

Children and adolescents with  
Type 1 Diabetes Mellitus  
– family dynamics and health-related  
quality of life after diabetes onset

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To Johan and Erik



# Abstract

**Aim:** The main aim of this thesis was to explore different aspects of family dynamics and health-related quality of life (HRQOL) after the onset of T1DM in children and adolescents. A second aim was to evaluate the effects of a two-year prospective family intervention randomized controlled trial (RCT) with additional psychological support after the onset of T1DM, focusing on facilitating communication skills within the family in the initial and ongoing diabetes care.

**Methods:** In Paper I, children and parents completed the Swedish versions of the PedsQL 4.0 and PedsQL 3.0 questionnaires measuring generic and diabetes-specific HRQOL, respectively. In Paper II, 30 parents and eight siblings participated in focus group discussions and individual interviews about their preconceptions about diabetes, their reactions to the child's diagnosis of T1DM, and its impact on family relationships. Papers III and IV examined different aspects of the two-year family intervention study in which children aged 3–15 years, recently diagnosed with T1DM, participated with their parents. In this RCT, two different treatment regimens at T1DM diagnosis were compared. The treatment-as-usual regimen provided support from the whole diabetes team except for the specific support of a family psychologist-psychotherapist with special training in diabetes. Families in the intervention group were also provided with therapy focusing on improving communication.

**Results:** In Paper I, the Total Score of the PedsQL 4.0 Generic Core Scales and the PedsQL 3.0 Diabetes Module exceeded the criterion for satisfactory internal consistency, for both child self-reports and parent proxy reports ( $\alpha$ -values  $>0.88$ ). In Paper II, fathers showed more uniform emotional and behavioral patterns than mothers did. Among mothers, more distinct differences appeared, depending on the age of the child with T1DM and the civil status of the mother. Siblings reported increased demands on them in terms of greater responsibility and maturity. Reactions such as competition and jealousy occurred at younger ages, whereas older siblings were more caring but also carried an increased burden of worry. In Paper III, a higher education level in the father was associated with a lower HbA1c level in the child. Furthermore, in Paper IV, at 24 months the children and their fathers in the intervention group rated the child's diabetes-specific HRQOL as significantly better and the child's worry as lower compared to the control group. Communication skills improved significantly over time in the intervention group.

**Conclusion:** The two-year prospective family intervention study showed promising results. The children in the intervention group showed several indications of improved generic and diabetes-specific HRQOL. Actively involving both parents, not only immediately after T1DM onset but also during two years of ongoing care, had a positive impact on the children's and adolescents' HRQOL.

**Keywords:** health-related quality of life, typ 1 diabetes, children, adolescents, parental education, family dynamics, glycemic control, family intervention.



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## List of papers

This thesis is based on the following papers, referred to in the text by their Roman numerals.

- I. **Sand P, Kljajić M, Schaller J, Forsander G.**  
The reliability of the Health Related Quality Of Life questionnaire PedsQL 3.0 Diabetes Module™ for Swedish children with Type 1 diabetes.  
*Acta Paediatrica* 04/2012; 101(8):e344-9.
- II. **Sand P, Kleiberg Nilsson A, Forsander G.**  
Paternal Influence on Glycemic control at Baseline and One Year Post Diagnosis in Children and Adolescence with Type 1 Diabetes Mellitus.  
*Diabetes Research and Treatment, Open Access* 12/2014; 1(4):1-6. DOI: 10.14437/DRTOA-1-115.
- III. **Sand P, Dellenmark Blom M, Forsander G, Sparud Lundin C.**  
Family dynamics when a child becomes chronically ill: impact of type 1 diabetes onset in children and adolescents.  
*Submitted for publication.*
- IV. **Sand P, Kljajić M, Forsander G.**  
Improved health-related quality of life a in children and adolescents with type 1 diabetes: a two-year prospective family intervention RCT study.  
*Submitted for publication.*



## **Sammanfattning på svenska**

När ett barn eller ungdom insjuknar i typ 1 diabetes påverkas hela familjen. Vardagen förändras plötsligt och följderna blir att familjen behöver vistas en tid på sjukhus för att sedan slussas ut till hemmet med uppföljningar inom diabetesmottagningens öppenvård. Vid diabetesdebuten kan symptomen ha olika allvarlighetsgrad från relativt milda tecken på förhöjt blodsocker till ett livshotande tillstånd med diabetisk ketoacidosis, då kroppens pH-värde sjunker. Sjukdomsbeskedet innebär ofta att en krisreaktion uppkommer inom familjen där tidigare erfarenheter inte överensstämmer med den uppkomna situationen, vilket bidrar till att göra den svårhanterlig och skrämmande. Avhandlingens övergripande syfte är att undersöka olika aspekter av familjedynamik i familjer där ett barn eller en ungdom har insjuknat i typ 1 diabetes samt att undersöka möjligheten att påverka den hälsorelaterade livskvaliteten bland dessa barn eller ungdomar med familjer. I samtliga genomförda studier är de deltagande barnen och ungdomarna mellan tre och sjutton år gamla.

Diabetes är en kronisk sjukdom som ställer höga krav på föräldrarna, vilka till att börja med är de som ansvarar för behandlingen. Barnet kommer senare allt efter mognad och ålder successivt att ta över ansvaret för behandlingen. För att denna skall bli så framgångsrik som möjligt, det vill säga ge minskad risk för att akuta och framtida medicinska komplikationer uppkommer, är det väsentligt att föräldrarna är engagerade vid barnets sjukdomsdebut. Av betydelse är också att föräldrarna bibehåller sitt engagemang över tid men att deras insats har en viss grad av flexibilitet i förhållande till barnets ålder.

Sveriges jämförelsevis generösa välfärdspolitik möjliggör för båda föräldrarna att delta vid sjukhus- och mottagningsbesök. Av olika skäl har ett stort antal tidigare publicerade studier inom området "familjer med barn och ungdomar med typ 1 diabetes" ofta saknat fäder i såväl stickprov som i kontroll- eller interventionsgrupper. Ofta har studier genomförts inom öppenvård där mödrar i större utsträckning har varit de som deltagit vid besök tillsammans med barnet och det som i studier beskrivits som "föräldrar" har i själva verket omfattat enbart modern.

För att undersöka och beskriva den familjedynamiska processen efter barnets insjuknande i diabetes inkluderades trettio föräldrar och åtta syskon från samma familj i fokusgruppsintervjuer (Paper II). Syftet med fokusgrupperna var att undersöka om det fanns skillnader mellan sammanboende, separerade eller ensamstående föräldrar och om psykologiska reaktioner, upplevelser av insjuknandet och förhållningssättet tiden efter skilde sig åt mellan mödrar och fäder. Fäderna i studien uppvisade mer enhetliga psykologiska reaktioner medan mödrarnas reaktioner i högre utsträckning var förbundna med barnets ålder och deras civila status. Ett annat tema i studien var att undersöka syskonets reaktioner. Perioden efter det att familjen skrivits ut från sjukhuset kännetecknas av att man skall tillbaka till skol- och arbetsliv vilket in-

nebär att det ställs krav på ökad mognad hos syskonet till barnet som har insjuknat i diabetes. Studien visar också att ju äldre syskonet var vid systemn eller broderns insjuknande i diabetes desto högre grad av inlevelseförmåga, medan det hos det yngre syskonet var mer vanligt med somatiska reaktioner och olika uttryck för rivalitet.

Särskilt tre av studierna i avhandlingen visar att fädernas aktiva deltagande vid barnets diabetesdebut har haft en omedelbar effekt på barnets hälsa och dess hälsorelaterade livskvalitet (Paper II, III och IV). Paper III kunde konstatera att fädernas utbildningsnivå hade den mest skyddande effekten på stabiliteten i barnets blodsockervärde över tid.

Inom ramen för avhandlingen har också en studie genomförts där ett diabetes-specifikt skattningsformulär översattes från engelska till svenska med syfte att mäta hälsorelaterad livskvalitet. För att undersöka hur detta formulär fungerar i en svensk kontext genomfördes en studie där dess psykometriska egenskaper prövades. I studien deltog 108 barn och 130 föräldrar (Studie I). Instrumentet som har använts uppfyller viktiga principer för att kunna användas i klinik eller i forskning, såsom att föräldrar och barn kan göra separata skattningar, att det finns en allmän del och en diagnosspecifik, att instrumentet har versioner för olika åldersgrupper där formuleringar och svarsalternativ har anpassats efter barnets mognad. Förutom formulärets goda psykometriska egenskaper visar studien också att tonåringarna rapporterade en sämre upplevd hälsorelaterad livskvalitet jämfört med barnen i de yngre åldersgrupperna, och flickor skattade en lägre grad av hälsorelaterad livskvalitet jämfört med pojkar.

Hälsorelaterad livskvalitet som utfallsmått har därefter använts för att utvärdera en randomiserad och kontrollerad familjeinterventionsstudie där totalt 98 familjer inkluderades konsekutivt efter det att barnet eller ungdomen hade nyinsjuknat i typ 1 diabetes (Paper IV). Med hjälp av detta frågeformulär har det framkommit att barnets diabetes-specifika hälsorelaterade livskvalitet förbättrades om de ingick i interventionsgruppen. Denna hade en kommunikativ inriktning, framför allt med fokus på att förebygga konflikter inom familjen och att resonera kring ansvarsfrågor i förhållande till diabetesbehandlingen samt att diskutera allmänna frågor relaterade till barnets utveckling.

## **Abbreviations**

HbA1c	Glycosylated hemoglobin (outcome measure for glucose control)
SMBG	Self-monitoring of blood glucose
T1DM	Type 1 diabetes mellitus
HRQOL	Health-related quality of life
ISPAD	International Society for Pediatric and Adolescent Diabetes
WHO	World Health Organization
SWEDIABKIDS	the Swedish pediatric diabetes quality register



## Introduction

Type 1 diabetes mellitus (T1DM) is classified as an autoimmune disease. Its onset is caused by the destruction of the insulin-producing cells, the beta cells in the pancreas. The term diabetes, meaning “to pass through”, was introduced into medicine in ancient Greece by Aretaeus of Cappadocia during the second century AD (1). In 1675 Thomas Willis added the term mellitus (“from honey”) when he noted that the urine of patients with diabetes had a sweet taste (2). Even though the term diabetes mellitus has a long history, the first injection of insulin wasn’t prescribed until the early 1920s (3). A person with T1DM needs insulin to survive; if untreated, the disease will cause acute complications and death, and unsatisfactory treatment incurs a high risk of severe long-term complications. The symptoms at the onset of T1DM are frequent urination (polyuria), increased thirst (polydipsia), increased hunger (polyphagia), loss of weight, and fatigue. Children and adolescents are frequently diagnosed with a severe condition known as diabetic ketoacidosis (4). Both the milder and the severe forms of the condition require insulin infusion therapy and usually hospitalization.

