

# Family-centered interventions for children and adolescents with type 1 diabetes mellitus: an integrative review

Aloysia Ispriantari<sup>1</sup>, Rismia Agustina<sup>2</sup>, Kennedy Diema Konlan<sup>3</sup>, Hyejung Lee<sup>4</sup>

<sup>1</sup>Graduate Student, College of Nursing · Mo-Im Kim Nursing Research Institute, Yonsei University, Seoul, Korea · Assistant Professor, Department of Nursing, Institute of Technology and Health Science, Malang, Indonesia; <sup>2</sup>Graduate Student, Department of Nursing, College of Medicine, National Cheng Kung University, Tainan, Taiwan · Assistant Professor, School of Nursing, Faculty of Medicine, Lambung Mangkurat University, Banjarbaru, Indonesia; <sup>3</sup>Graduate Student, College of Nursing · Mo-Im Kim Nursing Research Institute, Yonsei University, Seoul, Korea · Lecturer, Department of Public Health Nursing, School of Nursing and Midwifery, University of Health and Allied Sciences, Ho, Ghana; <sup>4</sup>Associate Professor, College of Nursing · Mo-Im Kim Nursing Research Institute, Yonsei University, Seoul, Korea

**Purpose:** The purpose of this study was to investigate the effect of family-centered interventions on improving health outcomes in children and adolescents with type 1 diabetes mellitus (T1DM). **Methods:** A literature search was conducted according to the PRISMA guidelines, using six electronic databases: EMBASE, CINAHL, Medline, CENTRAL, Scopus, and Web of Science. The inclusion criteria encompassed studies with populations of children and adolescents (age <18 years) and at least one parent/caregiver, or only parents/caregivers if the children were very young, and studies that investigated the health outcomes of children and parents/caregivers diagnosed with T1DM. **Results:** From 2,746 published studies, only nine studies met the inclusion criteria. The key interventions were non-technology-based interventions (n=4), technology-based interventions (n=2), and combined technology- and non-technology-based interventions (n=3). The interventions had effects on glycated hemoglobin, adherence to diabetes management, diabetes self-management behaviors, and parent-child teamwork in diabetes management. Other essential effects were children's quality of life, children's problem-solving skills, parents' quality of life, and parents' coping and depression. **Conclusion:** Family-centered interventions can effectively improve health outcomes in children and adolescents with T1DM. In the future, family-centered interventions integrated with other approaches, theories, and models should be developed to achieve the best possible outcomes.

**Key words:** Adolescent; Child; Diabetes mellitus; Family; Review

## Corresponding author

**Hyejung Lee**

College of Nursing, Yonsei University,  
50-1 Yonsei-ro, Seodaemun-gu, Seoul  
03722, Korea  
TEL: +82-2-2228-3345  
FAX: +82-2-392-5440  
E-MAIL: hlee26@yuhs.ac

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## INTRODUCTION

Children and adolescents are particularly vulnerable to the sequelae of type 1 diabetes mellitus (T1DM) because they have underdeveloped bodies and emotions with which to meet the rigorous requirements for medication and everyday monitoring [1]. The International Diabetes Federation has estimated that the number of children and adolescents (0-19 years) with T1DM was 1.2 million globally in 2021, with about 184,100 new cases being diagnosed annually [2]. T1DM is a serious condition where the blood glucose level is too high be-

cause the body cannot produce the hormone insulin for sugar control [3]. T1DM usually occurs when pancreatic beta-cells are destroyed, or cannot produce sufficient insulin to meet the body's demands [2]. This resultant lack or insufficient insulin production leads to high blood glucose levels. Increased blood glucose leads to microvascular and macrovascular complications, and increases in glycated hemoglobin (HbA1c), and indicator of glycemic control [2].

To control the adverse effects of T1DM on children and adolescents, a concerted effort must be tailored towards reducing complications, promoting recovery, reducing blood

glucose levels, and improving HbA1c [3]. The guidelines of the International Society for Pediatric and Adolescent Diabetes (ISPAD) indicate that the management of T1DM in children is aimed at maintaining HbA1c <7% [3]. Interventions to reduce the complications of diabetes in children and adolescents must include insulin management, nutrition, exercise, education, and self-monitoring [4]. These measures for children require continuous support and monitoring from parents and caregivers. Therefore, it is essential for a patient's family to play an active, optimal role in ensuring proper diabetes management during childhood and adolescence [5]. Parents' premature withdrawal from their diabetes management role has been found to worsen children's health outcomes, whereas their constant support and monitoring improve health outcomes [1]. Families play an important, unique role in caring for children with T1DM at home. Family-centered care as a philosophy in pediatric nursing supports and promotes the physical and physiological health development of families of children with special needs, including T1DM [6]. Family-centered interventions on children with T1DM are aimed at delaying the onset of complications by controlling glycemic levels and promoting children's health [7]. The specified method in these interventions is the participation and supervision of family members, especially parents, at home [7].

Increasing focus has been given to family-centered interventions to support patients' families in improving their physical and psychological health outcomes and overall experience during T1DM management [8]. Family-centered interventions refer to parental participation in care, the development of respectful and trusting partnerships, and information sharing between family members who provide and receive care [9]. Family-centered interventions are an acceptable healthcare approach and constitute an effective method of improving the quality of health outcomes and bringing satisfaction to both families and health professionals [10]. Reviews of family-centered interventions have reported positive outcomes among families having children with special conditions, including cancer [11], asthma [12], special needs [13], and T1DM [14]. This review focuses on family-centered interventions aimed at improving health outcomes for children/adolescents and parents, especially regarding diabetes management and glycemic control.

A previous systematic review of randomized controlled trials (RCTs) on family-centered interventions in children with T1DM reported varied outcomes for HbA1c, family relationships, and family conflict [14]. However, that systematic review by McBroom and Enriquez [14] was conducted over a decade ago. Family interventions may since have been influenced by the current fast-growing use of technology to man-

age chronic diseases. Therefore, it is critical to identify and appropriately situate the factors that currently influence family interventions among children with T1DM. This review shows the current development of family-centered interventions for children with T1DM, while noting the effectiveness of those interventions in improving the outcomes of diabetes management for both children with T1DM and their parents.

## METHODS

**Ethics statement:** This is an integrative review of the effect of family-centered interventions to improve health outcomes for children and adolescents with T1DM and was therefore exempt from institutional review board approval.

