980-81 cohort to 0.17 events/patient. Yr. in 1994 and 1995 **Short-term complications** (DKA) – No change reported in number of events/pt. yr. for IG
Nunn[55] 2006	123 RCT (parallel) Home (IG) diabetes center (both)	**IG** – 15-30-min. phone calls, 3 main topics: insulin, carbohydrate intake, and blood glucose values, events which may impact diabetes management, and education program, spoke to parent if child unable to make independent decisions **CG** – Standard care	Diabetes educator (IG), pediatric endocrinologist (IG and CG) 5-8 mo. Immediate	**HbA1c** – No significant differences between groups **Health care utilization** – No significant differences between groups **Knowledge** – No significant differences between groups **Psychosocial** (emotional score) – No significant differences between groups **Psychosocial** (conduct score) – No significant differences between groups **Pyschosocial** (hyperactive score) – No significant differences between groups **Psychosocial** (peer problem score) – No significant differences between groups **Psychosocial** (pro-social score) – No significant differences between groups

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention Duration of Intervention Followup Interval	Interventionist	Authors' Conclusions
Olmsted[56] 2002	85 RCT (parallel) Diabetes center	**IG** – 6 weekly 90-min. sessions adapted from a standardized intervention for eating disorders, parents and daughters in separate rooms, written and oral presentations on the nature of eating problems, strategies for change, patients asked to read chapters from a manual before each session **CG** – Standard care	Individuals with expertise in eating disorders, and adolescent diabetes (IG); NR (CG) 6 wk. 6 mo.	**HbA1c** – No significant differences between groups **Psychosocial** (binge episodes, past 28 days) – No significant differences between groups, though means suggest most improvement was in IG **Pyschosocial** (insulin omission, past 28 days) – No significant differences between groups **Psychosical** (drive for thinness) – Significant time effect for the IG ($p<0.00005$) compared to CG **Psychosocial** (bulimia) – No significant differences between groups **Psychosocial** (body dissatisfaction) – Significant time effect for the IG ($p<0.00005$) compared to CG
Panagiotopoulos[57] 2003	50 RCT (parallel) Home, diabetes center	**IG** – 1-2 times per week educator telephoned patients for 15-20 min., recorded blood glucose values and adjusted insulin, encouraged more frequent SMBG and record keeping, reinforced target blood glucose values, educated on insulin adjustment, addressed teen issues and encouraged individualized goal-setting **CG** – Standard care	NR 6 mo. 12 mo. (continuous)	**HbA1c** – Significant decreases at 6 mo. In both the CG ($p = 0.04$) and IG ($p = 0.01$), but no significant differences between the groups
Pichert[58] 1994a	83 RCT (parallel) Camp	**IG** – 3 45-min. groups sessions devoted to nutrition-related skills and knowledge, written material, video, made food choices for a 3-day high energy adventure **CG** – 3 45-min. session using flash cards to learn food group/exchange equivalents and meal planning	Diabetes educator (IG); dietitian (IG and CG) 3 45-min. sessions Tested at 2-4 d. and 5-6 d.	**Knowledge** (recall nutritional meal plans) – Significant improvement in both groups, group x time interaction ($p<0.01$) **Knowledge** (food groups, exchange equivalents, portions) – No significant difference between groups **Self-management skills** (behavioral measures) – No significant difference between groups, though both showed improvement **Self-management skills** (choosing