The incidence of diabetes is increasing worldwide and the medical care of children and adolescents is facing major challenges. During the past ten years the number of children and adolescents who develop T1DM has increased dramatically by about three percent per year. The tendency seems to be that younger children fall ill more often than before, but peak onset is still during adolescence. T1DM has about the same frequency in girls and boys. The incidence rate is highest in Finland, followed by Sweden (43.9 per 100 000 children, aged 0–14 years), but the increase of diabetes is not only a Northern European phenomenon (5, 6). Despite all the ongoing research, the cause of T1DM is still unknown and it is still too early to draw conclusions about whether the increased incidence rate is dictated by environmental aspects, lifestyle, or genetic factors. Medical research on the ethological factors behind the onset of diabetes continues in order to assess whether specific viruses accelerate or cause a degradation of already fragile beta cells. A vaccine to protect the beta cells has been tested in clinical trials (7).

There has also been an intense development of technology for diabetes care (8). Insulin pump therapy is a technique that helps children diagnosed with T1DM to have a more stable plasma glucose level, which is important because it is known that both hypoglycemia as well as hyperglycemia affect the child’s cognitive functions in the long term (9, 10). Another technique is continuous glucose monitoring (CGM), which continuously reports how the child’s tissue glucose levels vary during a day, reflecting the plasma glucose five to ten minutes later. Besides the possibility to reduce the number of finger-prick measurements, the transparency of the data, and the direct feedback through the alarm functions, this technique can help simplify the mission to develop workable strategies and approach normoglycemia. The technology today also allows the downloading of plasma glucose values as well as CGM

data and the pump memory to a computer at home or at the diabetes outpatient clinic. The results shown on the screen increase awareness of how the individual child is responding to the insulin delivered and how the child's diet and physical activity are associated with measured glucose levels.

What other issues, besides the medical and technical aspects, is diabetes care facing? The connection between glycemic control and family dynamics has for more than three decades been of interest for researchers and clinicians. Psychological and family-related factors have gained increasing attention. When a child or adolescent is diagnosed with T1DM, high demands are placed on the cooperation between the parents, but also within the family as a whole. Depending on the age of the child, the parents need to reorganize their everyday life for a shorter or longer period, and to establish clear routines around nutrition, physical activity, adjustment of insulin dose, and the monitoring of glucose levels (11). This diabetes management means that parents and children often need to cooperate and communicate more effectively. Finding the right balance between parental involvement and the child's level of maturity is a crucial psychological issue in the treatment of children and adolescents with diabetes (12).

Family studies have shown that parental involvement in diabetes management is often lower when their child is in the early teens, but that adolescents with good parental support to a greater extent achieve satisfactory glycemic control (13). Relatively few studies discuss the similarities and differences between how the fathers and mothers respond when their child has been diagnosed with T1DM. For various reasons, study samples do not always include both mothers and fathers (14). Additional insights are needed into how different parental constellations take on the shift in routines that is needed after the child has been diagnosed with T1DM (15). Another issue that is often overlooked is how siblings of children with a chronic illness such as diabetes reflect on their role in the family. In the clinical context, it is common for siblings to experience an increasing concern for the sick brother or sister, or to worry that they themselves will suffer from a chronic illness. Another common situation is that siblings of children who suffer from a chronic illness compete for parental attention to a greater extent than siblings in general (16).

Diabetes mellitus is a costly and life-threatening chronic illness, which is why it is essential to prevent microvascular and macrovascular complications of the disease. Studies have shown that well-functioning cooperation among the family members concerning the routines for the child's diabetes care helps to improve the child's health-related quality of life and prevent future complications. A systematic review and meta-analysis of ten studies that evaluated the efficacy of psychological treatment interventions, focusing on children and adolescents with diabetes, showed a slight improvement in glycemic control. This systematic review found that psychological interventions still need to be developed and refined (17-19). Crucial for a positive outcome of the treatment was that the intervention could be intensified and maintained for a period of at least six months. The importance of parents uphold-

ing their commitment and responsibility has also been noted (20). Family support around the child's diabetes self-care should be established as soon as the diagnosis is made. Family dynamics, such as well-developed communication skills and the ability to solve problems in the child's daily diabetes care, have been associated with better glycemic control (21). Studies have shown that the presence of family conflict is related to poorer diabetes management adherence and poorer glycemic control (22-24). An increased understanding of parents' and siblings' experiences when a child has been diagnosed with diabetes may further contribute to the care of children with diabetes, with improved support for families after the onset of T1DM.

Three fundamental questions have been considered in this thesis concerning the design of family-centered interventions from diagnosis and two years onward:

1. How does the onset of T1DM in the child affect the family as a unit?
2. What changes and demands are imposed on the family when the conditions for their everyday life are transformed?
3. Can psychological family-centered intervention focusing on the interaction between parents and children (family dynamics) promote diabetes care and contribute to providing the child with a better health-related quality of life?

The specific aim of the main study was to evaluate the impact of a family-centered intervention provided to families of children and adolescents at the onset of T1DM. The intervention was designed to improve relationships within the family and to promote parents' involvement in their child's diabetes care, to prevent conflicts, discuss questions in relation to responsibility, and to develop communication skills.



## Background

### Health-related quality of life

The concept of quality of life appeared for the first time in the 20th century and one of the earliest definitions was given by the World Health Organization (WHO) in 1948: "Health is a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity" (25). It is possible to find historical references to the concept in early philosophy, and Aristotle (BC 384–322) discussed "the good life" and "doing well" in his *Nicomachean Ethics*. Aristotle pointed out that the meaning of well-being has different connotations for different people and is dependent on their current life situation (26) (27).

Quality of life is a broad concept and has been used in different contexts, not only in the health sciences, but also by economists in the 1950s in the United States as a way of introducing a qualitative aspect to modern life. From the 1960s the term was applied in political contexts, alluding to general welfare and living standards, such as changes in purchasing power. The concept was used when proposing legislation for social reforms and as a new consideration in, for example, housing planning. Quality of life can also refer to life values, such as being satisfied with the working environment, or having access to culture (28). Today, the concept occurs in a range of scientific disciplines.

The distinguishing characteristic of quality of life is that the concept has several dimensions, including a personal, subjective dimension and an objective dimension based on external conditions which may be social and normative. This means that individuals can have their own internal criteria for quality of life, which in turn are influenced by the society's criteria for what an acceptable quality of life should encompass. It is also evaluative in the sense that quality of life may be higher or lower.

Interest in quality of life increased markedly in the 2000s. A systematic review of articles published on the database PUBMED shows that very few articles were published during the 1960s. Quality of life occurs as a keyword on the database MEDLINE from the mid-1970s onward. In 2007, 10,000 papers were published in the field (29). Initially, the concept of quality of life in medicine had its focus on function and independence in everyday life. The models for quality of life have evolved over the years, which means that the definitions of the term have varied. In two meta-analyses of articles focusing on quality of life in medicine, 44 different definitions were found in one and 100 definitions in the other (29).

The concept of health-related quality of life (HRQOL) was introduced to specify more precisely the quality of life concept in a medical context, as a complement to traditional objective measurements of the patient's health. In the HRQOL model, individuals identify different areas that together relate to their own health. The model focuses on how people's lives are affected by the disease and the treatment they

receive. Disease-specific instruments have been developed in order to identify the most relevant aspects for people with the disease in question.

Nonetheless, there are relatively few studies published regarding the HRQOL associated with chronic disease in children. Between the years 1980 and 1994, only 13% of the published articles focused on children's HRQOL. Younger schoolchildren (6–12 years) were studied the least and there were more articles that focused on adolescents (13–18 years).

Why are we interested in measuring quality of life? How can we explain the increasing interest in quality of life as a measure of the effects of chronic illness in children and adolescents? Improving HRQOL in children and adolescents has a value in itself, since it is connected with the psychological aspects of the disease. Another reason is that HRQOL can be used as an outcome measure of a treatment. HRQOL may also have an economic and political dimension that extends beyond the sick child and also includes the community and its resource allocation. From the patient's perspective it can also be used as an argument for different medical regimens or for providing technical facilities.

### **Methodology**

When selecting an instrument measuring HRQOL to be used in a pediatric clinical setting or in research, such a questionnaire must meet several criteria, including the following: 1) a clear definition of the HRQOL concept has been applied, 2) the areas covered are applicable for both children and parents, 3) both subjective and objective aspects are included, 4) parallel assessment questionnaires are available for children and parents, and 5) the questionnaire is adapted to the child's developmental age (31-33).

Several methodological issues have to be considered when using a HRQOL instrument (34). One of them is *reliability*, which refers to the consistency and reproducibility of the measure over time in the same population. One way of testing for reliability is through the test–retest method, in which the same questionnaire is administered to the same group at different times; the correlation between the two points of time is calculated, given the assumption that other factors that could affect the outcome have been controlled for. Another way of measuring reliability is by using Cronbach's alpha, which is a measure of the internal consistency of test items and, according to Nunnally 0.70 or above is an acceptable reliability coefficient (35).

The validity of an instrument refers to whether it covers the underlying domain assumed to be measured. It is possible to divide validity into three main elements: content validity relates to the degree to which the items reflect the domain of concern; criterion *validity* reflects whether the scale is consistent with established external criteria such as other well-known instruments; construct validity investigates the internal relationship of the items to each other and to the scales. Construct validity can be subdivided into convergent and discriminant validity. Convergent validity refers to items and scales that may be assumed to have a high degree of correlation.

Discriminant validity requires that an item should be highly correlated within the scale and that different scales should be relatively unrelated to each other (36).

*Sensitivity* is the ability of the instrument to identify differences between patients within a clinical population, differences between clinical groups or, for instance, differences between intervention and control groups in a randomized study.

*Responsiveness* is the ability of the instrument to identify changes in a patient's condition over time, which is important if the instrument is used as a repeated measure or to evaluate a treatment.