### 1. Research Design

This study is an integrative review of literature from 2009 to 2021 on the effect of family-centered interventions to improve health outcomes for children and adolescents with T1DM [15,16]. Integrative reviews serve as a critical strategy for advancing and understanding concepts that have broader dimensions [17]. This integrative review first identified that the outcome variable (family-centered interventions) was broadly conceptualized in various studies, therefore making an integrative review an appropriate strategy [15-17]. The year 2009 was chosen as the starting point for this review because an integrated review had already been published covering studies on family-centered interventions prior to 2009 [14]. Since that review was conducted over a decade ago, it was hoped that a new review study would provide more accurate information regarding the current status of family-centered interventions and T1DM, especially since various technological advances have been made in the intervening period. This study followed the criteria of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [18].

### 2. Research Method

A literature search was conducted in six electronic databases: EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, Cochrane Central Register of Controlled Trials (CENTRAL), Scopus, and Web of Science. The search terms were guided by the population, intervention, comparison, outcome, study design framework. In this review, the population was children and/or adolescents (age <18 years), along with at least one parent/caregiver. The interventions were family-centered interventions for children or adolescents with T1DM, and the comparison

was standard care. The primary outcome was HbA1c, and the secondary outcomes were other health outcomes regarding diabetes management and the effects of interventions on both the child and parent. We included HbA1c as a keyword for this study according to the ISPAD guidelines. HbA1c is the gold standard in successfully managing diabetes in children and adolescents because it predicts the occurrence of severe complications in the future [3]. Lastly, the study design was RCT alone. The detailed search outcomes are shown in Supplement 1.

The search strategy combined terms for children, adolescents, T1DM, family, interventions, and HbA1c, and it incorporated the appropriate Boolean operators. Synonyms were obtained using Emtree- and MeSH-controlled vocabulary and a thesaurus for free terms. All the articles were published in English, and the search was performed until December 19, 2021.

### 3. Search Results and Screening

From the six databases (EMBASE=436, Medline=112, CEN

TRAL=1,441, CINAHL=204, Scopus=11, Web of Science=542), 2,746 article results were imported and merged into the End-Note reference manager. Afterward, duplicate articles were removed either automatically (n=799) or manually (n=23), resulting in 1,947 articles. Two authors independently assessed the titles and abstracts retrieved to identify potential papers for inclusion. The total number of excluded articles was 1,911. After retrieving 36 articles, the authors examined the full-text papers. Any disagreements among the authors were resolved through discussions until consensus was reached. Finally, the authors included 9 studies. The selection process for this review is shown in a PRISMA flow diagram (Figure 1).

### 4. Inclusion Criteria

The authors included all RCTs analyzing family-centered interventions for children and adolescents with T1DM within the context of parental participation in interventions. The family-centered interventions were required to meet the following inclusion criteria: the population included children and/or adolescents (age <18 years), along with at least one

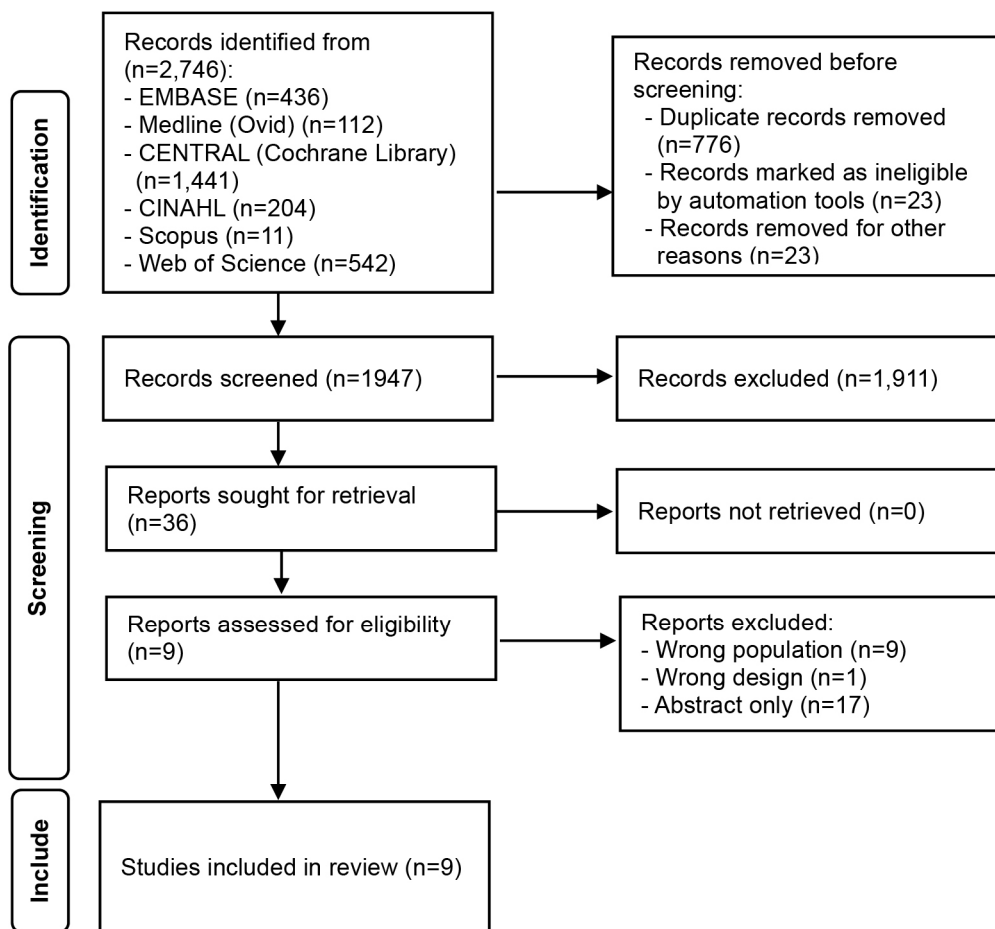


Figure 1. PRISMA flow diagram of the screening process.

parent/caregiver. In cases where there were very young children, only parents/caregivers were included. Considering HbA1c of children as an outcome, the interventions in this study included at least two people (the child and one parent, or only the parents in the case of younger children). According to the United Nations, young children are defined as being newborns to very early school age [19]. As the health development of children in this age group is the parents' responsibility, interventions can only include the parents [7].