				meals, overnight trip) – No significant

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Pichert 1994a (continued)				difference between groups, though both showed improvement
Pichert[59] 1994b	84 RCT (parallel) Camp	**IG** – 2 45-min. sessions, video and discussion, 9 guidelines for sick-day management **CG** – 2 45-min. sessions, viewed video, and completed paper and pencil activity (session 1), reviewed knowledge, played games that prompted rehearsal and application of sick-day guidelines, discussion (session 2)	Diabetes educator (IG and CG) 2 45-min. sessions 8 mo.	**Knowledge** – Older campers outperformed younger ($p<0.01$) but no significant difference between study groups **Knowledge** (overall recall) – Older campers outperformed younger ($p<0.01$) but no significant difference between study groups **Knowledge** (guideline rationale) – Older campers outperformed younger ($p<0.01$) but no significant difference between study groups **Knowledge** (guideline recall) – Older campers outperformed younger ($p<0.01$) but no significant difference between study groups **School performance** – No significant difference between study groups
Pichert[60] 1993	70 RCT (parallel) Camp	**IG** – 4 45-min. sessions during a 2-wk. camp, topics included guidelines for testing glucose and ketons, calculating snacks needed to cover for exercise, preventing dehydration, wearing identification and carrying sugar, all classes were presented according to IDEAL method **CG** – 4 45-min. sessions during a 2-wk. camp, topics included guidelines for exercise and diabetes, open discussion on social issues and diabetes, IG instructor videotaped sessions for CG, which was then show by a proctor to CG	Nurse, physician, camp counsellor (IG and CG) 4 45-min. sessions Immediate	**Knowledge** (diabetes-related exercise guidelines) – Older subjects outperformed younger ones ($p<0.001$), overall posttest scores were higher than pretests ($p<0.01$), the interaction between group and time of testing was significant ($p<0.05$) **Knowledge** (ability to apply knowledge) – Older subjects outperformed young ones ($p<0.001$), overall posttest scores were higher than pretests ($p = 0.08$), the interaction between group and time of testing was significant (0.058)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Povlsen[61] 2005	37 Uncontrolled before-and-after study Hospital	**IG** – 7 re-education sessions, parents and children focused on increasing knowledge, self-care and providing psychosocial support	Nurse Aug 2002–June 2003 6 mo.	**HbA1c** – Significant decrease after intervention (p = 0.01), but levels increased to no significant difference at 3 and 6 mo. **Short-term complications** (hypogycemic events) – Total number of events increased but not significantly **Short-term complications** (DKA) – One event occurred during intervention **Knowledge** – Mean increase in knowledge but with considerable differences between families
Remley[62]1999	237 CCT Camp	**IG1** – Week long camp, 1-hr. didactic lecture on assertive communication, 1-hour peer group discussion, 1-hr. play, 1-hr. nutritional education **CG** – Attended camp, no specialized education	Physician, nurse, camp counselor, nutritionist (IG); NA (CG) 1 wk. 3 mo.	**HbA1c** – No significant change for both groups **Knowledge** (carb. Counting) – No significant difference from pre to post camp **Knowledge** (food guide pyramid) – No significant difference from pre to post camp **Self-management skills** (meal planning self-efficacy) – IG decreased slightly, CG increased slightly from pre to post camp, significant time x group interaction (p<0.01), but not for 2 x 3 general linear model (p = 0.26) **Adherence** – No significant difference from pre to post camp **Pyschosocial** (family/social support) – No significant difference from pre to post camp **Psychosocial** (family/social support, diabetes) – No significant difference from pre to post camp **Psychosical** (family/social support,

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Remley 1999 (continued)				quality) – No significant difference from pre to post camp **Psychosocial** (self-efficacy) – No significant difference from pre to post camp. IG up slightly from pre to post then decreased at followup, CG down slightly pre-post then increased at (not significant)
Satin[63] 1989	32 RCT (parallel) Hospital	**IG1** – 2 90-min. sessions established group process, stressed that diabetes is a family disease and requires teamwork, discussion of feelings around diabetes, 4 90-min. sessions on diabetes management and adherence **IG2** – Same as IG1 plus, parents simulated diabetes self-management for 1 week, adolescents taught parents how to manage their diabetes **CG** – No intervention	Social worker, nurse practitioner (IG1 and IG2); NA (CG) 6 wk. 6 mo.	**HbA1c** – IG2 improved significantly compared to CG; IG1 showed improvements, but results were not significant **Psychosocial** (family/social relationships) – No significant changes
Schlundt[64] 1996	86 Uncontrolled before-and-after study Camp	**IG** – 2 sessions, 1-3 days apart, used a 17-min. video on obstacles faced by adolescents with diabetes, campers identified, analyzed and proposed solutions, then apply them to their own lives	Dietitian 2 wk. Immediate	**Psychosocial** (total, cognitive and behavioral) – Statistically significant increase in score after intervention ($p<0.01$) **Psychosocial** (patient belief in self-care abilities) – No significant change in score after intervention
Shobhana[65] 1997	37 Uncontrolled before-and-after study Diabetes center, hospital	**IG** – 1 day consisted of 1-hour didactic lecture on diabetes with a question and answer period, injection and monitoring skills, pamphlets and other reading material, individualized diet-counseling	Multidisciplinary team NR (approximately 1 d.) 6 mo.	**Knowledge** – Significant increases comparing initial testing and 3 mo. For IDDM, insulin, injections, hypoglycemia and total score. Significant increases comparing initial testing and 6 mo. For all knowledge areas except self-monitoring