### ***The Pediatric Quality of Life Inventory***

The quantitative instrument used in Paper I and Paper II was the Pediatric Quality of Life Inventory (PedsQL), which was developed in the United States. PedsQL is a modular instrument, incorporating a generic questionnaire and a disease-specific questionnaire. The conceptual assumption behind PedsQL follows the 1948 WHO definition of quality of life (25). PedsQL was originally developed in 1998 for use with children and adolescents with cancer, but today the instrument covers a wide range of chronic health conditions (37, 38). The generic form can be used with any diagnostic group to compare clinical groups with each other or to compare a clinical group with a healthy control group. The disease-specific questionnaires can be used to evaluate treatment strategies and to compare variables such as age, gender, and the severity of the disease within a clinical group. PedsQL assesses a range of aspects of the child's physical, emotional, social, and school functioning. The subjective estimation employs a scale from "never" to "almost always".

Following standardized procedures, the original US version of the PedsQL 3.0 Diabetes Module was translated into Swedish in 2008. These procedures included forward and backward translation of the questionnaires and pilot testing consisting of structured interviews with twenty families in 2009 (Paper I). The Swedish version of the PedsQL 4.0 underwent reliability testing in 2009 by Petersen, and the internal consistency estimates were satisfactory for both self-reports and proxy reports. They reached or exceeded Cronbach's alpha values of 0.70 (39).

### ***Previous studies***

HRQOL questionnaires represent an important tool for assessing quality of life among children and adolescents with T1DM. Therefore, HRQOL is an important construct in need of further evaluation on this patient group, as it could offer valuable information about how children and adolescents experience having diabetes (20, 40, 41).

Glycemic control has been the primary outcome measurement in a large number of intervention studies. Other outcomes, such as improved diabetes-specific HRQOL, would be a meaningful goal, and the assessment of HRQOL in a clinical setting has been recommended for children with T1DM (42). Measuring HRQOL is of

practical value, since it might help the diabetes team to understand how children and adolescents perceive having diabetes (43). Assessment of HRQOL might also indicate the presence of diabetes-related conflict within the family, lower psychological well-being or the occurrence of depression; it might also contribute to the understanding of poor glycemic control and the design of therapeutic interventions (22, 42, 44-46). Some studies have shown significant positive correlations between HRQOL and glycemic control (45, 47), and an association between diabetes-related family conflict and lower HRQOL has also been reported (48). Younger children have shown a lower level of generic HRQOL compared to healthy control groups (49). Mothers especially, but also fathers, commonly assess their child's HRQOL differently than the child's own judgment (50).

### **Glycemic control**

One of the formulated goals of diabetes treatment in children with T1DM is to achieve stable glycemic control in order to avoid long-term complications. Glycemic control refers to minimizing the fluctuation in blood glucose levels during the day, and self-monitoring of blood glucose (SMBG) is an important tool for maintaining more constant blood glucose levels. A finger-prick blood test is performed at several time intervals to measure the capillary blood glucose level at the time the test is performed. The recommended frequency of SMBG among children and adolescents is four to six times a day (51). Glycated hemoglobin (HbA1c) reproduces the average changes in blood glucose levels during the previous four to eight weeks and is the gold standard for evaluating glycemic control. In 1993, the Diabetes Control and Complications Trial (DCCT) stated that intensive insulin treatment and a goal of near normoglycemic control, measured as HbA1c, could prevent future complications (52). According to the International Society for Pediatric and Adolescent Diabetes (ISPAD), the recommended target for children and adolescents is an HbA1c of <58 mmol/mol (<7.5%) (51). One study showed that when parents encouraged their child (aged 10 to 15 years) to perform more frequent SMBG, the result was a markedly better HbA1c (13). Furthermore, less frequent SMBG has been associated with symptoms of depression and anxiety (53, 54).

### **Family dynamics**

The onset of T1DM in a child or adolescent means that a variety of psychological issues immediately emerge. Clinicians observe that the psychological effect on the entire family is pronounced, in particular the individual reactions in the parents, such as shock and sadness due to the unexpected changes in their everyday life. Optimal treatment is often easier to maintain if the parents have a relationship characterized by efficient communication and collaboration. When a child is diagnosed with a severe chronic illness it may also reawaken the parent's unique life history, which may influence the family's way of handling difficult situations. How one parent reacts may also be affected by personal medical and hospital experiences. Having a supportive network of grandparents or other relatives who can help the family in this difficult situation is often helpful. Another aspect is the parents' level of educa-

tion, which is related to their ability to process new information and handle stressful situations. A further important issue is how well the parents can establish rapport with the pediatrician, the diabetes nurse, and the extended diabetes team during the child's hospitalization and after the transfer to the outpatient clinic.

Besides severe stress reactions, specific reactions to the heredity aspect of diabetes etiology, such as feelings of guilt, are common. Stress reactions as a result of the diabetes onset may also inhibit the learning process and might have an impact on the child's and siblings' well-being in the family (55).

In this difficult period after the onset of diabetes in the child, emotional and irrational reactions are common. Various forms of crisis reactions are also common. Such reactions are defined as a response to a life situation in which the individual's past experiences are not sufficient to enable mastery of the situation without significant psychological distress (56). On the other hand, this new situation provides an opportunity to find new ways to communicate and relate to each other within the family.

### ***Family functioning***

A substantial number of papers have described how family factors are essential to well-functioning diabetes treatment in children (54). The importance of the parents' support for the child, their capacity for empathy, and their understanding of the disease has often been emphasized (57, 58). Moreover, it is important that the parents have a shared view of the respective responsibilities of parents and children for successful diabetes management (58).

Family functioning also concern a family's ability to communicate and to solve problems. The importance of parents upholding their commitment and responsibility during an extended period after the diabetes diagnosis has also been noted. It is vital to establish family support around diabetes care from the point of diagnosis, as the level of glycemic control is affected by family functioning, such as communication skills and the ability to solve daily diabetes care problems. If the parents have a history of conflicts or disagreements about parenting or bringing up children, old disputes may resurface, to be reinforced and repeated after the onset of diabetes in their child because of the emotional strain they are experiencing. The presence of family conflict is shown to be related to lower diabetes management adherence and poorer glycemic control. Adherence to the daily treatment of diabetes necessitates cooperation and involvement from the family and places high demands on the sharing of diabetes management roles and responsibilities (59).

The roles of family members typically vary with the child's age and developmental level. Research has established that there may be diabetes management problems if parents give their child a degree of autonomy which does not correspond with the child's social and cognitive maturation. As the child grows older, the question of transferring responsibility from the parent to the child will increasingly be in focus

(60, 61). Parents may transfer responsibility for diabetes management to adolescents according to their chronological age when in fact it is the degree of cognitive maturity and readiness to assume responsibility for diabetes management that are essential predictors of the maintenance of healthy glycemic control (59).

In families where the question of responsibility is well defined and shared, the child's glycemic control is more likely to be stable. Shared responsibility and decision-making have been shown to have positive outcomes for both the psychological and physical health of the child. One study found that children who reported a higher level of shared responsibility showed less depression and anger, as well as higher diabetes self-efficacy and better self-care. Furthermore, for older adolescents the perception of shared responsibility was also associated with better metabolic control (62).

In a clinical setting it is important to identify the perceived responsibility of the family for the child's diabetes management, since this issue is shown to be related to the diabetes outcome.

### **The development of the child**

Regarding the child's development, there is a risk that the parents act as if they are the ones suffering from diabetes. In the long run, this could limit the child's development and, by adolescence, an entrenched psychological bond between the teenager and the parent may have formed through a history of child–parent interaction characterized by negative comments, with parents worrying excessively or being overprotective. This could lead to aggressive reactions during a period in which the issue of independence is already at the fore. For the parents, it is a balancing act to determine in what way they are required in the teenager's direct or indirect diabetes care.

It is of great importance to minimize the effect of diabetes on the development of children and adolescents compared to those without a chronic illness. In order to mature, children need their own mental zone and need to be a part of the regular activities of their peer group, such as sports and social activities. Children and adolescents need other influences beyond the family; at the same time, the parents' identification with the child is essential, and the parents need to grapple with the issue of what it is like to be a preschooler, a middle-school child or a teenager with a chronic illness.

The child will have different needs at different stages of development, and the parents have to adjust to the situation and will face different challenges. At times the diabetes care might interfere with the child's development towards maturity. A general question that parents struggle with is whether their child's behavior and emotional reactions are part of normal development or should be considered as problems related to the diabetes onset or diabetes symptoms (11).

***The preschool child***

With increasing age, preschool children (3–6 years) gradually start to communicate their needs and desires, but they still have difficulties differentiating their perceptions (63). This is something parents must learn to recognize and interpret. The child's reactions may be related to their plasma glucose level or may actually be an expression of hunger, thirst, or sleepiness. Parents of preschoolers will have the main responsibility for diabetes care, and the major challenge for them is to ensure that their child's everyday life in preschool runs smoothly. Therefore, they have to train the staff to handle daily diabetes care and must themselves be on hand to help solve the diabetes-related difficulties that can occur during the day.

Being in a constant state of readiness in case something unexpected happens with the child places a severe stress on the parents (64). They may also experience an ongoing conflict between what they regard as doing their best for the child's health and meeting the expectations of their workplace.

To achieve a well-functioning everyday life, parents must develop trust in the preschool staff members who are involved in the daily care of the child; they have to establish daily routines and cooperate with each other. The preschooler needs limits but will at times show a desire to become more independent in the daily diabetes management routines.

***The school-aged child***

The school-aged child (6–12 years) is starting to communicate in a different way compared to the preschool child and gradually becomes capable of reporting changes in plasma glucose levels. The child is better able to differentiate symptoms of hyperglycemia and hypoglycemia. At this age, the child will need assistance at school for an optimal learning process, not only in terms of scholastic achievement but also to more accurately identify diabetes symptoms when they occur, and to understand how to prevent them (65). The parents still need to communicate with the school staff, but gradually the child will be able to independently ask for help if needed (66).

Measuring glucose levels is important, since low or high plasma glucose values will have an effect on the child's cognitive functioning such as attention and mental flexibility. To promote and stimulate the child's own ability to understand and create a mental concept of diabetes management, parents can invite the child to reflect on diabetes-related tasks through dialogue. At this age, children begin to spend more time outside the family and school in various social activities, which is an important part of child development and an opportunity to enhance self-esteem and develop some independence. Therefore, another important issue during these years is to encourage the child with diabetes to see friends and spend time in leisure activities.