## 5. Quality Appraisal

The authors used the Joanna Briggs Institute (JBI) critical appraisal tool for RCTs to assess the quality and eligibility of the studies included in this integrative review. This appraisal tool is specified for RCTs to evaluate the methodological quality and the risk of bias for each included study. It has 13 items: 1) Was true randomization used for assignment of participants to treatment groups? 2) Was allocation to treatment groups concealed? 3) Were treatment groups similar at the baseline? 4) Were participants blind to treatment assignment? 5) Were those delivering treatment blind to treatment assignment? 6) Were outcome assessors blind to treatment assignment? 7) Were treatment groups treated identically, other than the intervention of interest? 8) Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analyzed? 9) Were participants analyzed in the groups to which they were randomized? 10) Were outcomes measured in the same way for treatment groups? 11) Were outcomes measured in a reliable way? 12) Was appropriate statistical analysis used? 13) Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial? We can identify each item with the answer "yes", "no", "unclear", or "N/A (not applicable)". The decision to include each selected study was based on a minimum of 50% of the cut-off score, of which at least 7 out of 13 scores were "yes" from the JBI checklist. If the study has a minimum score of 70% (10 out of 13 "yes" scores), it is said to have good quality. A score range of 50%-69% (7-9 out of 13 "yes" scores) is moderate quality, and a score of less than 50% (fewer than 7 out of 13 "yes" scores) is considered to indicate poor quality. Two authors independently evaluated each study for methodological quality. Discrepancies in evaluation results were resolved through consensus. The results of the quality appraisal of the studies are shown in Table 1.

## 6. Data Extraction and Analysis

Two authors independently extracted the relevant infor-

mation and results from each study and compared the extracted information. These comparisons were then cross-checked by another author. Before the data extraction, a matrix was developed, discussed, and agreed upon by all authors. During the extraction, a matrix was developed with the main parameters including study characteristics (year and country), family characteristics (child's age, child's HbA1c, child's duration of diabetes, number of family members, and mother as caregiver), and intervention characteristics (duration, frequency, follow-up, measurement tools, and outcomes).

The data analysis was conducted using thematic synthesis [20,21]. The research findings were first transformed into qualitative statements and then coded to conduct the thematic synthesis. First, the data were coded, and similar codes were coalesced to form subthemes based on the relationship that existed between the identified codes [22,23]. These subthemes were then aggregated into main themes, based on the relationships between them. The themes that emerged from the analysis included the type and effectiveness of the interventions.

The type of intervention was categorized into three subthemes: non-technology-based interventions, technology-based interventions, and combined technology- and non-technology-based interventions. For the level of effectiveness of each intervention, there were two main themes: effects on diabetes management and effects on children and parents. There were four subthemes under effects on diabetes management: glyce-mic control (HbA1c), adherence to diabetes management, diabetes self-management behavior, and parent-child teamwork in diabetes management. Moreover, there were four subthemes under effects on children and parents: children's quality of life, children's problem-solving skills, parents' quality of life, and parents' coping and depression.

# RESULTS

## 1. Study Characteristics

Out of the nine RCTs included in this integrative review, six studies were conducted in the United States (US) (66.7%) [24-29], two in the United Kingdom (UK) [30,31], and one in Denmark [32]. All the studies targeted families with children under the age of 18 years. Four studies (44.4%) included adolescents [27,29,31,32], and four (44.4%) included both children and adolescents [24,26,28,30]. Only one study targeted families with children aged 1 to 12 years, and this intervention only included the parents [25]. The number of participant families ranged from 32 [26] to 390 [28]. Seven studies reported that diabetes duration was more than 4 years, but two studies did not report data regarding duration since diagnosis [25,26]. Eight studies reported that the children had an uncontrolled

**Table 1.** Results of Critical Appraisal of the Studies Using the Joanna Briggs Institute (JBI) Critical Appraisal Tool for Randomized Controlled Trials (RCTs) (N=9)

Items	Nansel et al. (2012) [28]	Fiallo-Scharer et al. (2019) [24]	Husted et al. (2014) [32]	Mayer-Davis et al. (2018) [27]	Lehmkuhl et al. (2010) [26]	Stanger et al. (2018) [29]	Grey et al. (2011) [25]	Murphy et al. (2012) [31]	Christie et al. (2016) [30]
1. Was true randomization used for assignment of participants to treatment groups?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was allocation to treatment groups concealed?	Yes	Unclear	Yes	Yes	Unclear	Unclear	Yes	Unclear	Yes
3. Were treatment groups similar at the baseline?	Yes	No	Unclear	Yes	Yes	Yes	Yes	Yes	No
4. Were participants blind to treatment assignment?	Unclear	Unclear	No	No	Unclear	Unclear	No	Unclear	Yes
5. Were those delivering treatment blind to treatment assignment?	Yes	Yes	No	No	Unclear	Unclear	No	Unclear	Yes
6. Were outcome assessors blind to treatment assignment?	Yes	Unclear	Unclear	No	Unclear	No	Yes	Unclear	Yes
7. Were treatment groups treated identically, other than the intervention of interest?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8. Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analyzed?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9. Were participants analyzed in the groups to which they were randomized?	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes
10. Were outcomes measured in the same way for treatment groups?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
11. Were outcomes measured in a reliable way?	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
12. Was appropriate statistical analysis used?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
13. Was the trial design appropriate, and any deviations from the standard RCT design accounted for in the conduct and analysis of the trial?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Yes/No/Unclear/Not Applicable	11/0/2/0	9/1/3/0	9/2/2/10	9/3/1/0	9/0/4/0	9/1/3/0	10/3/0/0	9/0/4/0	12/1/0/0

glycemic status (A1C >7.5%), while one reported that their glycemic control had improved [25]. Five studies reported that most of the caregivers involved in the interventions were mothers, with a percentage range of 69%-97% [24,26,27,29,30]. The remaining four studies did not report the caregivers' demographic characteristics [25,28,31,32]. The extracted information from the selected studies is shown in Table 2.