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Siminerio[66] 1999	32 Prospective cohort with concurrent control group Hospital (IG1); home (both); outpatient clinic (IG2)	**IG1** – 10-12 hr. of inpatient education sessions over 3 d., individualized, basic knowledge about diabetes, hypo- and hyperglycemia, self-management skills, nutrition and exercise, follow-up telephone calls made **IG2** – Same as IG1, except on an outpatient basis	Diabetes educator, dietitian 3-5 d. 1 mo.	**Health care utilization** – No reported episodes in either group during 1st month post diagnosis **Knowledge** – No significant differences between groups **Knowledge** (problem solving) – Outpatients scored significantly higher than inpatients on behavior control ($p<0.004$) and roles ($p<0.04$) at 1 mo. **Self-management/adherence** (BG regulation) – Inpatient group significantly higher than outpatient group ($p<0.01$) at 1 mo. **Self-management/adherence** (emergency precautions) – Outpatient group significantly higher than inpatient ($p<0.001$) at 1 mo. **Psychosocial** (family/social support) – Increase not significant ($p = 0.08$) in the outpatient group **Coping** – No significant differences between groups
Smith[67] 1993	120 Uncontrolled before-and-after study Camp	**IG** – Daily 1-hr. sessions during a 5-d. camp, provided information, facilitated sharing, opportunities to practice assertive communication, problem solving and negotiation skills, general and diabetes-specific situations discussed, sessions included 7-9 campers	Medical education staff 5 d. 3 mo.	**Pyschosocial** (self-perception) – Significant increase ($p<0.01$) comparing beginning of camp to last day of camp **Psychosocial** (family/social relationships) – No significant changes in degree of problems in communicating, adolescents reported significant decrease in open communication with fathers ($p<0.05$), and similar n.s. trend with mothers ($p<0.06$) post camp

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Smith[68] 1991	108 Uncontrolled before-and-after study Camp	**IG** – Daily 1-hr. sessions on stress and diabetes, management techniques described, modeled and practiced using relaxation, imagery, exercise, problem solving and challenging negative thoughts and cognitive distortions	Medical education staff NR NR	**Coping** – No significant change from pre to postcamp
Srinivasan[69] 2004	110 Prospective cohort with concurrent control group Outpatient day care program (IG); hospital (CG)	IG – Diabetes day care program attended by family for 2-3 successive d. for "survival skills" diabetes education, printed guide and instructions on when to contact on-call team for assistance, additional 3-4 formal education sessions, families attended an outpatient clinic CG – Hospitalized for 4-7 d. for detailed education program, families returned to new-patient clinic within 3-6 wk.	Multidisciplinary team 4-6 wk. (IG); 4-7 d. (CG) 12 mo.	**HbA1c** – No significant differences between groups **Knowledge** – No significant differences between groups **Psychosocial** (diabetes responsibility and conflict) – No significant differences between groups **Psychosocial** (parent-child conflict) – No significant differences between groups **Coping** – No significant differences between groups
Sundelin[70] 1996	38 RCT (parallel) Apartment on hospital grounds (IG); hospital (CG)	**IG** – Families lived in training apartment, all members encouraged to move in for 2 wk., family-orientated crisis therapy, interactions occurred through a variety of day-to-day situations using problems and questions formulated by family, customized management strategies, individualized dietary recommendations, followup according to Swedish standards **CG** – Child hospitalized with one parent, encouraged to attend informative meetings with medical staff, individualized dietary recommendations,	Multidisciplinary team (IG); Diabetes educator, dietitian (CG) 2 wk. (IG); 3 wk. (CG) 2 yr.	**HbA1c** – Statistically significant difference observed only in year 2 due to 3 extreme values in study group. **Psychosocial** (self-perception) – No statistically significant difference between groups **Psychosocial** (family/social relationships) (parent perception of child social activity/behavioral disturbances) – No statistically significant difference between groups