The parents have to inform the youth leaders in charge of the leisure activities, as well as the parents of their child's friends, about the main principles of diabetes care, such as how to handle different symptoms and in what way the child is in need of support. On reaching middle school age (10–12 years), the child begins to reflect

differently about diabetes as a disease. Although an understanding of cause and effect is not yet developed, the child has an emerging capacity for abstract thinking that can be applied to reflecting on illness as a concept. This qualitative change in cognitive processes often leads to emotional reactions. The fact that the disease makes the child in certain respects different than the peer group begins to arise. The child's response to the disease can often lead to a feeling of injustice that is more or less connected to the diabetes itself. The child can react emotionally to restrictions that might interfere with peer relationships.

### ***The young adolescent***

The adolescent (13–15 years) spends more time outside the family home and the parents' control of the diabetes care starts to decline. However, there is still a need for support and supervision by the parents (13, 60, 67, 68). In the early teens, adolescents can perform daily diabetes management tasks by themselves, such as insulin administration, checking blood glucose values, and telling others about their diabetes treatment; parents are still needed in the indirect management tasks such as informing school about the diabetes, remembering clinic appointments, and making sure the medical supplies are provided. Parental support is also needed in structuring the adolescent's everyday life, where diabetes management is fundamental to successful functioning in both school and social activities. Physical, emotional, and cognitive ability develops rapidly during this period, which often leads to new reflections; living with diabetes generally takes on a qualitatively different meaning for these adolescents, such as being different from their peers. They now have questions about what future to expect, and what barriers may exist because of the diabetes, but also thoughts about their prospects of living a good life consistent with their individual dreams, goals and life expectations. They must relate to and gradually integrate diabetes into their identity development (69). The experience of belonging and family support will enable adolescents with diabetes to deal with these increased demands.

### **Challenges in diabetes care**

To an even greater extent than in most other chronic diseases, diabetes treatment has to be administered and understood in collaboration and consensus between the health professionals and the parents, and also with the child with diabetes, depending on the child's age and maturity. T1DM disease management requires a strict treatment regimen including daily insulin doses, regular blood glucose testing, and regulation of the diet, including carbohydrate counting and monitoring of physical activities. These tasks have an impact on the family as a whole. Therefore, when a child or adolescent develops diabetes, the family will meet the diabetes team in order to establish a functioning working alliance. This often involves many psychological challenges, and it is an internal and external journey for both the family and the diabetes team (11). For the diabetes team it is part of an ongoing challenge to work with these families, but for the family with the newly diagnosed child it is a sudden and disruptive journey where all family members are confronted with a new and unfamiliar situation. What challenges are the family and the diabetes team confronted with until this working alliance can be established?

The multi-disciplinary diabetes team consists of various professions such as pediatrician, nurse, dietitian, social worker, and frequently a psychologist. The question of how the diabetes team should approach the family is to some extent an internal history that requires self-reflection and a constant effort. Well-defined routines help the team to address the psychological and social aspects that the family expresses or demonstrates, but at the same time the team must see each encounter with a new family as unique. The ongoing work within the diabetes team is to create a shared vision of exemplary child health care, to hold regular meetings for joint discussions and training, to develop written materials such as information to families, and to discuss how and in what way the families should be informed (70). What does it mean that each session with a new family must be unique? In this context, it means that the clinician is trying to understand the specific family situation and avoid bias; by applying empathy, the clinician strives to understand what the family members are experiencing from their own perspective.

The psychosocial work of a health care team functions on three levels (71), where the basic level is to offer empathic care, seeking to understand the family members' experience and thus empowering them to be actively involved in their treatment, with the diabetes team giving them information and support. In order to provide this fundamental support, it is of importance that the team members communicate with each other, and are allowed to develop in their profession with the appropriate support and supervision. The second level is to foster ongoing psychosocial development in the families; this may include refinement of the communication methodology (72), patient education, school information, and summer camps to enable the child or adolescent to get together with other children with diabetes. The third level is the specialist function of the diabetes team, such as research and psychotherapy. In a hospital setting, the diabetes team gets close to the families because they are referred at an early stage after the diabetes onset. Families are often expressive, seeking assistance, and professional boundaries are weakened as personal rapport develops. The first contact is important to the family and many of them want continuity of care with the members of the diabetes team.

What kind of locus of control the family has tells us something about the role the diabetes team members will assume in their interaction with the family. A high degree of internal locus of control means that the family members expect their own actions to affect the result, which is seen in families that are performing well and thus do not want to be controlled from the outside; they prefer to seek information independently about their new situation. In this case, the diabetes team has to work more as consultants. In contrast, families with a high degree of external locus of control have become overwhelmed by stress and experience stronger emotional reactions, and they assume that others or fate affect their situation; this creates a relationship that is characterized by dependence (73).

It has been observed numerous times before, but it is worth repeating, that when a child develops diabetes, the whole family is affected. During the first days, the

diabetes onset triggers strong emotions in the parents and the child. There are many reasons for all these strong emotional reactions. How the family reacts to the information of the diagnosis obviously depends on the severity of the child's medical symptoms but frequently also on the child's age and earlier development. A high degree of parental stress has an impact on the child (74). The psychological reaction of the siblings may manifest itself as strong worry and is usually related to the sudden change in everyday life and not getting the same attention as before.

How the family adapts to the new situation is related to the relationships within the family, for example, whether the psychological bond between the family members is strong and whether they find it easy to adapt to new and overwhelming situations; other factors are how the parents and the child handle stress, how parents, child and siblings communicate with each other, how experienced they are at listening to each other, and how they show emotions. Each family has its own identity, and is characterized by different ways of communicating, solving problems, managing conflicts and getting their everyday life to function smoothly (75).

### **Psychological concerns among children, adolescents, and their parents**

The course and prognosis of a chronic disease in children and adolescents are often associated with psychological and family-related issues. Earlier studies point to a high degree of psychological vulnerability among children and adolescents with diabetes (76). The importance of psychological support through childhood and adolescence has been highlighted, since psychological reactions often take a long time to manifest themselves (77-79). A high prevalence of depression in children with diabetes has been found (76). A relationship between poorer metabolic control and depression has also been demonstrated in adolescents. A longitudinal study showed that children at diabetes onset had more depressive symptoms, were more withdrawn and in a more dependent situation compared to a control group (77, 78). Two years after onset, major depressive disorders were more common in the diabetes group. Girls in particular are more likely to receive a psychiatric diagnosis, such as eating disorders. Adolescents with a history of poor glycemic control and diabetic ketoacidosis are also at risk (20).

Overall, the importance of socioeconomic status in relation to HRQOL, depression and glycemic control is highlighted in several studies. One study found that poorer glycemic control is associated with depression and lower socioeconomic status (80). Furthermore, a high parental education level has been shown to have an overall protective effect on the child's glycemic control (81). Research that examined how families take on board the fact that the child has been diagnosed with T1DM found that this can distinguish families with a good treatment prognosis from families with an expected need for extended treatment interventions. The following three factors emerged where extended treatment was needed: single mothers, fathers with lower levels of education, and strong emotional reactions in the parent. It was found

that psychosocial factors were a significant predictor of future HbA1c levels. Even one year after diagnosis, the level of glycemic control could predict a future need for extended treatment interventions (82). Fathers' reactions to chronic disease are described on a much smaller scale (83, 84). One study found that in families with teenagers who have T1DM, fathers were more withdrawn and less communicative (85). Another study suggested that fathers were more instrumental in learning to maintain glycemic control whereas mothers provided more support for the child's psychological adjustment (55). The study found that support for the child's emotional response at onset was intimately connected with the parents' psychological reactions, thus underlining the importance of adopting a family perspective. High stress levels in the parents at diabetes onset indicated the need for psychological treatment. One third of parents report stress reactions at diagnosis. Symptoms of depression have been found among mothers during the first year after the child's diabetes onset (86). When comparing parents of children and adolescents with chronic disease to parents of healthy children, psychological symptoms in response to the illness were found, and were especially severe among mothers of a child with T1DM (87, 88).

### **The psychological intervention**

The overall goal of diabetes care is easy to formulate: to ensure healthy diabetes management and to prevent future diabetes complications, as well as to help the child during the passage to adulthood to attain an acceptable quality of life. But behind the somatic disease is a psychological drama that must be handled urgently. The sudden change in everyday life after the onset of T1DM places high demands on parents and children. Pre-existing difficulties can be exacerbated. The greatest opportunity to improve parents' coping strategies is at diabetes onset, when the parents do not know how to respond to the crisis; if intervention is left too long, it is easy for them to revert to their previous interaction patterns.

The goal of the family intervention in this thesis was to mediate psychological challenges within the family associated with the family's past history, present situation and future changes in their everyday life. Effective communication must be established between the parents and the child in order to prevent future conflicts around diabetes management, and to encourage flexible parenting; in particular, the child will need more help during more difficult periods, but will also benefit from age-appropriate challenges in connection with diabetes care. Other goals of the intervention study were to encourage parents to work together to be able to discuss decisions and to support each other in finding a balance in relation to the diabetes care, to stay in control of the treatment together, and to share the responsibility.



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## Aims and Hypotheses

### Overall aim

The main aim of this thesis was to explore different aspects of family dynamics and HRQOL after the onset of T1DM in children and adolescents (Papers I and II).

A second aim was to evaluate the effects of a two-year prospective family intervention randomized controlled trial (RCT) with additional psychological support after the onset of T1DM, focusing on facilitating communication skills within the family in the initial and ongoing diabetes care (Papers III and IV).

### Specific aims

#### *Paper I*

The aim of Paper I was to explore the reliability of the PedsQL 3.0 Diabetes Module, Swedish version, and to conduct a limited validation of the instrument in a sample of Swedish children diagnosed with T1DM. A further aim was to investigate whether these children's HRQOL was associated with gender and age, and whether the child's self-report and parent's proxy report were consistent.

#### *Paper II*

The aim of Paper II was to describe the process of family dynamics when a child has been diagnosed with T1DM. Are experiences different depending on whether the parents are living together, separated with shared custody, or living as a single parent? Do the reactions within the family vary according to the child's age? Do the experiences of mothers and fathers diverge? What are the siblings' experiences? Are there differences depending on the age of the sibling?