## 2. Quality Assessment

Based on the results of quality appraisal using the JBI tool for RCTs, we identified six studies that were of moderate quality and three studies that were good quality. All studies had true randomization of assignment. The treatment groups were treated identically other than the intervention of interest, follow-up was complete, and the outcome was measured in

**Table 2.** Analysis of Research Articles According to General Characteristics (N=9)

Authors	Country	Age of children (year)	Duration of diabetes (year)	HbA1c (%)	Number of families (n)	Mothers as caregivers (%)
Nansel et al. (2012) [28]	USA	9-15	4.8	8.4	390	NR
Fiallo-Scharer et al. (2019) [24]	USA	8-16	5.4	9.2	214	84.6
Husted et al. (2014) [32]	Denmark	13-18	6.1	9.5	71	NR
Mayer-Davis et al. (2018) [27]	USA	13-16	6.5	9.7	258	84.0
Lehmkuhl et al. (2010) [26]	USA	9-17	NR	10.8	32	84.4
Stanger et al. (2018) [29]	USA	13-17	5.9	9.1	61	88.5
Grey et al. (2011) [25]	USA	1-12	NR	7.0	129	NR
Murphy et al. (2012) [31]	UK	11-16	5.6	9.3	305	NR
Christie et al. (2016) [30]	UK	8-16	5.7	9.9	365	91.2

NR, not reported.

the same, reliable way. Moreover, an appropriate statistical analysis and trial design were used. In addition, seven studies had participants analyzed in the groups to which they were randomized, six had a similar analysis at the baseline, five studies had concealed allocation, three had blind deliverers of treatment, and only one study had participants blind to the treatment assignment. Therefore, the risk of bias in the selected studies was considered to be acceptable.

### 3. Key Findings

Using thematic data analysis, two broad themes were identified 1) the type of interventions, and 2) the effectiveness of interventions. These themes identified as related to family-centered interventions in children and adolescents with T1DM were appropriate, as integrative reviews allow the formation of research themes [20,21].

#### 1) Type of interventions

Family-centered interventions have evolved and integrated different approaches and models to maximize their benefits. In this review, all studies had more than one method of intervention. To facilitate identification, the authors classified the types of interventions based on the main method used. The results are shown in Table 3. The key interventions were categorized into three groups: non-technology-based interventions (n=4), technology-based interventions (n=2), and combined technology- and non-technology-based interventions (n=3). Each intervention type is described in detail below.

##### (1) Non-technology-based interventions (n=4)

In this category, we identified two different approaches of

non-technology-based interventions: skills training interventions (n=2) and educational interventions (n=2).

##### ① Skills training interventions (n=2)

The term "skills training" in this study refers to programs that teach coping, problem-solving, and stress management techniques for children and adolescents with T1DM [33]. The goal of diabetes skills training is to develop an extensive skill set for managing diabetes in challenging situations [33]. In this review, two skill training interventions were identified: guided self-determination youth (GSD-Y) and coping skills training (CST) [25,32].

GSD-Y was delivered individually, and CST was delivered in groups [25,32]. GSD-Y focused on the patient's ability to recognize barriers to managing diabetes and communicate these to health professionals. Meanwhile, CST helped parents cope well in problematic situations, increased their self-efficacy, and promoted positive behavior. GSD-Y was delivered when the families made regular clinic visits, and sessions were mostly given to the child only. CST consisted of two to six families, and both parents and children participated in the sessions, with both parents being advised to participate. However, in the CST study, data from only one parent per child was included in the analysis, from which we assumed that the authors considered both parents as one unit. GSD-Y had eight 60-minute sessions, and CST had six 90-minute sessions [25,32].

##### ② Educational interventions (n=2)

Diabetes education is an essential key for understanding and improving diabetes management skills for families with children who have T1DM [34]. In this review, the authors identified two interventions based on education: the Families and Adolescents Communication and Teamwork Study

**Table 3.** Analysis of Family-Centered Interventions for Children and Adolescents with T1DM (N=9)

	Nansel et al. (2012) [28]	Fiallo-Scharer et al. (2019) [24]	Husted et al. (2014) [32]	Mayer-Davis et al. (2018) [27]	Lehmkuhl et al. (2010) [26]	Stanger et al. (2018) [29]	Grey et al. (2011) [25]	Murphy et al. (2012) [31]	Christie et al. (2016) [30]
<b>Intervention descriptions</b>									
Intervention	WE-CAN Manage Diabetes	Family-Centered Tailoring Diabetes Self-Management (FCT)	Guided self-determination youth (GSD-Y)	FLEX (Flexible Lifestyles Empowering Change)	Telehealth Behavior Therapy (TBT)	Web-Delivered Multicomponent Intervention (WebRx)	Coping skills training (CST) for parents	Families and Adolescents Communication and Teamwork Study (FACTS)	The Child and Adolescents Structured Competencies Approach to Diabetes Education (CASCADE)
Period Intervention	6-7 sessions, 30 minutes every session for 21 months, follow-up at 24 months	4 sessions, 75 minutes every session for 9 months, follow-up at 24 months	8 sessions, 60 minutes every session for 8-12 months, follow-up at 6 and 30 months	4 sessions, 40-60 minutes every session for 3 months, follow-up at 8 months	36 sessions, 15-20 minutes every session for 3 months, follow-up at 3 months	15 sessions, 20 minutes every session for 25 weeks, follow-up at 6 and 12 months	6 sessions, 90 minutes every session, follow-up at 12 months	6 sessions, 90 minutes every session for 6 months, follow-up at 18 months	4 sessions for 4 months, follow-up at 12 and 24 months
<b>Measurement tools</b>									
A1C	Decreased HbA1c after 24 months and also in adolescents (12-14 years) but not in preadolescents (9-11 years)	Decreased HbA1c in teens (13-16 years) site 1	NS	NS	NS	Decreased HbA1c	NS	NS	NS
Diabetes Self-Management Profile (DSMP)	NS			Increased in children's reports	NS				
Treatment self-regulation questionnaire			Decreased amotivation						
Motivation and Intention Questionnaire				Increased motivation					
Predictive of Glycemic Control in Diabetes Control and Complications (DCC1) Trial								Increased proactivity regarding insulin dose adjustment	
Fear of hypoglycemia, parent and child reports				Decreased children's helplessness or worry and increased parental efforts to maintain high blood glucose					
The Diabetes Family Conflict Scale				Decreased family conflict (parents' reports)					
Revised Diabetes Family Conflict Scale						Decreased family conflict			
Diabetes Family Responsibility Questionnaire (DFRQ)					NS			NS	NS
The Diabetes Responsibility and Conflict Scale (DRC)							NS		
Self-monitoring of blood glucose frequency						Increased self-monitoring of blood glucose			

HbA1c, glycated hemoglobin; NS, not significant.