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Sundelin 1996 (continued)		followup according to Swedish standards		**Pyschosocial** (family emotional climate) – No statistically significant difference between groups **Pyschosocial** (attribution, interest, isolation, chaos, enmeshment) – No statistically significant difference between groups
Svoren[71] 2003	301 RCT (parallel) Diabetes center	**IG1** – Care ambassador assigned to assist families in scheduling and monitoring appointments, help with billing and insurance issues and provide outreach after missed or canceled appointments **IG2** – Same as IG1, plus eight 15-30 min. psychoeducational modules delivered at quarterly clinic visits, family discussion encouraged, 2-3 pp. of written material given after each visit **CG** – No intervention	Research staff (IG1 and IG2); NA (CG) 24 mo. 24 mo.	**Health care utilization** (ED visits) – Significantly reduced rate in the CA+ group compared to the other two groups (p = 0.004) over 24 mo. **Health care utilization** (hospitalizations) – Significantly reduced rate in the CA+ group compared to the other two groups (p = 0.04) over 24 mo. **Short-term complications** (hypoglcemic events) – Significantly reduced rate in the CA+ group compared to the other two groups (p = 0.02) over 24 mo.
Szumowski[72] 1990	27 RCT (parallel) Outpatient clinic	**IG** – Six 60-90-min. meetings over 8 wk., children and parents seen separately, at meetings homework reviewed, lesson presented, children completed activities to facilitate learning, parents engaged in discussion, contact maintained with families via monthly mailings and telephone calls, specific diabetes behaviors targeted, goals set in first meeting **CG** – Same as IG, without diabetes behavior education or goal-setting	Multidisciplinary team 2 mo. 3 mo.	**HbA1c** – No significant difference comparing baseline to 3 mo. **Short-term complications** (hypoglycemia events) – No significant difference comparing baseline to 3 mo. **Knowledge** (behavioral principles as applied to children) – Significant group x time interaction (p<0.008) for both groups comparing 3 mo. to baseline **Knowledge** (diabetes, children) – Increase in scores from baseline to 3 mo., but statistical significance not reported **Knowledge** (diabetes, parents) –