#### *Paper III*

The aim of Paper III was to investigate the influence of family dynamics on the changes in the child's glycemic control from the onset of T1DM to one year after diagnosis in an RCT study design.

#### *Paper IV*

The aim of Paper IV was to investigate the children's HRQOL and glycemic control in a two-year prospective RCT.

### Hypotheses

#### *Health-related quality of life instruments*

Hypothesis 1: The Total Score on the Swedish version of the PedsQL 4.0 Generic Core Scales (and the PedsQL 3.0 Diabetes Module exceeds the criteria for satisfactory internal consistency and convergent validity).

***Paternal effects***

Hypothesis 2: Bringing in fathers in the child's diabetes care has a positive effect on outcome measures such as glycemic control.

***Children's and adolescents' health-related quality of life***

Hypothesis 3: The children and adolescents assigned to the intervention group report a higher degree of general and diabetes-specific HRQOL than the children in the control group.

***Glycemic control***

Hypothesis 4: Facilitating psychological support and communication skills training has a positive effect on glycemic control.

## Participants and Methods

This thesis includes three studies, A, B and C.

Study A was a cross-sectional study resulting in Paper I, study B involved focus group interviews and resulted in Paper II, and study C was an RCT intervention study resulting in Paper III and Paper IV. An overview of the methods is given in Table 1.

*Table 1. Overview of study design, inclusion criteria, participants, data collection, and data analysis*

Study	A	B	C	C
<b>Paper</b>	I	II	III	IV
<b>Design</b>	Cross-sectional study	Explorative	RCT	RCT
<b>Inclusion criteria</b>	6 months after diagnosis, fluency in the Swedish language	8–29 months after diagnosis, fluency in the Swedish language	Newly diagnosed, fluency in the Swedish language	Newly diagnosed, fluency in the Swedish language
<b>Participants</b>	Children aged 5–18 years, (N=108) and parents of children aged 2–18 years (N=130)	30 parents and eight siblings	Children aged 3–15 years (N=101) and their parents	Children aged 3–15 years (N=98) and their parents
<b>Data collection</b>	Self- and proxy-report inventories (PedsQL 3.0, PedsQL 4.0)	Focus group discussions and individual interviews	HbA1c, child's age and gender, parent education, PedsQL, <sup>TM</sup> Family Impact Module	Self- and proxy-report inventories (PedsQL 3.0, PedsQL 4.0), HbA1c
<b>Data analysis</b>	Descriptive and comparative statistics	Grounded theory	Descriptive and comparative statistics	Descriptive and comparative statistics

RCT = randomized controlled trial.

PedsQL = Pediatric Quality of Life Inventory.

(PedsQL 3.0 = Type 1 Diabetes Module, PedsQL 4.0 = Generic Core Scales)

### *Paper I*

The diabetes outpatient clinic in Falun was the main center of this cross-sectional study. To reach acceptable numbers of younger child participants, three other centers were involved (Jönköping, Kungsbacka, Örebro). The Swedish version of the PedsQL 4.0 and PedsQL 3.0 questionnaire together with a letter of information regarding the study were distributed to the participants by a diabetes nurse at each centre. Children with T1DM aged 5–18 years and parents of children T1DM aged 2–18 years participated in the study. Among the youngest group of children (between two and four years of age), only parental proxy reports were used. A total of

165 families were asked to participate in the study, of whom 130 (79%) families accepted. From these 130 families, 97 mothers and 25 fathers participated. (Eight of the families were non-responders.) There were 54 girls and 75 boys, of whom one was a nonresponder, in the child sample, comprising nine girls and 13 boys in the youngest age group (ages 2–4), 20 girls and 22 boys in the early childhood age group (ages 5–7), 13 girls and 25 boys in the preadolescent group (ages 8–12), and 12 girls and 15 boys in the adolescent group (ages 13–18). The average age was 9 years (SD = 4.5). The youngest child in the sample was one year old at the onset of diabetes and the oldest was 16 years old. Two of these were in the youngest age group, four were in the early childhood age group, six in the preadolescent group and 23 in the adolescent group. The data collection proceeded during January through March 2010.

### ***Paper II***

Focus group discussions and individual interviews were audio-taped, transcribed, and analyzed using a grounded theory methodology. The study sample consisted of family members of 21 children with T1DM aged 3–17 years. Thirty parents (18 mothers and 12 fathers) and eight siblings participated in nine focus group interviews at a pediatric diabetes outpatient clinic in Sweden. Seven individual interviews were conducted, one with a separated father, one with a single mother, and five with siblings. The participants were recruited at the pediatric diabetes center at the Queen Silvia Children's Hospital, Sahlgrenska University Hospital in Gothenburg during the period April 2009 to September 2009, from eight to 29 months after the onset of T1DM.

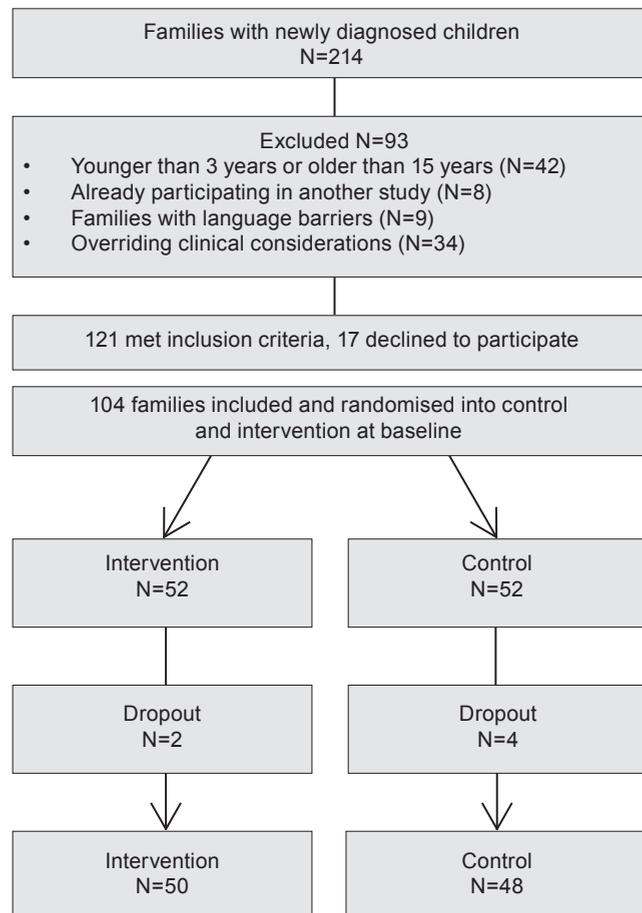
### ***Paper III***

This exploratory study examined data from part of the two-year prospective RCT using outcomes measured at baseline and at prospective follow-up one year after diagnosis. In this RCT, two different treatment regimens at T1DM diagnosis were compared. The treatment-as-usual regimen provided support from the whole diabetes team except for the specific support of a psychologist-psychotherapist with special training in diabetes. The intervention group was in addition provided with four scheduled psychological intervention sessions with such a team member during the first six months after diagnosis. Thereafter three booster sessions were offered during year one and two. The intervention was designed to facilitate communication between parents and child, and to develop their coping strategies and problem-solving skills in the child's daily diabetes management, starting at diabetes onset and continuing for two years. It also aimed to enable the family to give better emotional support to the child. The participants were recruited at the pediatric diabetes centre at the Queen Silvia Children's Hospital, Sahlgrenska University Hospital, Gothenburg, Sweden during the period October 2008 through December 2011. The total population consisted of 214 children, recently diagnosed with T1DM, and their primary caregivers. Of the 121 families who met the eligibility criteria, 104 (86%) agreed to participate in the study. At the end of year one, three of the 104 families had chosen to drop out of the study, leaving 101 families for follow-up. The change in the child's glycemic control from the onset of T1DM to one year after diagnosis

was measured against the following variables: the child's age, parent and family functioning (PedsQL Family Impact Module), and parent's level of education. Glycemic control measured as HbA1c at three months after diagnosis was used in the analysis as a baseline value.

#### ***Paper IV***

As part of the two-year prospective RCT described in Paper III above, 98 children aged 3–15 years, recently diagnosed with T1DM, participated with their parents. At six and 24 months after diagnosis, the child, mother, and father independently completed the PedsQL 4.0 Generic Scale and PedsQL 3.0 Diabetes Module, and the child's glycemic control (HbA1c value) was measured. At the end of year two, six of the 104 participating families had chosen to drop out of the study, leaving 98 families for follow-up (Figure 1).



*Figure 1. Overview of the participants in study C (Paper IV)*

## Measurements

### *Papers I and IV*

#### *Health-related quality of life instrument*

The PedsQL 3.0 Diabetes Module consists of 28 items and five scales: 1. diabetes symptoms (11 items), 2. treatment barriers (four items), 3. treatment adherence (seven items), 4. worry (three items), and 5. communication (three items).

The PedsQL 4.0 Generic Core Scales consists of 23 items and covers four scales: 1. physical functioning (eight items), 2. emotional functioning (five items), 3. social functioning (five items), and 4. school functioning (five items; in the age group two to four years, three items). The psychometric properties of the Swedish versions of the PedsQL 3.0 and the PedsQL 4.0 have shown acceptable psychometric properties.

Each item in the PedsQL 3.0 and PedsQL 4.0 is measured on a five-point Likert scale where 0 = never a problem and 4 = always a problem, except for the three-point Likert scale (where 0 = not at all, 2 = sometimes, 4 = a lot) used in the child report for the five- to seven-year-olds. Items are reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0); thus, higher scores indicate better functioning or less negative impact.

### *Paper II*

#### *Focus group discussions*

The discussions were guided by open-ended questions, such as the following for parents: “How were you were told about your child’s diabetes diagnosis?”, “What were your reactions at that time?”, and “Has your child’s social life been affected?”; examples of questions for siblings were: “What did you know about diabetes before you came to the hospital?”, “Do you remember what happened when your brother or sister became ill?”, and “How do you think it has affected your family that your sibling has diabetes?”.