**Table 3.** Analysis of Family-Centered Interventions for Children and Adolescents with T1DM (N=9) (Continued)

	Nansel et al. (2012) [28]	Fiallo-Scharer et al. (2019) [24]	Husted et al. (2014) [32]	Mayer-Davis et al. (2018) [27]	Lehmkuhl et al. (2010) [26]	Stanger et al. (2018) [29]	Grey et al. (2011) [25]	Murphy et al. (2012) [31]	Christie et al. (2016) [30]
Revised Parental Monitoring of Diabetes Care Questionnaire						Increased frequent reviews by parents of the adolescents' glucometers			
Perceived Competence in Diabetes Scale			NS						
Health Care Climate Questionnaire			NS						
Problem Areas in Diabetes (PAID)			NS					NS	
World Health Organization 5 scale (WHO5)			NS						
Perception of Parents Scale (POPS), parental autonomy and involvement subscale			NS						
Diabetes Family Behavior Scale (DFBS)					NS				
Diabetes Family Behavior Checklist (DFBC)					NS				
Clinical Global Impression Scale (CGIS)					NS				
Health Behavior in School Children (HBSC)								NS	
Pediatric Quality of Life Inventory (Peds-QL)		NS							NS
The Pediatric Quality of Life Inventory Generic Core Scales				Increased children's quality of life					
Diabetes Quality of Life Youth Scale (DQOLY-SF)								NS	
Revised version of the Social Problem Solving Inventory				Increased adolescents' cognitive, affective and behavioral abilities to resolve problems in everyday living					
The Parents Diabetes Quality of Life (PDQOL)							Improved quality of life for parents in treatment group		
PedsQL Family Impact Module		Improved quality of life for parents in site 1							
The Issues in Coping with IDDM (ICC) parent scale							NS		
Centers for Epidemiologic Study Depression Scale				NS			NS		

HbA1c, glycated hemoglobin; NS, not significant.



(FACTS) and the Child and Adolescents Structured Competencies Approach to Diabetes Education (CASCADE) intervention [30,31].

The FACTS combined conventional diabetes self-management education and family communication training focused on improving parental involvement and glycemic control. CASCADE used a modified psychology-led intervention through motivational interviewing and solution-focused brief therapy, focused on improving behavior changes in children and families regarding diabetes management. Both interventions organized the families into small groups (three to six families per group), who each attended four sessions. The FACTS and CASCADE had the same themes in their modules regarding food/blood glucose, including counting carbohydrates and blood glucose checks in the first two sessions. CASCADE included adjusting insulin doses in the third module, followed by a module focusing on living with diabetes. However, in the FACTS, adjusting insulin doses was discussed in the second module (along with blood glucose checking), followed by teamwork/communication, interdependence/sharing responsibility, and letting go in the last two sessions [30,31]. This difference was because the FACTS program focused on providing not only diabetes self-management education, but also family communication; therefore, the program included family communication training [31].

## 2) Technology-based interventions (n=2)

The use of technology in family-centered interventions for children with T1DM has garnered varying interest over the years. In this review, the authors identified two interventions based on technology and the following skills training approaches: Telehealth Behavior Therapy (TBT) and Web-Delivered Multicomponent Intervention (WebRx) [26,29].

TBT used telephone calls as a medium to improve parent-child relationships, decrease familial conflict, and address four primary barriers to adherence to diabetes management, while WebRx used web conferencing to improve self-monitoring and working memory in adolescents and improve parents' monitoring of their children's diabetes management. In TBT, both the parent and child participated in each session together. In WebRx, the child attended almost all sessions, while the parent was included for a few sessions only. The parent only attended some sessions because WebRx primarily focused on diabetes self-management in adolescents. Therefore, the parent was responsible only for supervising the child's development and managing child-parent relationships to reduce family conflict. TBT had 36 sessions, which were 15 to 20 minutes long, while WebRx had 15 sessions that were each 20 minutes long [26,29].

## 3) Combined technology- and non-technology-based interventions (n=3)

Interestingly, aside from using technology and media to deliver interventions, we found that technology can support the implementation of non-technological-based interventions. In this category, we identified three studies combining technology- and non-technology-based interventions. All were based on skills training approaches, which were Flexible Lifestyles Empowering Change (FLEX), WE-CAN Manage Diabetes, and Family-Centered Tailoring Diabetes Self-Management (FCT) [24,27,28].

FLEX aimed to promote self-management and improve blood glucose control, WE-CAN Manage Diabetes aimed to improve diabetes management through family collaboration and a problem-solving approach, and FCT aimed to provide solutions to eliminate the barriers to self-management associated with worsening glycemic control and quality of life in both parents and children with T1DM. In WE-CAN Manage Diabetes and FLEX, the intervention was delivered when the families made regular clinic visits. However, in WE-CAN Manage Diabetes, the parent and child were included together in each session. In FLEX, sessions were mostly given to the child only, with the parent only participating in some parts of the sessions. FCT was delivered using groups consisting of two to six families, and both the parent and child participated in the sessions. WE-CAN Manage Diabetes had six to seven 30-minute sessions, FLEX had four 40- to 60-minute sessions, and FCT had four 75-minute sessions. WE-CAN Manage Diabetes used technology to conduct assessment interventions and health advisor weekly conferences by telephone. FLEX used technology as a reminder or motivational booster (text messaging, alarms, and calendar), and FCT used video conferencing technology during the facilitators' initial training and meetings through communication technology [24,27,28].

## 4. Effectiveness of Interventions

The level of effectiveness of each intervention was assessed, and two main themes were identified: effects on diabetes management, and effects on children and parents.

### 1) Effects on diabetes management

Some subthemes were identified as being associated with the broader theme of the effect of interventions on diabetes management. These subthemes were glycemic control (HbA1c), adherence to diabetes management, diabetes self-management behavior, and parent-child teamwork in diabetes management.

#### (1) Glycemic control

All studies reported HbA1c as their primary outcome indicator. Three studies [24,28,29] reported significant decreases in HbA1c; however, Nansel et al. [28] found a significant decrease in adolescents aged 12 to 14 years, but not in children aged 9 to 11 years. Fiallo-Scharer et al. [24] found a significant decrease only in adolescents aged 13 to 16 years at one of their three sites. One study reported a decrease in HbA1c in the intervention group, but it was not statistically significant [26]. However, five studies reported no significant effect on HbA1c [25,27,30-32] with one reporting that the HbA1c of children at 12 months post-intervention had worsened, but remained within normal limits [25].

#### (2) Adherence to diabetes management

Three studies assessed adherence to diabetes management [26-28], and two studies assessed motivation for adherence to diabetes management [27,32]. One study reported increased adherence to diabetes management in children [27], and one reported no significant changes in diabetes management adherence [28]. Another reported that both the intervention and waitlist groups showed a non-significant increase in adherence to diabetes management [26]. In conclusion, significant increases in motivation for adherence to diabetes self-management were only found in adolescents [27,32].

