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Authors	Savage, Eileen;Farrell, Dawn;McManus, Vicki;Grey, Margaret
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UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

The science of intervention development for type 1 diabetes in childhood: systematic review

Correspondence to: E. Savage
Email: e.savage@ucc.ie

Eileen Savage PhD BNS RCN
Associate Professor
Catherine McAuley School of Nursing
Brookfield Health Science Complex
University College Cork
Ireland
e.savage@ucc.ie

Dawn Farrell BSc RGN
Research Assistant
Catherine McAuley School of Nursing
Brookfield Health Science Complex
University College Cork
Ireland

Vicki McManus MSc BA RCN
Lecturer
Catherine McAuley School of Nursing
Brookfield Health Science Complex
University College Cork
Ireland

Margaret Grey DrPh, RN, FAAN
Dean & Annie Goodrich Professor
Yale School of Nursing
100 Church Street South
New Haven,
CT 06535-0740

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Author contributions
ES and MG were responsible for the conception and design of the review. DF was responsible for literature searching. ES, DF & VMcM was responsible for data collection. ES was responsible for data analysis. ES and MG were responsible for drafting the manuscript. All authors were involved in proof reading the manuscript.

ABSTRACT

AIM: This paper is a report of a review of the science of intervention development for type 1 diabetes in childhood and its implications for improving health outcomes in children, adolescents, and/or their families.

BACKGROUND: Previous reviewers have identified insufficient evidence to support the application of effective interventions for type 1 diabetes in clinical practice. The need for quality randomized controlled trials to address shortcomings in previous study designs has been highlighted as a priority for future intervention research. However, there is also a need to consider the scientific development of interventions, which to date has received little attention.

DATA SOURCE: A search for published randomized controlled trials over 5 years (2004-2008) was conducted in electronic databases (Medline, CINAHL, Cochrane Library, Psychinfo, ERIC). Reference lists of papers identified from electronic searches were examined for additional papers.

METHODS: A systematic review was conducted. Studies were included if (i) an intervention for managing any aspect of type 1 diabetes was implemented, (ii) children, adolescents and/or their families were sampled, (iii) a randomized controlled trial, (iv) published in English.

RESULTS: Fourteen randomized controlled trials were reviewed on education (n=7), psychosocial (n=5) and family therapy (n=2) interventions. Compared to education interventions, family therapy and most psychosocial interventions were developed with greater scientific rigour, and demonstrated promising effects on more health outcomes measured.

CONCLUSION: Interventions developed within clearly-defined scientific criteria offer potential for improving health outcomes in children and adolescents with type 1 diabetes and their families. Future reviews on interventions for type 1 diabetes in childhood need to include criteria for assessing the science of intervention development.

Keywords: childhood, type I diabetes, , randomized controlled trails, science, intervention development, systematic review, nursing

WHAT IS ALREADY KNOWN ABOUT THIS TOPIC

- Psychosocial interventions are more promising than education interventions in improving glycaemic control and other outcomes for type 1 diabetes in childhood.
- Improvements in the quality of randomized controlled trial methods are needed to increase effectiveness of interventions for type 1 diabetes in childhood
- Theory-based interventions demonstrate greater efficacy than atheoretical interventions

WHAT THIS PAPER ADDS

- A systematic and rigorous approach to the scientific development of interventions is necessary in order to establish a range of effective interventions for managing type 1 diabetes in childhood
- Psychosocial and family therapy interventions have been developed in recent years with greater scientific rigour than education interventions
- Future reviews on the effectiveness of interventions for childhood type 1 diabetes need to include criteria for assessing the science of intervention development.

IMPLICATIONS FOR PRACTICE AND/OR POLICY

- Education of children and adolescents with TID, and their families, needs to be supported by psychosocial and possibly family therapy interventions.
- Interventions built from theory and that are systematically-developed

demonstrate greater efficacy and thus potential for future application, in practice settings compared to interventions that are atheoretical and not systematically developed.

- Further research is needed to test existing efficacious interventions in terms of their effectiveness in clinical practice, and prior to widespread implementation in practice settings.

INTRODUCTION

Type 1 diabetes (T1D) is a growing chronic health problem in childhood with an estimated 1 in 400-600 children affected (Haller *et al.* 2005) and an estimated worldwide trend of a 2.5 to 3% annual increase since the 1970s (The Diamond Project Group 2006). The onset of vascular complications (e.g. renal failure, cerebrovascular disease) resulting in early mortality can be reduced by achieving optimum glycaemic control with a mean blood glucose level (HbA1c) of $\leq$7.5% in children and adolescents with T1D (National Institute of Clinical Excellence 2004). Standards from the USA recommend a lower goal for children under 6 years ($\leq$8.5% but $\geq$7.5%) and aged 6 to 12 years ($\leq$8%) because of increased risk of hypoglycaemia in these groups (American Diabetes Association 2009). However, many children and adolescents do not achieve optimum glycaemic control (Diabetes UK 2004, Springer *et al.* 2006).

Achieving optimum glycaemic control requires life-long self and family management involving daily insulin replacement, blood glucose monitoring, dietary regulation and exercise. Psychological and social aspects of managing T1D include coping, adaptation, maintaining positive family and peer relationships. The need to achieve optimum glycaemic control through effective management of TID has resulted in a growth of interventions broadly categorised as education, psychosocial, or family interventions. Education interventions generally address diabetes-related knowledge (e.g. physiology of disease) and skills (e.g. testing blood glucose levels). Psychosocial interventions are typically aimed at developing coping, problem-solving, and communication skills to help deal with emotional, cognitive and behavioural challenges of having T1D. Family interventions target family behavioural and relationship dynamics (Grey 2000).