### *Paper III*

#### *Parent and family functioning*

Parent and family functioning was measured with the PedsQL™ Family Impact Module. This is a 36-item questionnaire consisting of six scales measuring parent self-reported functioning (Physical Functioning, six items; Emotional Functioning, five items; Social Functioning, four items; Cognitive Functioning, five items; Communication, three items; Worry, five items), and two scales measuring parent self-reported family functioning (Daily Activities, three items; Family Relationships, five items). Each item in the PedsQL™ Family Impact Module is measured by a five-point Likert scale where 0 = never a problem and 4 = always a problem. Items are reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), thus higher scores indicate better functioning or less negative impact.

### *Papers III and IV*

#### *Parent educational level*

Parent educational level was measured in the demographic questionnaire as a two-point categorical variable. Parents were asked to report their educational level as 12 years or less (primary school, college), or more than 12 years of education.

***Papers II, III, and IV******Glycemic control***

HbA1c was measured with DCA Vantage (Siemens Healthcare Diagnostics Inc., Tarrytown NY, USA) with a normal value of 27–42 mmol/mol (4.6–6.0% NGSP). The quality was assured in accordance with Equalis (External quality assurance in laboratory medicine in Sweden, www.equalis.se). There was no deviation from the set targets during the study period. All patients were initially treated with intravenous insulin for one to three days, thereafter with multiple daily injections (MDI) or insulin pump. Eleven patients (11%) suffered from diabetic ketoacidosis, defined as blood pH < 7.3 mmol/l at the time of diagnosis.

***Paper IV******Follow-up questions after the intervention related to motivation and satisfaction***

When the family had completed the family intervention, they were asked to answer four follow-up questions about their motivation to participate in the study and whether they were satisfied with the group to which they were randomized. The questions were posed individually to each parent; when a parent was not present he or she was contacted by phone. A higher proportion of mothers than fathers answered the follow-up questions (93% compared to 79%) (Table 5).

**Statistics and data analysis*****Paper I: The reliability of a health-related quality of life questionnaire***

Internal consistency for each scale was assessed using Cronbach's alpha. The construct validity was assessed using the convergent validation approach by means of Pearson's correlations between the PedsQL 4.0 Generic Core Scales and PedsQL 3.0 Diabetes Module. The paired t-tests were used for comparisons between children's self-reported HRQOL and parent proxy reports. Independent sample t-tests were used to test for gender differences. One-way ANOVAs (including the Bonferroni post hoc correction) were used to test for the possible age-related differences in HRQOL. The level of significance for all tests was set to  $p < 0.05$ .

***Paper II: Family dynamics when a child has been diagnosed with T1DM***

Focus group discussions and individual interviews were audiotaped, transcribed, and analyzed using grounded theory methodology. The transcriptions of the interviews were read and reviewed, and initial coding was performed line by line, statement by statement, and discussed on a continuous basis throughout the analysis process. The interview statements were classified and coded based on frequency and meaning. Recurrent latent patterns in the data were searched for, leading to iterative development of subcategories and categories in a hierarchical structure. By going back and forth between the emerging data, the core category evolved. When no new properties of the categories emerged, they were considered to be saturated.

***Paper III: The change in the child's glycemc control from the onset of T1DM to one year after diagnosis***

A linear mixed model was used for longitudinal analysis. The variables parental and family functioning, parental educational level, and age of the child were regarded as potentially explanatory for the continuous variable HbA1c. Cross-correlations were performed prior to the analysis in order to determine the strength of the relationship between the variables in the models. Variables with correlations  $>0.70$  were omitted from the model. In order to control for high baseline HbA1c levels, i.e. HbA1c measured immediately at diabetes onset, HbA1c at three months after diagnosis was used in the model. Internal consistency of the total PedsQL™ Family Impact Module, as well as of the subscales, was assessed with Cronbach's alpha for mother and father reports. The level of significance was set to  $p<0.05$ .

***Paper IV: Health-related quality of life and glycemc control***

For both HRQOL and HbA1c, Fisher's permutation test was used to test the differences between control group and intervention group regarding HbA1c (89, 90). Internal consistency of the PedsQL 3.0 and PedsQL 4.0 Total Scores was assessed with Cronbach's alpha for child, mother, and father reports. Correlations between gender and HRQOL and between age and HRQOL were made using the Pearson product-moment correlation coefficient. The level of significance was set to  $p<0.05$ .

***Paper IV: Power analysis***

The purpose of a power analysis is to calculate the smallest required sample size to have the probability to detect a statistically significant effect. The larger the sample size, the higher the power of the study, and the better possibility of finding a statistic difference. Whereas the level of HbA1c varies the most during puberty, the power calculation was based on the distribution of the variation in measurements taken in 2004 on 2883 patients in the age group 10–15 years (SWEDIABKIDS). The estimated standard deviation of the individual HbA1c measurements was set to 0.7%. This means that the difference between two individual measurements should be one standard deviation. If the average change in the two groups in the family intervention study (fifty families in the intervention group and fifty families in the control group) is differentiated by 0.7 percentage points, then the power is 0.89, in other words, an 89% probability of detecting such a difference at the 5% level of significance.

**Ethical considerations**

The studies included in this thesis were all performed according to the Declaration of Helsinki and were reviewed and approved by the Regional Ethical Review Board of Western Sweden. Children and parents were encouraged to prospectively fill in questionnaires at altogether five occasions during the study. Some family members considered this procedure to be time-consuming. In order to simplify the administration of the questionnaires, they were completed at scheduled outpatient visits. On rare occasions, because of lack of time, parents filled in the questionnaires at home and sent them by post to the clinic.

Some families found the outcome of the randomization procedure problematic, and some had a preference for a particular randomization group, usually the intervention group. The missed opportunity to see a clinical psychologist was of concern to a majority of the families in the control group. In order to meet the needs of the families in this situation, they were all given the option of seeing a social worker, as this was scheduled into the treatment-as-usual regimen. If necessary, the child and accompanying family could also be referred to the child psychiatry department.

An additional possibility could be that the families might have found it hard to decline to participate in the study because they were in a vulnerable situation. All the participants received both verbal and written information stressing that the participation was voluntary and could be terminated if they no longer wanted to participate. The parents and children who agreed to participate in the study were asked to fill out separate informed consent forms. Age-adapted written consent forms were developed and enclosed for older children and adolescents.

The outcomes of the study are to a large extent measured by questionnaires. Therefore, to participate, families had to be able to read and understand Swedish. This criterion excluded some families with a different language background from participation.



## Results

### *Paper I: The reliability of a health-related quality of life questionnaire*

Sand P, Kljajić M, Schaller J, Forsander G. The reliability of the Health Related Quality Of Life questionnaire PedsQL 3.0 Diabetes Module™ for Swedish children with Type 1 diabetes. *Acta Paediatrica* 04/2012; 101(8):e344-9.

#### *Reliability*

The Total Score of the PedsQL 4.0 Generic Core Scales exceeded the criteria for satisfactory internal consistency, with a Cronbach's alpha of 0.91 for parent proxy reports and 0.88 for child self-reports. The only subscale with Cronbach's alpha under 0.70 was the School Functioning Scale of the self-report (Table 3).

The Total Score of the PedsQL 3.0 Diabetes Module also exceeded the criteria for satisfactory internal consistency, with a Cronbach's alpha of 0.91 for parent proxy reports and 0.90 for child self-reports. The majority of the subscales in the PedsQL 3.0 Diabetes Module reached satisfactory reliability and Cronbach's alpha at or above the 0.70 level. Exceptions were seen in the Treatment Barriers Scale of both the self-report and proxy report, and in the Worry Scale of the self-report (Table 2).

*Table 2. Cronbach's alpha values for PedsQL 4.0 Generic Core Scales and PedsQL 3.0 Diabetes Module: parent proxy report and child self-report*

<b>PedsQL 4.0 Generic Core Scales</b>	<b>Parents (N=124–128)<sup>a</sup></b>	<b>Children (N=103–107)<sup>a</sup></b>
Total Score	0.91	0.88
Physical functioning	0.83	0.75
Emotional functioning	0.83	0.72
Social functioning	0.77	0.77
School functioning	0.82	0.63
<b>PedsQL 3.0 Diabetes Module Scales</b>	<b>Parents (N=124–128)<sup>a</sup></b>	<b>Children (N=103–107)<sup>a</sup></b>
Total Scores	0.91	0.90
Diabetes symptoms	0.83	0.80
Treatment barriers	0.54	0.49
Treatment adherence	0.73	0.72
Worry	0.89	0.59
Communication	0.88	0.70

<sup>a</sup> The number of respondents completing the different scales varied within this range. The average Cronbach's alpha is above 0.70 for both instruments.

### *Validity*

The PedsQL 4.0 Generic Core Scales and PedsQL 3.0 Diabetes Module showed satisfactory convergent validity, with a correlation value of 0.76. In other words, the fewer diabetes-related difficulties the child or parents report, the higher the scores on the generic HRQOL scale.

### *Gender*

There were significant differences in the way girls and boys experienced their psychological functioning and treatment adherence. The results showed that there were significant gender differences in children's self-reports concerning PedsQL 4.0 Emotional Functioning and PedsQL 3.0 Treatment Adherence Scales ( $p < 0.05$ ), with girls reporting worse outcomes.

### *Age*

In terms of age differences, this study showed that the adolescent group, aged 13–18 years, reported the lowest diabetes-specific HRQOL compared to the younger age groups, 5–7 and 8–12 years. The results revealed a significant main effect for age in all subscales, and for the Total Score of the PedsQL 4.0 Generic Core Scales. Additional post hoc tests revealed that the age differences were significant in seven comparisons concerning the PedsQL 4.0 Generic Core Scales ( $p < 0.05$ ). Children in the middle age group (8–12 years) had the most positive scores, as shown in five of the post hoc comparisons. Post hoc testing for the PedsQL 3.0 Diabetes Module resulted in significant age-related differences on five scales, as well as on the Total Score. In all of these six comparisons, children from the oldest age group (13–18 years) had significantly lower diabetes-specific HRQOL than the age groups 5–7 and 8–12 years ( $p < 0.05$ ).

### *Children versus parental reports*

There were no significant differences between parental proxy reports and children's self-reports on the PedsQL 4.0 Generic Core Scales. However, there were two significant differences on the PedsQL 3.0 Diabetes Module. First, the parents in our study reported overall that their children had lower diabetes-specific HRQOL than the children themselves did ( $p < 0.01$ ). Second, significant differences between children and parents were found in how they reported treatment adherence ( $p < 0.01$ ).