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Szumowski 1990 (continued)				Increase in scores from baseline to 3 mo., but statistical significance not reported **Pyschosocial** (roles/responsibilities) – Significant interaction (p = 0.09) comparing baseline with 3 mo. **Pyschosocial** (family/social relationships) – No significant difference comparing baseline to 3 mo. **Self-management/adherence** (physical activity) – No significant difference comparing baseline to 3 mo. **Self-management/adherence** (nutritional management) – No significant difference comparing baseline to 3 mo.
Templeton[73] 1988	30 Uncontrolled before-and-after study Diabetes center	**IG** – Adolescents met in groups (5-7 people) for 1 90-min. session, arrived at the clinic fasting, took blood sugar then administered insulin while nurse observed, with dietitian, group converted each person's breakfast into exchanges, blood glucose measured at 30-min. intervals and plotted on a graph, discussion about SMBG	Multidisciplinary team 1 90-min. session Immediate	**Knowledge** (present knowledge, nutritional concepts) – Percent correct range from 35%-92% (M = 76%; median = 84%), no comment on statistical significance of results **Knowledge** (knowledge gain, nutritional concepts from session topics) – Percent correct range from 96%-100% (M = 97.6%; median = 96%), no comment on statistical significance of results
Thomas-Dobersen[74] 1993	20 CCT NR	**IG** – 14 90-min. sessions over 3 mo., adolescents learned self-management skills, importance of diet and exercise and knowledge around hypoglycemia, manuals for both adolescents and adults, parents offered 13 sessions covering strategies to support weight-loss, methods to alter family diet and	Psychologist, dietitian, child health associate (IG); NA (CG) 3 mo. 1 yr.	**Knowledge** – Statistically significant increase in IG (p<0.01) compared to CG at 3 or 15 mo. **Pyschosocial** (self-perception) – 1 CG subject showed improvement at 15 mo., compared to 4 in IG (significance not stated)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention Duration of Intervention Followup Interval	Interventionist	Authors' Conclusions
Thomas-Dobersen 1993 (continued)		activity patterns and improve parenting and communication skills **CG** – Standard care		
Verrotti[75] 1993	30 Uncontrolled before-and-after study NR	**IG** – 9 2-hr. education sessions over 15 d., delivered one-to-one using simple language, new sessions evaluated discussion from previous one, self-management skills, hyper- and hypoglycemia, nutrition, diet and exercise, diabetes complications and one session dedicated to mixing insulin, parents attended session on diet	Physician, nurse 15 d. 12 mo.	**HbA1c** – At 12 mo. followup mean levels ahd decreased significantly (p = 0.019) **Short-term complications** (hypogycemic events) – Significantly lower number of incidents at 12 mo. **Knowledge** – Significantly higher scores at 12 mo. compared to baseline
Viner[76] 2003	21 CCT NR	**IG** – 6 weekly sessions, groups broken down by age, motivational and solution-focused therapy techniques, systematic questions, a narrative approach and cognitive behavioural therapy used, parent group run to facilitated parental support for change **CG** – No intervention	NR 6 wk. 1 yr.	**HbA1c** – At 4–6 mo. IG significantly decreased compared to CG (p<0.05), at 7–12 mo. IG decreased compared to CG but not significant (p>0.06) **Pyschosocial** (social skills) – No significant changes in scores **Psychosocial** (self-efficacy) – Significant improvement in scores for cases receiving intervention (p = 0.014)
von Sengbusch[77] 2006	107 Uncontrolled before-and-after study Hospital	**IG** – 5 d. of inpatient education by Mobile Diabetic Teaching Team, children grouped (4-6 people) by age, included knowledge, self-confidence, age appropriate independence and self-management, parents trained in groups, or one-on-one, 1-2 times on insulin, sick days and everyday challenges	Physician, nurse 5 d. 6 mo.	**HbA1c** – No statistically significant changes after 1 yr. **Short-term complications** (hypoglycemia) – No statistically significant changes after 1 yr. **Health care utilization** – Statistically significant reduction (p<0.05) comparing pre and post treatment **Knowledge** – Statistically significant improvement for children <12 yr. (p<0.01) and children >12 yr. (p<0.05) compared to baseline

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
von Sengbusch 2006 (continued)				**Quality of life** – Statistically significant improvement at both 6 mo. ($p<0.05$) and 12 mo. ($p<0.01$) compared to baseline
Vyas[78] 1988	63 Uncontrolled before-and-after study Camp	**IG** – Camp, 10 d. for children 5–7 yr. and 14 days for children 9–14 yr., similar activities during each camp, children learned self-management and problem solving skills	Camp medical staff, camp leaders 10–14 d. 3 mo.	**Self-management skills** (self-testing blood/urine) – Statistically significant increase of testing ($p = 0.003$) comparing before holiday to 3 mo. **Self-management skills** (independent self-injection) – Statistically significant increase in ability ($p = 0.042$) comparing before holiday to 3 mo.
Wadham[79] 2005	67 RCT (parallel) Clinic	**IG** – 4 sessions: food enjoyment with carbohydrate counting, insulin dose adjustment, blood sugar testing and HbA1c, teamwork and communication to support blood glucose and independence, sharing responsibility and letting go **CG** – No intervention	Nurse, physician, dietitian (IG); NA (CG) 12 mo. Ongoing with intervention	**HbA1c** – reliminary results indicate no significant difference for either group
Webb[80] 1999	66 RCT (parallel) Outpatient clinic	**IG** – Presentation on the importance of goal setting, 5 guidelines for goal setting given to parent and child, therapist encouraged child-parent dyads to select 1 goal in 4 self-care behavioral areas, parents worked closely with children, trained to use goal setting worksheets to assist recording and monitoring goal process **CG** – Child-parent dyads worked with therapist to set goals using goal setting worksheet	Research staff (IG and CG) 12 wk. 3 mo. (IG); 2 mo. (CG)	**HbA1c** – No significant interaction between groups and assessment phases (all $p>0.05$) **Self-management/adherence** (GAS for insulin administration) – Significant increase ($p<0.042$) in CGS at 3 mo. compared to GSO **Self-management/adherence** (GAS for SMBG) – No significant differences between groups at 3 mo. **Self-management/adherence** (GAS for physical activity) – Significant increase ($p = 0.011$) in CGS at 3 mo. compared to GSO