Over the past decade, a number of reviews on interventions for childhood TID have been published (e.g. Grey 2000, Hampson *et al*. 2000, Gage *et al.* 2004, Urban *et al.* 2004, Armour *et al*. 2005, Northam *et al*. 2005, Winkley *et al.* 2006, Wysocki, 2006, Murphy *et al.* 2006, Couch *et al*. 2008). Evidence from these reviews suggests that psychosocial interventions show promising effects on improving glycaemic control and other health outcomes. In contrast, there is little evidence to support the use of education interventions alone. If combined with psychosocial interventions, the potential of education for improving health outcomes might be increased. A difficulty with interpreting the results of most previous reviews is that evidence was synthesized from diverse types of studies, including randomised controlled trials (RCTs), non-RCTs and pilot studies. In the hierarchy of study designs, RCTs provide the best evidence for assessing the effects of interventions (Centre for Reviews and Dissemination (CRD) 2008). However, the quality of RCTs may be limited in terms of sample sizes, validated outcome measurements, and methods of randomization. The need to improve RCTs methods to CONSORT standards has been identified by previous reviewers (Winkley *et al.* 2006).

The CONSORT statement provides standards for optimum reporting of RCTs (Altman *et al*. 2001, Boutron *et al.* 2008). Standards specific to reporting of interventions include: details on intervention and comparator; description of intervention components; standardization method or tailoring to intervention participants; interventionist expertise; and details on assessment of and adherence to protocols (treatment fidelity). Commentary on the CONSORT statement points to additional standards: training and supervision of interventionists; and assessment of patient preferences to types of treatment (Davidson *et al.* 2003). Therefore, when

reviewing RCTs for evidence on the efficacy or effectiveness of healthcare treatments, there is a need to assess the scientific development of interventions as well as the quality of RCT methods.

Additional criteria for assessing the science of intervention development emphasise a phased approach (Whittemore & Grey 2002). Phase I involves initial basic research to establish theoretical underpinnings, content, strength and timing of intervention, and to establish outcome measures. Phase II involves pilot testing to refine the intervention and outcome measures. In Phase III, an RCT is conducted to test the clinical efficacy of an intervention in optimum circumstances. Phase IV involves an RCT to determine clinical effectiveness. Phase V involves widespread implementation of effective interventions in practice settings. Other frameworks for intervention development offer similar sequential steps (e.g. Medical Research Council 2008).

Previous reviewers have paid little attention to the science of intervention development and its implications for improving health outcomes in childhood TID. In a review of papers published between 1999 and 2004, Murphy *et al* (2006) found some progress since an earlier review (Hampson *et al*. 2000). Fifty percent of interventions were theory-based, and detailed reports were provided on what the interventions involved, some of which were guided by manuals. Although the reviewers raised questions about the relative contributions of some aspects of interventions (content vs contact, interventionist skills) to outcome effectiveness, there was little discussion about how the science of intervention development could be advanced. The emphasis for strengthening future studies was on recruiting larger sample sizes and moving toward multicentre RCTs.

While improving the quality of RCT methods may go some way toward developing a range of effective interventions, there is also a need to consider the science of intervention development. In this review, we were interested in going beyond previous reviews by focusing on the science of intervention development and how this has progressed in recent years. For this, we used criteria from the CONSORT standards for reporting RCTs (Boutron *et al.* 2008), and guidelines on the systematic and progressive development of interventions (Whittemore & Grey 2002). Future directions for advancing the science of intervention development for childhood T1D will be discussed.

THE REVIEW

Aims

The aims of this review were to (1) assess the science of intervention development for T1D in childhood, and (2) to examine its implications for improving health outcomes in children, adolescents and/or their families. We planned to examine the efficacy or effectiveness of interventions, depending on whether the development of RCTs had reached Phase 111 or IV (Whittemore & Grey 2002). We also planned to assess outcomes of interventions developed to the phase of widespread implementation, if available.

Design

The review was conducted using guidelines published by the CRD (2008). We reviewed RCTs of interventions with a methodological focus on assessing the science of intervention development.

Search methods

Inclusion/exclusion criteria

We included published RCTs of education, psychosocial and/or family therapy interventions for children and/or adolescents (up to 19 years) with T1D, and/or family members. Interventions conducted in home, school or healthcare settings were included because these are typically associated with daily routine diabetes care. Trials published in the English language only were included. Additionally, for RCTs that met our inclusion criteria, we searched for related papers on earlier development work on interventions (e.g. basic research, pilot studies).

Studies were excluded if they were non-RCTs or pilot studies on which no further development of the trial was published. Trials conducted in camp or other holiday settings were excluded because daily routine diabetes care is not typically associated with these settings. Studies involving technology (e.g. telehealthcare) without an education, psychosocial or family component were also excluded.

Data sources

The electronic databases MEDLINE, CINAHL, Psychinfo, Cochrane Library and ERIC were searched within a 5-year time limit (1st January 2004-31st December 2008). Our cut-off point of 2004 was used because RCTs conducted prior to this had already been included in one or more published systematic reviews. The search strategy used a combination of free-text words - 'intervention', 'randomized controlled trial', 'control trial', 'child', 'adolescent', 'family', 'education', 'psychological', 'psychosocial'. The term 'diabetes' was used for all searches, and all combinations were applied to the database fields of title and abstract. Reference lists of all full text papers located electronically and assessed for eligibility were scanned for additional potentially eligible papers. An electronic search of Diabetes Care and

Diabetic Medicine was conducted. For each RCT published between 2004 and 2008 that met our inclusion criteria, we conducted a search for any related papers on earlier development of interventions (i.e. published prior to 2004).

Search outcome

Following removal of duplicates from 199 electronic records published between 2004 and 2008, the titles and abstracts of 139 papers were screened for eligibility. Of these, 85 were excluded. Full texts of 54 papers and an additional 10 papers located from reference lists of full text papers were assessed for eligibility. Of these, 35 were excluded. A total of 29 papers (reporting on 14 RCTs) published between 2004 and 2008 met the inclusion criteria. The additional search for related papers on earlier phases of the 14 RCTs yielded a further 13 papers. These related to 6 of the included RCTs. Figure 1, modelled on the PRISMA statement (Liberati *et al*. 2009), summarises the search process and output, including reasons for excluding papers.