### ***Paper II: Family dynamics when a child has been diagnosed with T1DM***

Sand P, Dellenmark Blom M, Forsander G, Sparud Lundin C. Family dynamics when a child becomes chronically ill: impact of type 1 diabetes onset in children and adolescents. Submitted Feb 2015.

### *Family dynamics*

The onset of T1DM in a child changed everyday life for the entire family. The experience of being a parental couple was reinforced as a result of the child's sudden hospitalization. In addition, the parent's individual history came into play and, guided by memories and preconceptions, individual psychological reactions and ac-

tion patterns developed and affected interactions with significant others among the family members.

The findings are outlined in the core category, the child's sudden loss of health, and in three related categories: preconceptions, psychological reactions, and impact on family relationships (Figure 2).

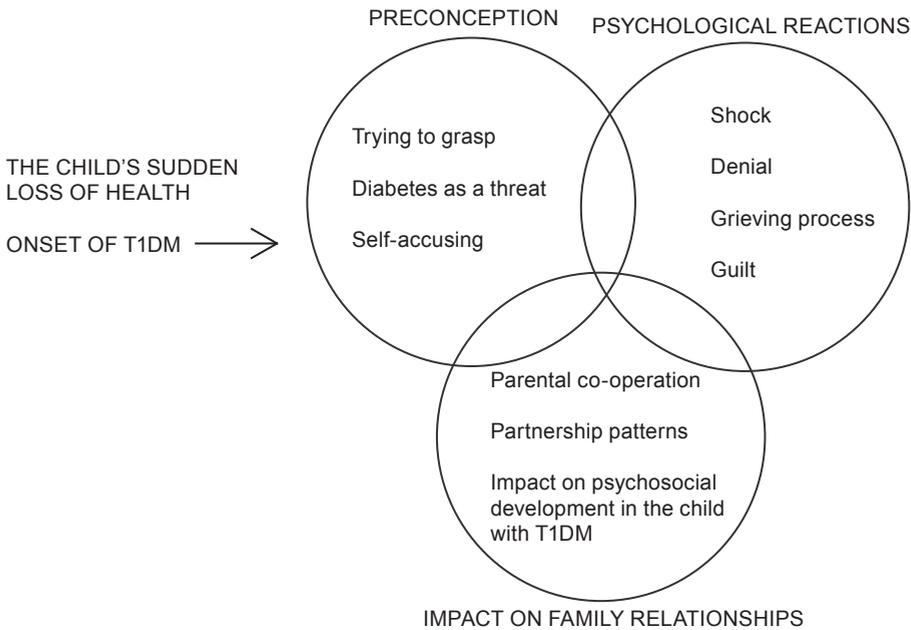


Figure 2. Ongoing family dynamics

### *Mothers and fathers*

Our main findings suggest that fathers showed more uniform emotional and behavioral patterns than mothers did. Among mothers, more distinct differences appeared, depending on age of the child with T1DM and the civil status of the mother. Preconceptions about T1DM played a critical role when trying to grasp and respond to the diagnosis. Most cohabiting mothers reported a psychological reaction of shock, which neither the single mother nor the separated mothers did. Mothers of older children with T1DM were more worried about the child's future than the mothers of the younger children. In terms of family relationships, the psychological bond to a younger child was strengthened by the diagnosis, as manifested by increased control in social situations. Compared to mothers, fathers paid more attentions to the siblings and to the sick child's perspective. Parents described a child–sibling dilemma characterized by the impossible ideal of parents sharing their emotional closeness, time, and attention equally among their children.

### Siblings

Adolescent siblings showed a greater degree of empathy toward the child with T1DM, whereas preadolescents and preschool siblings tended to fall into rivalry with the sick child. In younger siblings reactions such as jealousy, competition, anger, and psychosomatic reactions were found. The preschool and preadolescent siblings did not have the cognitive ability to express the changes that had taken place in their family and what this had meant for themselves. From adolescence, the siblings began to take the sick child's perspective and their insight into the sick child's situation appeared to gradually increase. The siblings in this group indicated that they were apprehensive about being alone with the child who has diabetes because of the accompanying demand for maturity.

### ***Paper III: The change in the child's glycemc control from the onset of T1DM to one year after diagnosis***

Sand P, Kleiberg Nilsson A, Forsander G. Paternal Influence on Glycemc control at Baseline and One Year Post Diagnosis in Children and Adolescence with Type 1 Diabetes Mellitus. *Diabetes Research and Treatment*, Open Access 12/2014; 1(4):1-6. DOI: 10.14437/DRTOA-1-115.

### Repeated measures

The child's age, parent's level of education, and parent and family functioning (PedsQL™ Family Impact Module) were used in the analysis (Table 4). Baseline glycemc control was measured as HbA1c at three months after diagnosis. The linear model in this study showed that the father's level of education was the only explanatory variable of the child's glycemc control one year after diagnosis. A higher education level in the father was associated with a lower HbA1c level in the child (Table 3).

*Table 3: Linear model for repeated measures (baseline and 12 months)*  
Dependent Variable: HbA1c

Dependent Variable: HbA1c			
Model	$\beta$	SE $\beta$	Sig.
Age	.302	.231	.196
Education, Fathers	5.052	1.636	.003*
Education, Mothers	2.178	1.773	.223
PedsQL, Fathers	.029	.058	.613
PedsQL, Mothers	-.047	.050	.345

### Internal consistency

The total PedsQL™ Family Impact Module reached high Cronbach's alpha coefficients both for mother and father reports,  $\alpha=0.97$  and  $\alpha=0.96$ , respectively. The Cronbach's alpha coefficients for the subscales ranged from 0.77 to 0.94 for both mother and father reports. The Parent Functioning Scale had alpha coefficients of

0.96 (mother reports) and 0.95 (father reports) and the Family Functioning Scale had alpha coefficients of 0.90 (mother reports) and 0.92 (father reports).

***Paper IV: Health-related quality of life and glycemc control***

Sand P, Kljajić M, Forsander G. Improved health-related quality of life in children and adolescents with type 1 diabetes: a two-year prospective family intervention RCT study.

*Health-related quality of life*

At six months after diagnosis, the children in the intervention group had better generic HRQOL compared to the children in the control group ( $p<0.03$ ). At 24 months, the children and their fathers in the intervention group rated the child's diabetes-specific HRQOL as significantly better ( $p<0.01$ ,  $p<0.04$ ) and the child's worry as lower ( $p<0.02$ ,  $p<0.03$ ) compared to the control group. Communication skills improved significantly over time in the intervention group ( $p<0.01$ ) (Table 4).

*Glycemc control*

There were no significant differences between control and intervention group regarding glycemc control, measured as HbA1c, either at six or 24 months.

*Internal consistency*

The Total Score of the PedsQL 3.0 Diabetes Module reached high Cronbach's alpha coefficients for child, mother, and father reports ( $\alpha=0.88$ ,  $\alpha=0.89$ , and  $\alpha=0.87$ , respectively). The Total Score of the PedsQL 4.0 Generic Core Scales also reached high Cronbach's alpha coefficients for child, mother, and father reports ( $\alpha=0.88$ ,  $\alpha=0.89$ , and  $\alpha=0.89$ , respectively).

*Follow-up questions: Motivation and satisfaction*

When the families had finished the study, the parents were asked about their motivation to participate in the study and about their satisfaction with the group they ended up in after the randomization procedure (Table 5). The motivation to participate in the study was higher in the intervention group: 80% of parents said they were motivated, compared to 65% in the control group. When the responses were broken down by the age of the child, the most motivated parents in the intervention group were somewhat surprisingly those with children above eight years (Table 6). A lower level of motivation was particularly linked to the following comments: "too many questionnaires", "strange questions", and "time-consuming". The satisfaction with the group the families were randomized to differed markedly: 84% were satisfied in the intervention group and only 33% in the control group (Table 7). The same response pattern was seen in both groups when considering mothers and fathers separately (Table 8). The low satisfaction with randomization to the control group was connected to willingness to see a psychologist. Answers such as "would have needed a psychologist" or "wishing everyone could see a psychologist" were common answers.

Table 4. Comparison between mothers, fathers and children in the control and intervention groups at 24 months after onset of type 1 diabetes.

	Intervention		Control		p-value
	Mean	SD	Mean	SD	
<b>PedsQL 3.0 Mothers</b>					
Total Score	1.121795	.5766048	1.035135	.5051378	0.4887
Diabetes Symptoms	1.265	.6406705	.257297	.5775315	0.9565
Treatment Barriers	1.032895	.7356075	.9662162	.6722738	0.6827
Treatment Adherence	1.110527	.8005501	.9297296	.6128284	0.2760
Worry	.8502631	.7507635	.8472973	.7009623	0.9684
Communication	.8654054	.8553186	.7567568	.8378745	0.4841

<b>PedsQL 3.0 Fathers</b>					
Total Score	.7921875	.3865457	.9839392	.4958138	0.0401 * +
Diabetes Symptoms	.9721875	.4085518	1.224242	.6145175	0.0342 * +
Treatment Barriers	.84375	.6530018	.9166667	.5918281	0.6451
Treatment Adherence	.6737501	.5526753	.8339394	.5893586	0.2494
Worry	.4945162	.5156539	.8684849	.7763542	0.0287 * +
Communication	.644	.8829208	.6566667	.7887042	0.6744

<b>PedsQL 3.0 Children</b>					
Total Score	.7196668	.4000732	1.074848	.5738203	0.0095 ** +
Diabetes Symptoms	1.209	.6393276	1.434848	.6942944	0.0822
Treatment Barriers	.6	.4806605	.9948486	.7969281	0.1032
Treatment Adherence	.2756667	.3910612	.6475758	.5358115	0.0597
Worry	.3443333	.4502389	.7776667	.8131916	0.0136 * +
Communication	.4223334	.6315536	1.188667	.8337026	0.0001 *** +

<b>PedsQL 4.0 Mothers</b>					
Total Score	.7210345	.439743	.6056666	.4821339	0.1963
Physical Functioning	.4996552	.4798697	.3766667	.4530611	0.3198
Emotional Functioning	1.02931	.6589383	.8066666	.6570222	0.1959
Social Functioning	.4758621	.5565551	.4933334	.5959248	0.6598
School Functioning	1.013793	.6610186	.8866666	.6140501	0.1592

<b>PedsQL 4.0 Fathers</b>					
Total Score	.514138	.3530734	.6048277	.3784707	0.0664
Physical Functioning	.3513793	.3959863	.3265517	.3203043	0.8571
Emotional Functioning	.6482758	.4770601	.9724138	.7024938	0.0054 ** +
Social Functioning	.3655172	.3857052	.5241379	.4997537	0.0938
School Functioning	.7931035	.6011483	.7655173	.481275	0.2257

<b>PedsQL 4.0 Children</b>					
Total Score	.6231034	.4310959	.7644828	.5957144	0.0926
Physical Functioning	.4610345	.3891322	.54	.5711642	0.1502
Emotional Functioning	.8068967	.6557063	1.048276	.8596596	0.2789
Social Functioning	.5310345	.6552553	.5586207	.771602	0.5614
School Functioning	.7931035	.5056333	1.028572	.6029906	0.1847

Test of correlation by use of Fisher's permutation test, the + or – sign in the column p-value indicates whether the correlation is positive or negative. \*p<0.05, \*\*p<0.01, \*\*\*p<0.001.