#### (3) Diabetes self-management behaviors

Two studies assessed diabetes self-management behaviors with different outcomes. One reported that there was an increased frequency of adjusting insulin doses for snacks, meals, and recent blood glucose levels [31], and another reported significant effects on two domains: decreased helplessness or worry among children and increased efforts by parents to maintain high blood glucose levels [27].

#### (4) Parent-child teamwork in diabetes management

Six studies assessed parent-child teamwork in diabetes management with outcomes including family conflict, responsibility, and monitoring in diabetes management. Family conflict, which is related to the parent-child relationship, was found to decrease significantly in two studies [27,29]; however, the study by Mayer-Davis et al. [27] found that significant results were only obtained from parent reports. Regarding responsibility in diabetes management, which refers to how children and adolescents with T1DM share responsibilities with their caregivers in managing diabetes, no significant effects were found for either children or their parents [25,26,30,31]. As pertains to monitoring diabetes management, a significant increase was found in adolescents' self-monitoring of blood glucose and parents' frequent reviews of the adolescent's glucometer [29].

## 2) Effects on children and parents

Under this broad theme, the following subthemes were identified: children's quality of life, children's problem-solving skills, parents' quality of life, and parents' coping and depression.

#### (1) Children's quality of life

Four studies assessed children's quality of life [24,27,30,31]. Only one study reported improvements in children's quality of life from children's reports [27]. Three others reported no significant effect on children's quality of life [24,30,31].

#### (2) Children's problem-solving skills

One study assessed children's problem-solving skills and found a significant increase in adolescents' cognitive, affective, and behavioral abilities to resolve problems in everyday living [27].

#### (3) Parents' quality of life

Two studies assessed parents' quality of life [24,25] and reported no significant improvement; however, Grey et al. [25] found an improvement in parents' quality of life in the intervention group. In the study by Fiallo-Scharer et al. [24], parents' quality of life improved considerably in one of their three study sites.

#### (4) Parents' coping and depression

Only one study assessed parents' coping and depression [25]. It reported no significant effect; however, parents' coping improved in the treatment group [25].

## DISCUSSION

This integrative review assessed family-centered interventions incorporated into the care of families with children and adolescents with T1DM. The main themes of emerging family-centered interventions involved skills training, health education, and integrating technology in the care of children and adolescents with T1DM. The critical factor identified in this review that differentiates it from that conducted by McBroom and Enriquez [14] over a decade ago is the use of technology in family-centered interventions for children and adolescents with T1DM. Technological advances have been critical tools, especially in the last two decades, and have been used in health and chronic disease management for diagnosing, monitoring prognosis, issuing reminders for medication and treatment, and promoting the general well-being of people with chronic diseases. Family-centered interventions have received considerable attention and have effectively improved how people with diabetes are managed at home and

within health facilities. Healthcare professionals must leverage this growing trend in technological advancement by incorporating simple internet-based or tools-based interventions that will promote family involvement and monitoring of children and adolescents with T1DM. These measures can also be used as reminders for children and adolescents to take their medications or to keep their hospital follow-up appointments.

The authors identified considerable variation and complexity in the methods used to implement family-centered interventions in terms of the outcome variables, measured variables, measurements, and methods adopted. This poses a challenge for conducting a meta-analysis of study outcomes due to the heterogeneity of the measured variables for each intervention. Due to these challenges, an integrative review of family-centered interventions on children and adolescents with T1DM was deemed appropriate.

The authors found that family-centered interventions for families with children and adolescents with T1DM had satisfactory results regarding decreased HbA1c as a primary outcome in three studies. The results in each study were different and ranged from significant differences between the intervention and control groups [24,28,29], and pre- and post-intervention changes [26] to no significant changes at all [25,27,30-32]. The differences in the results regarding HbA1c, the primary indicator of successful management of diabetes in children, are influenced by many factors, including failure to attend interventions [30-32], insulin dosing behavior (as insulin deficiency causes persistent hyperglycemia in T1DM) [27], and participants' heterogeneity regarding the intervention response and HbA1c [24,27]. Grey et al. [25] and Husted et al. [32] argued that because adolescents' HbA1c tends to worsen from the age of 10 to 16-17 years, an increase in insulin resistance related to puberty can influence HbA1c outcomes. Therefore, the worsening of HbA1c during puberty must be considered as a major focus when managing children's T1DM [25,32]. Hopefully, earlier interventions will improve the likelihood of preventing an exacerbation of HbA1c during puberty [30].

According to the American Diabetes Association, family involvement in diabetes management is an integral part of optimizing diabetes mellitus control indices during childhood and adolescence. Therefore, a family-centered approach should be applied to improve the quality of diabetes care [35]. Children with T1DM depend entirely on family involvement for effective management. As children become adolescents, the role of family members decreases, and adolescents begin to take responsibility for managing their diabetes [7]. In this family situation, pediatric nurses have additional duties, extending beyond simple care to advocacy for the other family members, especially parents, to supervise and follow-up on their child-

ren's diabetes management at home [7]. Therefore, as these children grow, they must be empowered to self-manage and monitor their blood sugar levels independently.

The authors also noted that in addition to improving diabetes management, family-centered interventions improved parent-child relationships and reduce miscommunications [26,27,29,32]. Adolescence is a vulnerable period for adolescents with T1DM. During this period, adolescents start learning diabetes self-management, but parents and adolescents have different expectations. Parents feel their children cannot do all these tasks, while children think their parents control them too much. This disconnect leads to miscommunication and family conflict [36]. The family-centered interventions in this review had effects on diabetes management, such as increased adherence [26,27], increased motivation [32], increased diabetes self-management behaviors [27,31], decreased diabetes-related family conflict [27,29], increased self-monitoring of blood glucose frequency in adolescents, and increased frequent parental reviews of adolescents' glucometers [29]. It is possible that these effects result from improved knowledge and acceptance of the disease and its management process. The results of these combined outcomes facilitate positive outcomes in terms of blood glucose levels, along with improved living conditions for children with T1DM [26,29]. This further emphasizes the need to use collaborative means to provide interventions to families of children with T1DM. Improving families' knowledge and acceptance of diabetes interventions for children is therefore essential when planning family interventions.