Quality appraisal

Quality appraisal was conducted using the CRD (2008) guidelines for undertaking reviews and the CONSORT standards for reporting RCTs (Boutron *et al.* 2008). Assessment was based on: power calculations of sample sizes; methods of randomization (sequence generation, allocation concealment); blinding, and use of valid and reliable outcome measures. For sample size calculations, we used published recommendations to detect small, medium, or large differences in HbA1c and psychosocial measures (Murphy *et al*. 2006). For each RCT, two reviewers (ES DF) independently recorded a judgement of 'adequate' or 'inadequate' on a checklist

against each quality criterion. Disagreements were resolved by discussion to consensus. Quality appraisal was not applied to pilot studies.

Data abstraction

Studies were categorised according to whether they included education, psychosocial, or family therapy interventions. Data abstraction on study characteristics related to sample size, age groups, intervention details, and end point outcome measurements (Tables 1 & 2). These data were extracted by DF and checked by ES for accuracy. As illustrated in Table 3, data abstraction on the scientific development of interventions was guided by the CONSORT standards (Boutron *et al.* 2008) and guidelines on the phased development of clinical trials (Whittemore & Grey 2002). Based on Keller *et al's* (2009) work, data were abstracted on theory fidelity by examining the fit between selected theories, problem conceptualization, the critical inputs or components that defined the intervention, mediating variables, and outcome variables. These data were extracted by ES and checked by VMcM for accuracy.

Synthesis

A narrative approach was adopted for data synthesis. Meta-analysis was not appropriate because of marked differences between RCTs, for example types of intervention, outcome measures, and quality of trials.

RESULTS

Fourteen RCTs (in 29 papers) conducted over a 5-year period and that collectively recruited 1511 participants were identified for review. In addition, 13 papers reporting

earlier or related work on 6 of the 14 eligible RCTs were found. Seven interventions were educational (n=825), 5 were psychosocial (n=455), and 2 were on family therapy (n=231)(Tables 1 & 2).

Scientific development of interventions

Phase of development

As shown in Table 3, there was no explicit evidence indicating the phase of development for any of the 7 education interventions or for 1 of the psychosocial interventions. For the remaining 6 RCTs, it was explicitly stated that the efficacy of interventions was tested. Of these, 4 were psychosocial interventions involving automated text-messaging support (Franklin *et al.* 2006), motivational interviewing (Channon *et al*. 2007), diabetes personal trainer (Nansel *et al*. 2007), and coping skills training (Ambrosino *et al.* 2008). The remaining 2 efficacy trials were on family therapy interventions. In one, most families were of ethnic minority (69%) and almost half were single parent families, which were described as 'high risk' (Ellis *et al*. 2005a, b 2007a,b,c 2008). In the second family therapy intervention, families 'exhibiting problematic management' of diabetes were sampled (Wysocki *et al.* 2006, 2007, 2008).

Two psychosocial and one family therapy intervention were developed from pilot studies (Franklin *et al*. 2003, Channon *et al*. 2003, Ellis *et al.* 2003, 2004, 2005c). The coping skills training intervention for school-aged children developed by Ambrosino *et al.* (2008) was an extension of earlier work with adolescents (Grey *et al*. 1998a, b, 2000). Wysocki and colleagues first implemented a 'behavioral family systems therapy' intervention (1997, 1999, 2000, 2001) which was later developed to include

diabetes-specific behavioural components (BFST-D) (Wysocki *et al.* 2006, 2007, 2008). For one efficacy trial (Nansel *et al.* 2007), there was no evidence of earlier pilot work. However, it was reported that the development of a motivational interviewing intervention was guided by empirical and theoretical literature, thereby indicating some degree of systematic and progressive development from basic research. Apart from one RCT, which was ongoing at the time of this review (Ambrosino *et al*. 2008), further developments of interventions were proposed to identify what components of interventions contributed to effectiveness (Channon *et al*. 2007, Ellis *et al*. 2007b), to determine long-term effectiveness of interventions, and to determine the clinical utility of interventions (Franklin *et al*. 2006, Nansel *et al*. 2007, Wysocki *et al*. 2007, 2008).

Theoretical components

Of the 14 interventions reviewed, only 6 were explicitly reported as theory-based (Table 3); the theories including social cognitive theory (Franklin *et al.* 2006, Nansel *et al.* 2007), self-regulatory theories (Channon *et al.* 2005), a stress adaptation theoretical framework (Ambrosino *et al.* 2008), and family systems theory alone (Wysocki *et al.* 2006) or with social-ecological theory (Ellis *et al*. 2004). Clinical problems and the defining components of all 6 interventions were conceptualised from their respective underpinning theories. For example, in a multi-systemic therapy intervention, social-ecological theory and family systems theory guided the conceptualisation of the problem of 'severe noncompliance' of adolescents with diabetes care as multiply determined by family and extra-family systems such as healthcare, school, and peer group systems (Ellis *et al.* 2004). These systems were the

critical components that defined the multi-systemic therapy intervention, such that the problem of noncompliance was addressed using strategies to improve family relationships, enlist peer support, improve family-school communications, facilitate school personnel to support diabetes care, help families to keep clinic appointments, and improve relationships between family and healthcare teams (Ellis *et al*. 2005a).

For the most part, fidelity to theory was evident in the theory-based interventions on the fit between outcome variables and underpinning theories, such as self-efficacy from social cognitive theories (Franklin *et al.* 2006, Nansel *et al.* 2007) or self-regulatory theories (Channon *et al*. 2005, 2007), family relationships from family systems theory (Ellis *et al.* 2005a, Wysocki *et al*. 2006), and coping skills from a stress-adaption theoretical framework (Ambrosino *et al*. 2008). Apart from one intervention (Ellis *et al.* 2007a), mediating variables consistent with theoretical underpinnings or otherwise were not reported.

While it is possible that education interventions were underpinned by learning theories, this was not explicitly reported in any of the relevant papers. However, for one intervention on family-centred education, it was reported that some sessions were based on social learning theory (Murphy *et al.* 2007).