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Webb 1999 (continued)				**Self-management/adherence** (GAS for food intake) – Significant increase ($p = 0.001$) in CGS at 3 mo. compared to GSO assessment phases (all $p>0.05$) **Self-management** – No significant interaction between groups and assessment phases (all $p>0.05$)
Wolanski[81] 1996	41 RCT (parallel) Camp	**IG** – Camp, 1-2 individualized 15-30 min. sessions, self-testing under supervision, received corrections, discussed importance of correct testing, small group discussion (based on age) concerning self-testing **CG** – Attended camp, no specialized education	Trained observer, supervisor (IG); NR (CG) 1-2, 15-30 min. sessions Immediate	**Self-management skills** (absolute syst. error in SMBG) – No significant difference between groups when comparing baseline to post-intervention **Self-management skills** (random errors) – No significant difference between groups when comparing baseline to post-intervention **Psychosocial** (IBC: adolescent negative communication) – BFST significantly decreased compared to other groups at 6 and 12 mo. **Psychosocial** (IBC: mother negative communication) – BFST significantly improved compared to other groups at 6 and12 mo. **Psychosocial** (IBC: negative reciprocity) – BFST families significant improvement compared to other groups at 6 and 12 mo. **Psychosocial** (IBC: problem resolution) – BFST families significant improvement compared to other groups at 6 and 12 mo.

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Wysocki[82] 2007	104 RC**T (parallel)** Diabetes center	**IG1** – Standard care, plus 12 90-min. meetings within 6 mo., groups included 3-5 families, meetings emulated a common mental health service for families of chronically ill teens, content followed chapters of an ADA curriculum for teens, family communication and conflict resolution skills were excluded **IG2** – Standard care, plus 12 behavioral family systems therapy sessions, 4 components—problem-solving training, communication skills, cognitive restructuring, functional and structural family therapy **CG** – Standard care	Nurse (IG1); psychologist (IG2 and CG); diabetes educator, pediatric endocrinologist (CG) 6 mo. 12 mo.	**HbA1c** – BFST-D significantly lower than CG ($p<0.05$) at 6, 9, 12, 15, and 18 mo.; BFST-D significantly lower than ES ($p<0.05$) at 9, 15, and 18 mo. **Self-management/adherence** – BFST-D significantly better scores than SC at each followup, but no significant difference between BFST-D and ES or between ES and SC at any time, significant main effects for groups ($p<0.03$) but group-by-time interaction not significant **Psychosocial** (family/social relationships) – BFST-D significantly lower than CG and ES only at 6 mo. significant main effect for groups ($p<0.03$), but group x time interaction effect not significant
Wysocki[83] 2000	119 RCT (parallel) Doctor's office	**IG1** – Standard care, plus 10 sessions of BFST, 4 components—problem-solving training, communication skills, cognitive restructuring, functional and structural family therapy, families received individualized plans, session activities included problem solving discussions, feedback, modeling, rehearsal, homework **IG2** – Standard care, plus 10 group meetings, emphasized education and social support, 2–5 families per group, family communication and conflict resolutions skills excluded **CG** – Standard care	Psychologist (IG1); social worker, health educator (IG2); physician (CG) 3 mo. 12 mo.	**HbA1c** – No significant differences between groups at 3 mo. **Self-management/adherence** – Some improvement in younger children at 3 mo. (n.s.) but effect dissipated by 6 mo. **Psychosocial** (PARQ extreme beliefs) – BFST significantly lower scores compared to either group at 3 mo. FU ($p = 0.006$)

Table F2. Characteristics and effectiveness of studies of diabetes education for children with type 1 diabetes and their families (continued)