Furthermore, family-centered interventions had significant effects on children, including improved quality of life and increased cognitive, affective, and behavioral abilities to resolve problems in everyday living [27]. However, children's quality of life improvement only increased according to self (children's) reports. Nonetheless, self-reported improvement in children's emotional support and improvement in health is a more reliable measure than reports from parents [37]. In addition, the parents of children with T1DM may have trouble distinguishing between normal and diabetes-related behavior, making it difficult to assess well-being accurately [38]. One study reported this improvement [27], while three other studies reported no improvement in children's quality of life [24,30,31]. This may have been due to the low participation rate, as only 50%-53% of participants attended all sessions [30,31]. The intervention period also had an effect because interventions held only once in 3 to 4 months are likely to be less effective compared to weekly interventions [24]. Diabetes management interventions involving the families of children with T1DM can significantly improve their health. Parents of children with T1DM are more likely to experience physical

and psychological problems and tend to be more stressed and worried, as well as have more family conflict and less social interaction [39]. Only two studies reported outcomes regarding parents and found positive effects on improving parents' quality of life and coping skills [24,25].

Family-centered interventions are critical in the care of children and adolescents with diabetes. These interventions must be integrated into appropriate nursing-based theories for effective implementation while providing a basis for the continuous monitoring of the impact of such interventions. These integrations affect glycemic control, diabetes management, and quality of life for children with T1DM and their families [28]. One of these integrations included up-to-date developments in technology. Since the early 1990s, technology has been applied to diabetes management interventions. Early interventions were based on telephone communication, which in later years began to evolve [40]. Technology-based interventions may be the solution to overcoming the difficulties of face-to-face interventions because of the improved geographical and economic conditions and efficient implementation [26,29]. Five studies in this review integrated technology into their interventions. Two integrated a telehealth and web-based approach to implement their primary interventions [26,29], and three used technology for telephonic follow-ups and health advisors' weekly conferences, communication of reminders or motivational boosters, and video conferencing during the facilitators' initial training sessions and meetings [24,27,28]. Using technology to assist clients at home without scheduling face-to-face consultations can promote high completion rates and low costs, which will improve glycemic control; therefore, these methods should be integrated into regular diabetes care [26,29].

This review highlighted several issues requiring further attention regarding family-centered intervention implementation with children and adolescents with T1DM. First, limitations include insufficient staff skill levels following short and insufficient training periods before the intervention [30], the length of time taken by the staff to deliver the interventions [28], factors that hindered the staff from completing all intervention sessions [27], and a lack of staff to deliver the interventions [30]. Second, the interventions, especially those with technology integration, were expensive and complex; therefore, such interventions were only accessible to the middle class [29]. Third, there were issues regarding the participants. These included the heterogeneity of participants, as the interventions implemented only targeted specific needs [31]. In addition, the lack of data in incomplete participant evaluation sheets inhibited the evaluations of intervention effects [32]. There was insufficient support for empowerment and enduring motivation during the interventions [31]. One inter-

vention was delivered in coordination with routine clinic visits, which were only conducted once every 3 to 4 months. This led to the results not being as visible compared to interventions delivered once a week or over several weeks [24]. Family-centered interventions should be designed to integrate technology such as continuous glucose monitoring and hybrid closed-loop insulin pumps, which can be vital to future interventions. Moreover, the ongoing coronavirus disease 2019 situation has highlighted opportunities for communication technology to increase intervention efficiency, especially regarding health care for families who live far from clinics and cannot make routine check-up visits.

This integrative review has the following limitations. First, the literature search only included English-language studies; therefore, this review did not include studies in other languages that described family-centered interventions. As a result, the studies in this review only came from three countries on two continents, and differences in culture and values between the countries may have affected the outcomes of the interventions. Second, the findings of this review covered a wide range of variation in methods, measurements, and outcomes, which led to difficulties in synthesizing. However, the use of integrative design methods was critical in incorporating all the different facets of the themes generated from the data [20,21]. To overcome this challenge, the authors were meticulous and consulted each other often to be confident of the integrated results. Where discrepancies existed in authors' opinions, a third person was consulted to arbitrate, and decisions were arrived at using consensus. Finally, the development and usage of templates for quality appraisal and data extraction were critical in integrating all study findings.

## CONCLUSION

This review identified the effects of family-centered interventions on children and adolescents with T1DM. Family-centered interventions have improved the health outcomes of children and parents, especially regarding diabetes management. One critical and significant finding of this study is the use of technology to promote family-centered interventions in children with diabetes and improve their health outcomes. With the increasing development of technology, family-centered interventions integrating technology may create good opportunities for positive outcomes in children and adolescents with T1DM. Therefore, future research should focus on testing the efficacy and cost-effectiveness of technology-based family-centered interventions for improving the health outcomes of children and adolescents with T1DM. Additionally, nursing-based family-centered interventions must integrate other approaches, theories, or models in development and

testing. This will ensure that those interventions address the individual families' cultural, socioeconomic, and geographical characteristics in order to achieve better health outcomes.

## ORCID

Aloysia Ispriantari <https://orcid.org/0000-0002-2415-4018>  
Rismia Agustina <https://orcid.org/0000-0001-6988-8608>  
Kennedy Diema Konlan <https://orcid.org/0000-0002-1994-3792>  
Hyejung Lee <https://orcid.org/0000-0001-9357-0640>

## Authors' contribution

Conceptualization: Aloysia Ispriantari, Hyejung Lee; Data collection, Formal analysis: all authors; Writing-original draft: Aloysia Ispriantari; Writing-review and editing: all authors; Final approval of published version: all authors.

## Conflict of interest

No existing or potential conflict of interest relevant to this article was reported.

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## Data availability

Please contact the corresponding author for data availability.

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Supplement 1. Database Search Strategies