Other criteria

Theory-based and systematically-developed interventions were found to meet most of the remaining criteria for assessing the scientific development of interventions (Table 3). Both family therapy interventions met all criteria apart from seeking treatment preferences of participants, which was a criterion not evident in any of 14 interventions reviewed. Most criteria were met in the psychosocial interventions, apart

from one (De Wit *et al.* 2008). The use of manuals to guide intervention procedures was not reported for any of the psychosocial interventions. Assessment of treatment fidelity was explicitly reported in 3 psychosocial and 2 family therapy interventions. Methods included a review of audio-recorded treatment sessions (Nansel *et al*. 2007, Channon *et al.* 2007, Ambrosino *et al.* 2008), video-recordings of sessions (Nansel *et al*. 2007, Channon *et al.* 2007), a method also used for one family therapy intervention (Wysocki *et al.* 2006). Objective measurement and statistical analysis of fidelity was reported in one trial (Ellis *et al.* 2007c). Although not explicitly reported as a method of assessing treatment fidelity, qualitative evaluative data from participants in one RCT indicated that they received support as planned in a text-messaging support intervention (Franklin *et al.* 2008a, b). In contrast to psychosocial and family therapy interventions, few scientific criteria were reported in education interventions, and only one criterion (content details on what was delivered) was consistently reported across all interventions (Table 3).

Effects of interventions on outcomes measured

There was little similarity in outcomes measured across trials, apart from HbA1c levels (Table 4). Outcomes were measured at multiple time-points in most trials, and end-point measurements ranged from 6 to 24 months following completion of the intervention (Tables 1 & 2). Outcome data provided mixed results. Only four of the 7 education interventions demonstrated positive effects for some outcomes at end-point measurement (Table 1). A 'self study' programme with brochures and videotaped recordings of patient experiences reduced the rate of hypoglycaemic events (Nordfeldt *et al.* 2005). Telephone case management improved adherence to diabetes related

tasks (Howe *et al*. 2005). A structured group education programme for children and parents, supported by computer-assisted consultations with adolescents directing them to useful education links, improved quality of life (Graue *et al*. 2005). A group-based family centred education programme integrated into clinic consultations reduced HbA1c by 0.29% and improved parental involvement in diabetes care for families that attended at least 2 sessions over 12 months (Murphy *et al.* 2007). Apart from Murphy *et al*.'s RCT, none of the education interventions improved HbA1c levels.

All psychosocial interventions demonstrated positive effects for some outcomes measured (Table 2). Statistically significant reductions in HbA1c at 12 months follow up were evident in 3 psychosocial interventions: automated text-messaging support combined with intensive insulin therapy (Franklin *et al.* 2006); personal trainer (Nansel *et al.* 2007); and motivational interviewing (Channon *et al*. 2007). In both family therapy interventions, some aspects of family relationships improved (Ellis *et al.* 2007a). Family therapy was also found to improve HbA1c levels significantly following completion of intervention, but was maintained long-term (18 months) in one RCT only (Wysocki *et al.* 2007). One RCT was ongoing and so end-point measurements from coping skills training were not available (Ambrosino *et al* 2008).

Quality of RCTs

Based on recommended sample sizes needed to detect effect sizes on HbA1c and psychosocial measures (Murphy *et al*. 2006), sample sizes at end-point measurements were inadequate in all RCTs. Attrition was over 25% in 6 RCTs (Table 1 & 2). Reasons for attrition were explicitly reported for 2 RCTs only, and related to relocation (Graue *et al.* 2005) and lower socioeconomic groups (Wysocki *et al.* 2007).

On methods of randomization, sequence generation was adequate in all but 3 RCTs (Viklund *et al.* 2007, Murphy *et al.* 2007, De Wit *et al*. 2008). Adequate allocation concealment procedures were reported in only 4 RCTs (Lawson *et al.* 2005, Franklin *et al*. 2006, Channon *et al.* 2007, Ambrosino *et al.* 2008). Application of blinding procedures was reported for some RCTs relating to participants (Nordfeldt *et al*. 2003, Channon *et al.* 2007), assessors of outcome measures (Channon *et al*. 2007, Nansel *et al*. 2007), and care providers (Nordfeldt *et al*. 2003, Lawson *et al.* 2005, Channon *et al.* 2007, Nansel *et al*. 2007, Ambrosino *et al*. 2008). Outcome measures were stated in all RCTs, but details on psychometric properties were missing or incomplete in 6 (Howe *et al.* 2005, Graue *et al.* 2005, Nunn *et al.* 2006, Murphy *et al*. 2007, Channon *et al*. 2007, De Wit *et al.* 2008).

DISCUSSION

Review limitations

The review has some limitations. Only RCTs published in the English language were included, and it is possible that unpublished RCTs and trials in other languages are available. Authors of RCTs were not contacted for information missing from papers. Therefore, the evidence presented in this review may be incomplete. Notwithstanding these limitations, our attention to the science of intervention development offers much strength to this review, since to date there has been no systematic examination of this science in the field of childhood T1D. Furthermore, there has been little discussion about how the science of intervention development could be enhanced in future research

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Review Findings

To date, the emphasis on enhancing interventions for T1D in childhood toward positive outcomes has been on improving the quality of RCT methods. In particular, the need to address underpowered sample sizes and inadequate methods of randomization has been highlighted (e.g Hampson *et al.* 2001, Murphy *et al.* 2006). Based on the findings of our review, we support previous recommendations on the need to improve RCT methods. However, we argue that this alone is insufficient for developing a range of effective interventions for managing childhood T1D. There is a need to think about the scientific development of interventions and the implications of this science for improving health outcomes.

The findings of this review indicate that there is an emerging maturity of the science in relation to psychosocial and family therapy interventions. Both family therapy interventions and most psychosocial interventions were developed to a stage of efficacy-testing using a phased approach. However, in efficacy RCTs, moderators and mediators should be determined (Whittemore & Grey 2002), yet mediating variables were reported in one trial only. Attention to moderators is important for identifying for whom and under what conditions an intervention has different effects. Mediators provide information about why and how an intervention has effects (Kraemer *et al.* 2002).

Previous reviewers have consistently reported on the efficacy of interventions (e.g. Northam *et al.* 2005; Wysocki 2006). However, there is little evidence available to date on the effectiveness of interventions for childhood TID, and our review offers no new insights since none of the 14 interventions had been tested for effectiveness.

However, plans for this were noted by some researchers. Testing the effectiveness of interventions is important to establishing external validity in terms of application to diverse groups of children, adolescents, and families in clinical practice settings. Unless the science advances to effectiveness-testing of interventions, a gap will remain between the evidence from existing RCTs on intervention efficacy and the practice of scientifically-supported effective interventions for childhood T1D.