Author Year	Sample Size (n) Study Design Setting	Intervention	Interventionist Duration of Intervention Followup Interval	Authors' Conclusions
Zorumski[84] 1997	56 CCT Day camp (IG); doctor's office (CG)	**IG** – 1-wk. camp, covered all aspects of diabetic self-management, used active participation and educational presentations, observed and demonstrated behaviors **CG** – Standard care	Diabetes educator, health care professional (IG); physician (CG) 1 wk. (IG); NR (CG) 4 mo.	**HbA1c** – No statistically significant difference between groups **Psychosocial** (self-perception) – CG statistically higher score than IG ($p<0.05$) at 4 mo. **Psychosocial** (self-management) – No statistically significant difference between groups

Table F3. Methodological quality of uncontrolled before-and-after and cohort studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families

	Selection bias			Allocation bias			Confounding			Blinding		Data collection methods			Withdrawals/ dropouts		Intervention integrity
Author Year	**Representative of target population?**	**% agreed to participate**	**Rating**	**Study design**	**Rating**	**Between group differences prior to intervention?**	**Relevant confounders specified**	**Confounders adequately managed in analysis?**	**Rating**	**Assessor(s) blinded to intervention status?**	**Rating**	**Data collection tools valid?**	**Data collection tools reliable?**	**Rating**	**% participants completed**	**Rating**	**% participants receiving intervention**
Caravalho[11] 2000	Somewhat likely	<60	W	Uncontrolled before-and-after study	W	NA	Age, sex, duration, SES	NA	M	No	W	Yes	Yes	S	60-79	M	≥80
Christensen[12] 2000	Not likely	≥80	W	Uncontrolled before-and-after study	W	NA	Sex, duration	NA	W	No	W	No	No	W	≥80	S	≥80
Greco[20] 2001	Somewhat likely	60-79	M	Uncontrolled before-and-after study	W	NA	Age, sex, duration, SES	NA	M	NR	W	Yes	Yes	S	≥80	S	≥80
Harkavy[27] 1983	Somewhat likely	NR	M	Uncontrolled before-and-after study	W	NA	Age, sex, duration, SES	NA	M	NA	W	No	No	W	≥80	S	≥80
Harris[28] 2005	Not likely	<60	W	Uncontrolled before-and-after study	W	NA	Age, sex, SES	NA	W	NR	W	Yes	Yes	S	≥80	S	≥80
Hill[29] 2006	Somewhat likely	NR	W	Prospective cohort with concurrent control	M	Can't Tell	Age, sex	NA	W	No	W	Yes	Yes	S	<60	W	≥80

M = moderate; NA = not applicable; NR = not reported; SES = socioeconomic status; W = weak

Table F3. Methodological quality of uncontrolled before-and-after and cohort studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

	Selection bias			Allocation bias		Confounding				Blinding		Data collection methods			Withdrawals/ dropouts		Intervention integrity
Author Year	Representative of target population?	% agreed to participate	Rating	Study design	Rating	Between group differences prior to intervention?	Relevant confounders specified	Confounders adequately managed in analysis?	Rating	Assessor(s) blinded to intervention status?	Rating	Data collection tools valid?	Data collection tools reliable?	Rating	% participants completed	Rating	% participants receiving intervention
Karaguzel[34] 2005	Not likely	NR	W	Uncontrolled before-and-after study	W	NA	Age, sex, duration	NA	W	No	W	No	No	W	≥80	S	≥80
Kemp[35] 1986	Somewhat likely	NR	W	Uncontrolled before-and-after study	W	NA	Age	NA	W	No	W	Yes	Yes	S	NR	W	≥80
Koontz[37] 2002	Somewhat likely	60-79	M	Uncontrolled before-and-after study	W	NA	Age, sex, duration, SES	NA	S	No	W	Yes	Yes	S	<60	W	≥80
Lawson[39] 2000	Somewhat likely	NR	W	Retrospective cohort	W	No	Age, duration	NA	W	NR	W	Yes	Yes	S	≥80	S	≥80
Likitmaskul[40] 2002	Very likely	NR	M	Prospective cohort with historical control	W	No	Age, sex, duration	NA	W	No	W	Yes	Yes	S	≥80	S	≥80
Lipman[41] 1988	Somewhat likely	≥80	M	Retrospective cohort	W	No	Age, sex, duration	NA	W	No	W	Yes	Yes	S	≥80	S	<60
Marteau[44] 1987	Not likely	NR	W	Uncontrolled before-and-after study	W	NA	None	NA	W	No	W	No	No	W	≥80	S	≥80
Monaco[50] 1996	Very likely	NR	M	Uncontrolled before-and-after study	W	No	Age, sex	NA	W	No	W	Yes	Yes	S	≥80	S	≥80