Database	#	Search syntax	Citations found
EMBASE	1	(child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*):ti,ab,kw	25,539
	2	"juvenile"/exp	4,061,899
	3	(diabet* OR 'type 1 diabet*' OR IDDM OR T1D* OR 'insulin* depend*' OR 'juvenile diabet*'):ti,ab,kw	1,079,118
	4	'insulin dependent diabetes mellitus'/exp	130,245
	5	((famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR 'sibling*') AND (management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*)):ti,ab,kw	2,918,518
	6	'family therapy'/exp	14,329
	7	('glycemic index' OR 'glycemic control*' OR 'glucose target*' OR 'glucose control*' OR 'glucose level*' OR A1C OR HbA1C):ti,ab,kw	195,479
	8	"hemoglobin A1c"/exp	124,556
	9	(#1 OR #2) AND (#3 OR #4) AND (#5 OR #6) AND (#7 OR #8)	6,284
	10	#9 AND (2009:py OR 2010:py OR 2011:py OR 2012:py OR 2013:py OR 2014:py OR 2015:py OR 2016:py OR 2017:py OR 2018:py OR 2019:py OR 2020:py OR 2021:py) AND 'randomized controlled trial'/de	436
Medline (Ovid)	1	(child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*):tw	1,653,139
	2	exp "child"/ OR exp "adolescent"/	3,210,980
	3	(diabet* OR 'type 1 diabet*' OR IDDM OR T1D* OR 'insulin* depend*' OR 'juvenile diabet*'):tw	695,532
	4	exp "Diabetes Mellitus, Type 1"/	80,947
	5	((famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR 'sibling*') AND (management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*)):tw	1,990,285
	6	exp "Family Therapy"/	9,061
	7	("glycemic index" OR "glycemic control*" OR "glucose target*" OR "glucose control*" OR "glucose level*" OR A1C OR HbA1C).tw	120,348
	8	exp "Glycated Hemoglobin A"/	38,602
	9	(1 OR 2) AND (3 OR 4) AND (5 OR 6) AND (7 OR 8)	3,376
	10	limit 9 to (english language and full text and humans and yr="2009-Current" and randomized controlled trial)	112
CENTRAL (Cochrane Library)	1	(child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*):ti,ab,kw	180,412
	2	[mh "child"] OR [mh "adolescent"]	138,460
	3	(diabet* OR 'type 1 diabet*' OR IDDM OR T1D* OR 'insulin* depend*' OR 'juvenile diabet*'):ti,ab,kw	103,960
	4	[mh "Diabetes Mellitus, Type 1"]	5,872
	5	((famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR 'sibling*') AND (management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*)):ti,ab,kw	349,712
	6	[mh "family therapy"] OR [mh "family nursing"]	1,037
	7	('glycemic index' OR 'glycemic control*' OR 'glucose target*' OR 'glucose control*' OR 'glucose level*' OR A1C OR HbA1C):ti,ab,kw	72,485
	8	[mh "Glycated Hemoglobin A "] OR [mh "Glycemic Control"]	158
	9	(#1 OR #2) AND (#3 OR #4) AND (#5 OR #6) AND (#7 OR #8)	1,441
CINAHL	1	TI (child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*) OR AB (child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*)	600,969
	2	MH ("Child+" OR "Adolescence+")	1,057,409
	3	TI (diabet* OR 'type 1 diabet*' OR IDDM OR T1D* OR 'insulin* depend*' OR 'juvenile diabet*') OR AB (diabet* OR 'type 1 diabet*' OR IDDM OR T1D* OR 'insulin* depend*' OR 'juvenile diabet*')	224,120
	4	MH ("Diabetes Mellitus, Type 1+")	27,349



**Supplement 1. Database Search Strategies (Continued)**

Database	#	Search syntax	Citations found	
CINAHL	5	(TI (famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR sibling*) AND TI (management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*)) OR (AB (famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR sibling*) AND AB (management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*))	771,336	
	6	MH ("Family therapy+" OR "Family centered care+")	14,325	
	7	TI ("glycemic index" OR "glycemic control*" OR "glucose target*" OR "glucose control*" OR "glucose level*" OR A1C OR HbA1C) OR AB ("glycemic index" OR "glycemic control*" OR "glucose target*" OR "glucose control*" OR "glucose level*" OR A1C OR HbA1C)	38,675	
	8	MH ("Hemoglobin A, Glycosylated+" OR "Glycemic control+")	26,856	
	9	(S1 or S2) AND (S3 OR S4) AND (S5 OR S6) AND (S7 OR S8)	451	
	10	S9 and (MH ("randomized controlled trials" OR "double – blind studies" OR "single – blind studies" OR "random assignment" OR "pretest – posttest design" OR "cluster sample") OR TI (randomised OR randomized) OR AB (random*) OR TI (trial) OR MH (sample size) AND AB (assigned OR allocated OR control)) OR MH (placebos) OR PT (randomized controlled trial) OR AB (control W5 group) OR MH ("crossover design" OR "comparative studies") OR AB (cluster W3 RCT)) NOT ( (MH ("animals+" OR "animal studies") OR TI (animal model*)) NOT MH (human))	204	
	Scopus	1	title-abs-key (child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*)	12,713
		2	title-abs-key (diabet* OR type 1 diabet* OR iddm OR t1d* OR "insulin* depend*" OR "juvenile diabet*")	336,466
		3	title-abs-key ((famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR sibling*) AND (management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*))	4,785,339
		4	title-abs-key (glycemic index OR glycemic control* OR glucose target* OR glucose control* OR glucose level* OR a1c OR hba1c)	45,248
5		#1 AND #2 AND #3 AND #4	14	
6		#6 ND (LIMIT-TO (PUBYEAR, 2021) OR LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2016) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2013))	11	
Web of Science	1	ti=(child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*) OR ab= (child* OR juvenil* OR paediatric* OR pediatric* adolesc* OR preadolesc* OR pre-adolesc* teen* OR preteen* OR pre-teen* OR youth* OR young* kid*)	1,707,881	
	2	ti=(diabet* OR "type 1 diabet*" OR IDDM OR T1D* OR "insulin* depend*" OR "juvenile diabet*") OR ab= (diabet* OR "type 1 diabet*" OR IDDM OR T1D* OR "insulin* depend*" OR "juvenile diabet*")	731,619	
	3	(ti=(famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR sibling*) AND ti= (management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*)) OR (ab=(famil* OR caregiver* OR care* OR parent* OR mother* OR father* OR paternal* OR maternal* OR relative* OR sibling*) AND ab=(management* OR teach* OR counsel* OR program* OR therap* OR intervention* OR treatment* OR educat* OR train*))	1,949,385	
	4	ti=("glycemic index" OR "glycemic control*" OR "glucose target*" OR "glucose control*" OR "glucose level*" OR A1C OR HbA1C) OR ab=("glycemic index" OR "glycemic control*" OR "glucose target*" OR "glucose control*" OR "glucose level*" OR A1C OR HbA1C)	110,405	
	5	#4 AND #3 AND #2 AND #1	1,443	
	6	#4 AND #3 AND #2 AND #1 and 2009 or 2010 or 2011 or 2021 or 2020 or 2019 or 2018 or 2017 or 2016 or 2015 or 2014 or 2013 or 2012 (Publication Years) and English (Languages)	1,117	
	7	#6 AND (TS=clinical trial* OR TS=research design OR TS=comparative stud* OR TS=evaluation stud* OR TS=controlled trial* OR TS=evaluation stud* OR TS=prospective stud* OR TS=random* OR TS=placebo* OR TS= (single blind*) OR TS= (double blind*))	542	