The development of interventions through clearly-defined phases paves the way for the application of scientific rigour to the conceptual, methodological and operational elements of intervention development. A key area of work in the early stage of development is writing protocol manuals. Manuals are important for mapping and tracking procedural steps in developing interventions focusing on what needs to be done, how, when, and where (Bowman *et al.* 2002). We identified the use of manuals for family therapy interventions only. This finding compares unfavourably with an earlier review which showed that a quarter of the studies reviewed reported on the use of manuals (Murphy *et al.* 2006).

Another key area for advancing the science of intervention development is treatment fidelity, that is, adherence to the delivery of an intervention as planned. Monitoring treatment fidelity is important to controlling for unsystematic variations which pose threats to statistical conclusions about the effects, effectiveness and validity of an intervention (Santacroce *et al*. 2004). Although seldom addressed, as evident in 9 of the 14 RCTs reviewed in this paper, Santacroce *et al.* (2004) have argued that attention to treatment fidelity is essential and should not be considered 'elective'. Dumas *et al.* (2001, p.38) suggested that monitoring treatment fidelity needs to be guided by two fundamental questions: 'Are interventionists following the

protocol as set out in a manual?' and 'Is there consistency in delivering the protocol to all participants?' While manuals and the training and supervision of interventionists are necessary to promote treatment fidelity, there is also a need to assess the performance of interventionists regularly in order to ensure adherence to protocol process and content (Dumas *et al.* 2001).

In our review, assessment of treatment fidelity was reported for both family therapy interventions, and for 3 of the 5 psychosocial interventions. The most common method of assessment was by reviewing audio-recordings of sessions delivered in interventions. Other methods proposed in the literature include interventionist self-report evaluation checks, quality assurance checks, and participant evaluation (Spillane *et al*. 2007). Evaluation data may be useful for explaining the intervention components to which participants are more or less likely to adhere and why. The contribution of qualitative evaluation data from participants to assessing treatment fidelity was evident in the RCT on a text-messaging support system for young people (Franklin *et al.* 2008a, b). They commented that their 'engagement' with the intervention could be enhanced by increasing the database of messages to include content that better met their needs. According to Santacroce *et al*. (2004), there is also a need to measure objectively and analyse statistically treatment fidelity (Santacroce *et al*. 2004); this was evident in just one intervention in our review (Ellis *et al*. (2007c). Although there has been some discussion in the literature on the measurement of treatment fidelity (Santacroce *et al*. 2004, Spillane *et al.* 2007), this is an area that requires further debate and reporting in RCTs in order to advance knowledge on valid and reliable methods of assessing fidelity.

The findings of this review support evidence from previous reviews (e.g. Hampson *et al.* 2001, Murphy *et al*. 2006) that theory-based interventions demonstrate greater potential in achieving positive health outcomes compared to atheoretical interventions. In all 6 theory-based interventions, positive effects were found at end-point measurement for more than one outcome, 5 of which included significant reductions in HbA1c. In contrast, none of the 7 education interventions were explicitly reported as theory-based. Only 4 education interventions demonstrated positive effects, but at most on only one outcome measured. One of these interventions was found to reduce HbA1c (Murphy *et al*. 2007). Interestingly, this family education intervention had some sessions underpinned by social learning theory.

The need for theory-based interventions for T1D in childhood has been highlighted by previous reviewers as a priority for future research (Hampson *et al*. 2000; Murphy *et al.* 2006). However, there has been little discussion on what is meant by a theory-based intervention and how this can be evaluated. A major challenge for intervention scientists is to ensure fidelity to theory, such that there is a fit between selected theories, problem conceptualization, the critical inputs or components that define the intervention, mediating variables, and outcome variables (Keller *et al.* 2009). Selected theories for all 6 theory-based interventions identified in this review were, for the most part, explicitly translated into operational elements of each intervention.

It is evident from our review that the science of intervention development has progressed in relation to family therapy and most psychosocial interventions. However, several critical issues need to be addressed in the future development of education interventions. Evidence of more promising effects seen in psychosocial and

family therapy interventions suggest that if education interventions undergo rigorous processes of scientific development, their potential to yield more positive effects may be enhanced. It has been suggested in the past that education and behavioural interventions should be combined (Murphy *et al.* 2006). While the education interventions reviewed in this paper may have had a behavioural component, this was not explicitly reported. Future development of interventions could combine components of education and psychosocial interventions, and possibly family therapy, about which less is known. As evident in our review, the growth of family therapy interventions lags behind education and psychosocial interventions - a finding consistent with previous reviews (Grey 2000; Urban et *al.* 2004). There is a need to develop more family interventions, given that family dynamics play an important role in managing childhood diabetes. Their application needs to go beyond 'high risk' families and those only experiencing 'problematic' diabetes management. Future investigations into the complementary or synergistic effects of combined interventions on health outcomes could make an important contribution to advancing the current state of intervention science.

A further area about which little is known is the effects that treatment preferences of participants could have on health outcomes. Questions about whether treatment preferences of patients can positively influence outcomes have raised debates (Halpern 2003, McPherson 2009), but not in the field of childhood diabetes. Recent evidence on the positive effects of patient preferences in the case of musculoskeletal treatments (Preference Collaboration Review Group 2008) points to the need for intervention scientists to explore this area further in the case of children and adolescents with T1D.

CONCLUSION

Our findings point to the need for future research to go beyond previous calls for improvements in the quality of RCT methods to include attention to the science of intervention development and its implications for improving health outcomes in childhood TID.

On the whole, progress was evident for both family therapy and most psychosocial interventions in terms so being systematically developed and theory-based. Although promising effects of these interventions were evident, conclusions about their effectiveness and whether they can be widely disseminated in clinical practice cannot be made from this review. Effectiveness clinical trials are needed, and this phase is necessary before wide-scale dissemination of an intervention can be evaluated. Unless there is continued development of interventions beyond efficacy trials in the future, knowledge of what works best in clinical practice towards helping children, adolescents and their families to manage T1D will remain limited.