Table F3. Methodological quality of uncontrolled before-and-after and cohort studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

	Selection bias			Allocation bias		Confounding				Blinding		Data collection methods			Withdrawals/ dropouts		Intervention integrity
Author Year	Representative of target population?	% agreed to participate	Rating	Study design	Rating	Between group differences prior to intervention?	Relevant confounders specified	Confounders adequately managed in analysis?	Rating	Assessor(s) blinded to intervention status?	Rating	Data collection tools valid?	Data collection tools reliable?	Rating	% participants completed	Rating	% participants receiving intervention
Nordfeldt[54] 1999	Very likely	≥80	S	Prospective cohort with historical controls	W	NA	Age, sex, duration	NA	W	No	W	No	No	W	≥80	S	≥80
Nordfeldt[53] 2002	Very likely	NR	M	Uncontrolled before-and-after study	W	NA	Age, duration (average)	NA	W	No	W	Yes	Yes	S	NR	W	60-79
Povlsen[61] 2005	Somewhat likely	NR	W	Uncontrolled before-and-after study	W	NA	Age, duration	NA	W	NR	W	Yes	No	W	60-79	M	≥80
Schlundt[64] 1996	Somewhat likely	NR	W	Uncontrolled before-and-after study	W	NA	Age, sex, duration	NA	W	No	W	Yes	Yes	S	<60	W	≥80
Shobhana[65] 1997	Somewhat likely	NR	M	Uncontrolled before-and-after study	W	NA	None	NA	W	NR	W	No	No	W	<60	W	≥80
Siminerio[66] 1999	Somewhat likely	NR	M	Prospective cohort with concurrent control group	W	No	Sex, age, SES, duration	NA	M	NR	W	Yes	Yes	S	≥80	S	≥80
Smith[68] 1991	Somewhat likely	60-79	M	Uncontrolled before-and-after study	W	NA	Age, sex, duration	NA	W	NA	W	No	Yes	W	≥80	S	≥80

Table F3. Methodological quality of uncontrolled before-and-after and cohort studies assessing the effectiveness of diabetes education for children with type 1 diabetes and their families (continued)

	Selection bias			Allocation bias		Confounding				Blinding		Data collection methods			Withdrawals/ dropouts		Intervention integrity
Author Year	Representative of target population?	% agreed to participate	Rating	Study design	Rating	Between group differences prior to intervention?	Relevant confounders specified	Confounders adequately managed in analysis?	Rating	Assessor(s) blinded to intervention status?	Rating	Data collection tools valid?	Data collection tools reliable?	Rating	% participants completed	Rating	% participants receiving intervention
Smith[67] 1993	Somewhat likely	≥80	M	Uncontrolled before-and-after study	W	NA	Age, sex, duration, SES	NA	M	No	W	Yes	Yes	S	<60	W	≥80
Srinivasan[69] 2004	Very likely	NR	M	Prospective cohort with concurrent control group	W	No	Age, A1c, SES	NA	W	No	W	Yes	Yes	S	≥80	S	≥80
Templeton[73] 1988	Somewhat likely	NR	W	Uncontrolled before-and-after study	W	NA	Age, duration	NA	W	No	W	No	No	W	≥80	S	≥80
Verrotti[75] 1993	Somewhat likely	NR	W	Uncontrolled before-and-after study	W	No	Age, sex, duration, SES	NA	M	NR	W	Yes	Yes	S	≥80	S	≥80
von Sengbusch[77] 2006	Somewhat likely	≥80	M	Uncontrolled before-and-after study	W	Yes	Age, sex, duration, family structure	NA	M	NR	W	Yes	Yes	S	≥80	S	≥80
Vyas[78] 1988	Very likely	NR	M	Uncontrolled before-and-after study	W	NA	Age, sex, duration	NA	W	No	W	Yes	Yes	S	60-79	M	≥80