The evidence from this review suggests that education offers less potential for improving T1D related health outcomes compared to psychosocial, or family therapy interventions. This is a concern in terms of its practice implications for nurses, who can be expected to use education as a principal method of helping children, adolescents and their families integrate diabetes care into their daily lives. However, rather than assuming that education has little role to play in the management of T1D, it is first necessary to consider education interventions identified in this review within the context of their scientific weaknesses. To advance the potential of education interventions, much can be learned from the progress made in recent years for

psychosocial and family therapy interventions. Future development of interventions also needs to combine education, psychosocial and family therapy components to determine if combined approaches would lead to greater efficacy and effectiveness in improving physiological, psychosocial and/or family outcomes in the case of T1D in childhood.

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*Papers on randomized controlled trials of interventions published within time limit of review (2004-2008)

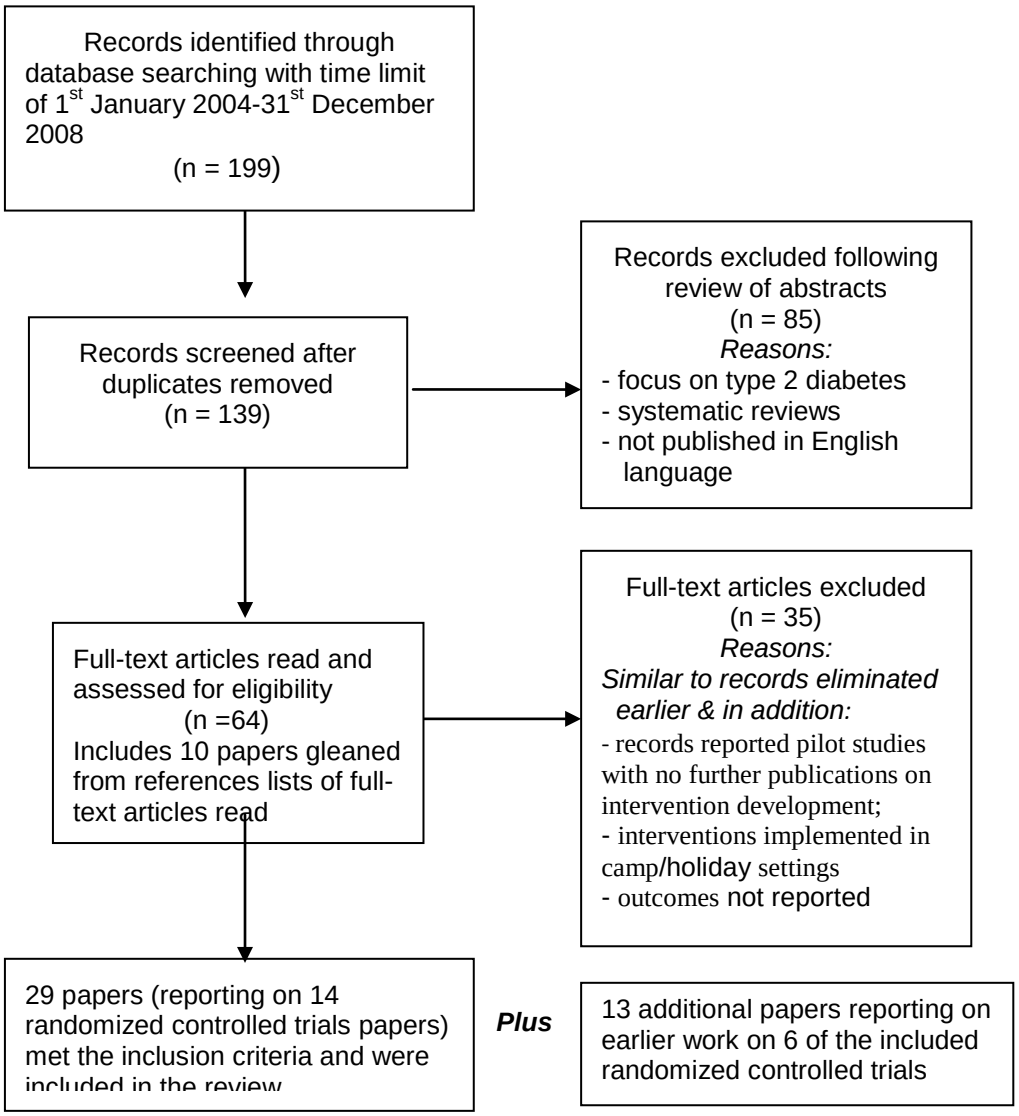


Figure 1. Flow diagram of search process and output of papers identified in the systematic review

Table 1 Summary of included randomized controlled trials on education interventions

Authors	*n* (randomized) & age range	Intervention & control/comparisons (n = number allocated to each group)	Outcomes at end time points (n= number analyzed)
Nordfeldt *et al.* (2005)	332, 2-19yrs	Detailed skills self study using video & brochures (n=111) vs. general diabetes information (n=111) vs. SC (n=110) *Mode of delivery:* Individual *Setting:* Home *Duration:* Self study material for ongoing use	**24 months from baseline** (n=249): *IG (n=80) vs. both CGs (n=86 & 83)* Reduction in yearly incidence of severe hypoglycaemia (p=0.024) in IG; no reduction in CGs No significant differences between groups for HbA1c and self-reported daily blood glucose readings
Howe et *al al.* (2005)	Aimed to recruit 135 but 'closed' the study with 75 completed subjects 2-16 yrs	Education & telephone case management (n=26) vs. education (n=21) vs. SC (n=28) *Mode of delivery:* Individual *Setting:* Home *Duration:* 6 months	**6 months from baseline at end of intervention (n= 75):** *IG (n=26) vs. both CGs (n=21 & 28)* Greater improvement in adherence to diabetes control tasks in IG compared to CGs (p=.0003) No significant differences between groups for HbA1c, diabetes knowledge and parent-child teamwork
Lawson *et al.* (2005)	46, 13-17yrs	Telephone contact with SC (n=23) vs. SC (n=23) *Mode of delivery:* Individual *Setting:* Home *Duration:* 6 months	**6 months from baseline at the end of intervention (n=46):** *IG (n=23) vs. CG (n=23)* No effect on any of the outcomes measured – HbA1c, glucose monitoring compliance, insulin requirements, diabetes QOL, family functioning
Graue *et al*. (2005)	116, 11-17yrs	Group visits & computer assisted consultations (n=64) vs SC (n=52) *Mode of delivery:* Group *Setting:* Clinics *Duration:* 15 months	**9 months follow up after completion of intervention (n=83):** *IG (n=45) vs.CG (n=38)* Greater improvements in QOL for diabetes related impact (P=0.018), worries (P=0.029), mental health (P=0.46) and general behaviour (P=0.29) in IG for older adolescents ≥13yrs No significant effect for HbA1c
Nunn *et*	146, 11-15yrs	Telephone contact (n=60) vs SC (n=63)	**7 months from baseline at the end of intervention (n=123):**

al.(2006)	(7 declined to proceed)	*Mode of delivery:* Individual *Setting:* Home *Duration:* 7 months	*IG (n=60) vs.CG (n=63)* No significant differences between groups for HbA1c, hospital admissions, diabetes knowledge, adherence, social and family functioning, strength and difficulty perception
Viklund *et al.* (2007)	55, 12-17yrs	Empowerment programme (n=28) vs. 6 month wait list control (n=27) *Mode of delivery:* Group *Setting:* Not explicit *Duration:* 6 weeks	**24 months follow up after completion of intervention (n=32):** *IG (n=18) vs. CG (n=14)* No significant differences between groups for HbA1c or empowerment levels
Murphy *et al.* (2007)	78, 6-17yrs	Family centred education programme (n=40) vs. 12 month wait list control (n=38) *Mode of delivery:* Group *Setting:* Clinic *Duration:* 24 months	**12 months from baseline at the end of intervention (n=78):** *IG(n=40) & CG (n=38)* Decrease in HbA1c by 0.23% (P =0.04) and increased parental involvement (P =0.01) in those who attended at least 2 of 4 education sessions compared to those who did not attend at least 2 sessions of the programme No significant changes in QOL

SC, standard/ usual care typically delivered at treatment centre(s). IG, intervention group. CG, control group. QOL, quality of life

Table 2 Summary of included randomized controlled trials on psychosocial and family therapy interventions

Authors	***n* (randomized) & age range**	**Intervention & control/comparisons (n = number allocated to each group)**	**Outcomes at end time points (n= number analyzed)**
Franklin *et al.* (2006)	92, 8-18yrs	Text messaging motivational support (Sweet Talk) with intensive insulin therapy (IIT) (n=31) vs. Sweet Talk with conventional insulin therapy (n=33) vs. conventional insulin therapy alone (n=28) *Mode of delivery:* Individual *Setting:* Home *Duration:* 12 months	**12 months from baseline at the end of intervention (n=90):** *IG-(n=31); CG with Sweet Talk (n=32) & without Sweet Talk (n=27)* Decrease in HbA1c by 1% (P=0.001) in IG but not in CGs Improvement in both sweet talk groups for diabetes self efficacy (P=0.003), adherence to diabetes related tasks (P=0.042), perceived support from diabetes team (P<0.05), and increased use of emergency hotline (P=0.36) Greater increase in clinic visit attendance (significant only between IG and CG without sweet talk) (P=0.016) No significant increases in acute complications (hyper/

			hypoglycaemia) No effect on diabetes knowledge score or patients' perceptions of support from family or friends
Nansel *et al.* (2007)	81, 11-16yrs	Diabetes personal trainer (n=40) vs. SC (n=41) *Mode of delivery:* Individual *Setting:* Home or 'public location' *Duration:* 2 months	**12 months follow up after completion of intervention (n=73):** *IG (=36) vs. CG (n=37)* Decrease in HbA1c by 0.19% (P=0.06) compared with an increase in CG; the effect was greater in older youths aged 14-16 years (P =0.04) Youths in IG reported lower on beliefs about positive outcome expectations (p=0.05) and reported higher disease impact (p=0.05) No significant differences between groups for adherence, self-management efficacy or QOL (worry or satisfaction scales)
Channon *et al.* (2007)	80, 14-17yrs	Motivational interviewing (n=43) vs. support visits (n=37) *Mode of delivery:* Individual *Setting:* Home *Duration:* 12 months	**12 months follow up after completion of intervention (n=47)** *IG (n=27) vs. CG (n=20)* Decrease in HbA1c by 0.6% compared to an increase in CG (P=0.003) Significant differences in QOL scores for life satisfaction (P<0.008), life worry (P=0.001) and anxiety (P=0.001) favouring in IG Stronger beliefs among IG that certain actions were more likely to prevent complications (P < 0.001) No significant differences found between groups for locus of control, self-efficacy,and diabetes knowledge.
De Wit *et al.* (2008)	91, 13-17yrs	Consultations on health related quality of life (n=46) vs. SC (n=45) *Mode of delivery:* Individual *Setting:* Clinic *Duration:* 12 months	**12 months from baseline at end of intervention (n=81):** *IG (=41) vs. CG (n=40)* Improvement in psychosocial well-being, mainly behaviors (P<0.001), self-esteem (P<0.001), mental health (P<0.001) and family activities (P<0.001) (except those with baseline HbA1c > 9.5%); no change in psychosocial wellbeing in CG No significant differences between groups for HbA1c
Ambrosino *et al.* (2008)	111, 8-12yrs	Coping skills training (n=65) vs group education (n=46) *Mode of delivery:* Group	**3 months from baseline (n=79):** *IG (n=49) vs. CG (n=30)* Greater improvement in children's QOL for life satisfaction in IG

		Setting: Not stated *Duration:* Not stated	(p=0.07) Greater improvement reported by parents for family adaptability in IG (p=0.09) No significant differences between groups for HbA1c, and child psychosocial variables (coping, self-efficacy, family support behaviours) ***Note:*** Trial is ongoing - end point data collection planned for 12 months post intervention
Ellis *et al.* (2005a,b, 2007,a,b,c, 2008)	127, 10-17yrs	Multisystemic therapy (family centred & community based) (MST) (n=64) vs. SC (n=63) *Mode of delivery:* Family *Setting:* Home *Duration:* 6 months	**18 months follow up after completion of intervention (n=127)**†**:** Fewer hospital admissions for diabetic ketoacidosis in IG (P=0.034) Greater costs savings from reduced hospital admissions in IG **6 months follow up after completion of intervention (n=85)**††**:** *IG (n=49) vs. CG (n=52)* Initial post treatment improvement in HbA1c not maintained (p< 0.05) Initial post treatment improvement in adherence to blood glucose monitoring (BGM) was maintained in IG adolescents from 2 parent families (p < 0.01) but not from single parent families **7 months from baseline at the end of intervention (n=85)**††† *IG (n=64) vs. CG (n=63)* Improvements in IG family relationships in 2 parent families with increased support for adolescents from primary (p=0.01) and secondary caregivers (p<0.05) but not in single parent families(p=.018) ***Note****: Data extracted for different time points represents the endpoint data for outcomes published to date*
Wysocki *et al.* (2006, 2007,2008)	104, 11-16yrs	Behavioural family systems therapy for diabetes (n=36) vs educational support (ES) (n=36) vs. SC (n=32) *Mode of delivery:* Family *Setting:* Not explicit *Duration:* 6 months	**18 months follow up after completion of intervention (n=85**) ††††: *IG (n=28) vs.ES CG (n=31) &. SC CG (n=26)*: Decrease in HbA1c by 0.8% (p<0.03) in IG - 'appeared to be mediated by improvements in treatment adherence; no changes in CGs Higher percentage of IG achieved improvement in treatment adherence (p<0.05); change in adherence correlated with change in HbA1c 9 (p < 0.03) Improvements in individual communication of adolescents (p<0.05)

	and mothers (p=0.03) in IG but not in fathers; differences were significant for SC but not for ES Greater improvement in quality of family interactions in IG in terms of problem solving (p=0.03) and positive reciprocity (p<0.04); differences were significant for SC but not for ES *Correlation analysis for IG only* Significant associations between improvements in positive communications and improvements in HbA1c, diabetes self management, diabetes responsibility and conflict found at 6and 12 months follow up were not maintained Significant associations between improvements in quality of family relationships and HbA1c, diabetes self-management, diabetes responsibility and conflict found at 6 and 12 months follow up were not maintained

SC, standard/ usual care typically delivered at treatment centre(s). IG, intervention group. CG, control group. QOL, quality of life. ES, educational support. †, data extracted from Ellis *et al.* (2008), number analyzed not stated. ††, data extracted from Ellis *et al.* 2007b). †††, data extracted from Ellis *et al.* (2007a). ††††, data extracted from Wysocki *et al.* (2007, 2008)

Table 3 Assessment of scientific development of interventions

Explicit statement & evidence of the following criteria reported	Education							Psychosocial				Family		
Phased intervention development & testing: (Whittemore & Grey 2000)	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**N**
(i) basic research/ review to establish content, theory, outcome measures								√	√	√	√		√	√
(ii) pilot testing to refine intervention & outcome measures/earlier related work								√		√	√		√	√
(iii) determining clinical efficacy in a clinical randomized controlled trials under optimum conditions								√	√	√	√		√	√
(iv) determining clinical effectiveness in prospective randomized controlled trials under usual conditions														
(v) Wide scale implementation														
Theoretical Component (Keller et al. 2009)														
Explicit statement of theoretical base(s)								√	√	√	√		√	√
Fidelity to theory: i.e. theory base consistent with: Problem conceptualisation								√	√	√	√		√	√
Critical components of intervention								√	√	√	√		√	√
Mediating variables													√	
Outcome variables								√	√	√	√		√	√
Other Criteria (The CONSORT Statement, Boutron et al. 2008) & Davidson et al. 2003)														
Manual(s) to guide intervention procedures													√	√
Training of interventionist(s)/care-provider			√			√		√	√	√		√	√	√
Supervision of interventionist (s)						√			√	√			√	√
Content details on what was delivered during intervention (e.g. topics, sessions)	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Content details of comparator group(s)	√	√	√	√				√	√	√	√	√	√	√
Standardization of intervention delivery or		√	√									√		√
Tailoring to participants								√	√	√	√		√	
Seeking treatment preferences of participants														
Treatment fidelity-details on how adherence to the intervention protocol was assessed & monitored									√	√	√		√	√

A. Nordfeldt *et al.* (2002, 2003, 2005);

B.Howe et *al* (2005); **C**. Lawson *et al.* (2005); **D.** Graue *et al*. (2005); **E**. Nunn *et al.*(2006); **F.** Murphy *et al.* (2007) & Wadham *et al* . (2005); **G.** Viklund *et al.*(2007); **H.** Franklin *et al*. (2003, 2006, 2008a, b), Waller *et al*. (2006), Tasker et al. (2007); **I**. Nansel *et al*. (2007); **J.** Channon *et al.* (2003; 2005, 2007); **K.** Ambrosino *et al*. (2008) & Grey *et al.* 1998a,b, 2000); **L**. De Wit *et al*. (2008); **M**. Ellis *et al.* (2003; 2004; 2005a,b;c 2007a,b,c 2008); **N**. Wysocki *et al*.(1997, 1999, 2000, 2001, 2006, 2007, 2008).

Table 4 Outcomes measured across trials and in order of frequency

Outcomes	**Interventions**			**Total**
	Education (n=7)	**Psycho-social (n=5)**	**Family (n=2)**	**14**
HBA1c level	7	5	2	14
Adherence	3	2	2	7
Quality of life	3	3		6
Service utilisation **(**hospital admissions/clinic attendance)	1	1	2	4
Knowledge	2	2		4
Support from caregivers/family		3		3
Responsibility and/or conflicts for care	1	2		3
Family functioning	2	1		3
Self-efficacy		3		3
Emotional & behavioural problems/mental health status		3		3
Hypo/ hyperglycaemia	1	1		2
Family relations/interactions			2	2
Support from diabetes care team		2		2
Coping		1		1
Insulin dosages	1			1
Empowerment	1			1
Costs		1		1