Table 5. Response rate of parents answering the follow-up questions

Response rate	%
Mothers	94
Fathers	83
Total	88

Table 6. Parents' motivation

Question 1. Have you felt motivated and engaged in the study?	Control (n=78) Yes (%)	Intervention (n=89) Yes (%)
All parents	65	80
Parents of a child <8 years	28	85
Parents of a child >8 years	71	78

Table 7. Satisfaction: mothers and fathers combined

Question 2. Are you satisfied with the group that you were initially randomized to?	Control (n=78) %	Intervention (n=89) %
Yes	33	84
No	52	7
Nothing to compare with	15	7
Cannot answer	0	2

Table 8. Satisfaction: Mothers vs. fathers

Question 2. Are you satisfied with the group that you were initially randomized to?	Control (n=78) Yes (%)	Intervention (n=89) Yes (%)
Mothers	33	88
Fathers	33	80

## Review of the hypothesis

### *Health-related quality of life instruments*

It was hypothesized that the Total Score on the Swedish version of the PedsQL 4.0 Generic Core Scales and the PedsQL 3.0 Diabetes Module would exceed the criteria for satisfactory internal consistency and convergent validity. This hypothesis was supported in Paper I.

### *Paternal effect*

It was hypothesized that bringing in fathers into the child's diabetes care would have a positive effect on the outcome measures HRQOL and glycemic control. This hypothesis was supported in Paper III.

***Children's and adolescents' health-related quality of life***

It was hypothesized that the children and adolescents assigned to the intervention group would report a higher degree of generic and diabetes-specific HRQOL than the children in the control group. This hypothesis was supported in Paper IV.

***Glycemic control***

It was hypothesized that facilitating psychological support and communication skills training will have a positive effect on the glycemic control. This hypothesis was not supported in study IV.



## Discussion

### *Strengths, limitations, internal and external validity*

The strength of study A (Paper I) was that it was possible to determine acceptable psychometric properties of the PedsQL instrument and to use it in both research and clinical practice. Internal consistency and convergent validity were demonstrated. In addition, the instrument worked well in study C (Paper IV) as an outcome measure, and demonstrated sensitivity and responsiveness.

Four diabetes clinics from different parts of Sweden were involved in study A, with a response rate of 79%. The majority of those who declined to participate were 35 families from one study site. There were two nonresponders in the youngest age group (2–4 years), four in the early childhood age group (5–7 years), six in the pre-adolescent group (8–12 years) and 23 in the oldest age group (13–18 years). Overall, the nonresponder rates were considered low.

The majority of the PedsQL 3.0 and PedsQL 4.0 questionnaires were filled in at home. However, the data collection was mixed. In the age group 5–7 years, the forms were administered during the clinic visits and the children were assisted by a nurse, following the recommendation that all children should fill in their questionnaires separately from their parents. The postal administration of the questionnaires may have negatively influenced the families' willingness to participate. Face-to-face administration may have been less burdensome to the respondents and thus increased the participation rate. Another implication of the postal administration is the lack of control on how well families complied with the instructions that the questionnaires were to be answered independently by family members. Especially in families with younger children, there might have been cases of parents assisting the child.

Since four different clinics were involved in study A, it was not possible to retrieve records of the children's HbA1c from all clinics. Thus, HbA1c measurements were not included in this analysis, which could affect the internal validity of the study, and makes it more difficult to make direct comparisons with other studies. Furthermore, a matched healthy control group would have strengthened the generalizability even more.

Study B (Paper II) was a qualitative study exploring family dynamics. Most earlier qualitative studies have been based on individual interviews, analyzed with phenomenological or content analysis. The strength of this study was that the analysis applied grounded theory, which makes it easier to explore themes and to deepen the understanding of the material, thus enhancing the internal validity. Another strength of this study was that mothers and fathers from the same family were interviewed, and they were assigned to different focus groups according to civil status and the child's age. There were nine families in which both parents participated and in three cases one of the siblings participated as well.

The study enrolled a limited number of younger siblings, and siblings with separated parents or single parents were generally not interested in participating in the focus groups. In order to compensate for this, individual interviews were conducted. Different data collection methods could affect the results, as could the diverse numbers of participants attending each focus group. A consecutive sampling procedure was applied from each focus group that included cohabiting parents, with an over-representation of parents of preadolescents in one of the focus groups and of parents of adolescents in the other focus group. This qualitative study only involved Swedish-speaking family members, which means that the results might be less transferable to families of other ethnic and cultural backgrounds.

Future studies should explore age-specific experiences and reactions among siblings and target in what way they could obtain support from the diabetes team. It was difficult to include separated and single parents and therefore further studies are needed. It would also be preferable to modify the study design and to adapt the interviews to the parents' circumstances, for example by conducting individual interviews at home.

The strength of study C (Papers III and IV) was the RCT study design and the fact that there were only six families who dropped out of the study at the end of year two, which reinforces the internal validity. Moreover, the results suggest that offering families psychological support with the child and parents together could enable these children to adapt to living with diabetes and still perceive themselves as having a normal everyday life. At 24 months, the children and adolescents in the intervention group gave higher ratings for their communication skills than they did at six months. The results are encouraging, since the intervention was to a large extent based on supporting communication skills within the family. This study found that the fathers, children, and adolescents in the intervention group reported an improved diabetes-related HRQOL at 24 months.

The study sample consisted of a homogeneous group with respect to the educational level, which could reduce the generalizability of the results. Furthermore, the fact that only 7% had an immigrant background adds to the homogeneity of the sample. Finally, the motivation to participate and the satisfaction with the randomization procedure could have had an impact on the willingness to participate in the study. The randomization process did not control for gender and, by chance, more girls were randomized to the intervention group. The fact that 56% in the intervention group were girls whereas only 35% in the control group were girls could have had an effect on the outcome.

### ***Challenges and experiences of research in a clinical setting***

The whole family is affected by the onset of T1DM in a child or adolescent. Diabetes is a chronic disease that places high demands on the parents, who are initially responsible for the diabetes care. The child will later on, depending on maturity and

age, gradually take over the responsibility for self-management. For this to be as successful as possible, that is, to reduce the risk of acute complications arising in the future, it is essential for the parents to be involved at diabetes onset. They must also maintain their commitment over time and their contribution should have a certain degree of flexibility in relation to the child's age.

After the onset of diabetes in a child, everyday life changes drastically: the family has to spend some time in hospital and then the child is transferred home with follow-ups in the diabetes outpatient clinic. The initial symptoms may vary in severity, from relatively mild signs of elevated blood sugar to the life-threatening condition of diabetic ketoacidosis, where the body's pH decreases. At the time of the diagnosis there is often a crisis reaction within the family because past experience does not correspond to the current situation, which is frightening for them. The overall aim of the thesis was to investigate various aspects of family dynamics after the onset of T1DM in a child or adolescent, as well as evaluating the potential to influence HRQOL among these children, adolescents and families.

Sweden has a more generous welfare policy than most other countries, allowing both parents to attend inpatient and outpatient visits without loss of earnings. For various reasons, a large number of previously published studies of families of children and adolescents with T1DM have failed to include fathers in samples and in either the control or intervention group. Often, studies have been conducted in outpatient clinics, where mothers to a greater extent have been the one who accompanied the child; thus, samples presented as parents may in fact be composed entirely of mothers. In the family intervention presented here, both parents were invited to attend.

It has in many ways been a challenge to carry out this two-year family intervention study that started in October 2008 and whose recruitment period lasted until December 2011. The follow-up continued until the study ended in December 2013. For some families, it was essential to them that their sessions with the psychologist could be coordinated with clinic appointments. If the study were to be repeated, this administrative part should be better planned through tighter team collaboration. The only criticism of the study from the parents themselves concerned the number of forms they were asked to fill in during the study and the time required to complete them. These comments will be taken into consideration in future studies.

Since the family intervention focused largely on strengthening the parents in their care of the child or adolescent after diabetes onset, it was important that both parents were able to attend the sessions. This required extensive planning. Even if the study content and application were largely structured, some flexibility was necessary. Some parents wanted the psychologist to meet their children individually and in some cases, particularly in the older age groups, this was justified after the joint psychological intervention was established. On the whole, the wide range of ages between three and 15 years presented a challenge; in the younger age groups, the focus was mainly on conversations with parents and also strengthening them in the

transformation in their lives after the child's diagnosis. They were given the opportunity to quickly learn communicative patterns to prevent conflict and to promote shared responsibility, which in itself is a joint strength. Parents of younger children generally expressed stronger reactions to the crisis, which was a recurring theme during the sessions. In some families, there were preexisting disagreements and conflicts that were intensified by the onset of the diabetes and in some of these cases it was not appropriate for the child or youth to be present for this reason.

The current method obviously puts a limit on the scope of the therapeutic conversation, but it identifies the central themes, which was the goal of the intervention. The research approach and methodology steers the conversation but, depending on the individual family, the conversation also developed in somewhat different ways. In some families, there were discussions at a deeper level while in other families they remained on a surface level; for example, some parents wanted to discuss in depth the possible obstacles and limitations to the child's development as a result of the onset of diabetes. Some families were active in formulating their own needs while others expected more input from the psychologist.

Despite these considerations and the overall limitations and strengths of the study, the majority of participants were pleased to have been included in the study. Continued research on family interventions is needed, not only within the group of children and adolescents with T1DM but also in other clinical groups within pediatric care, where the experience drawn from this study could to some extent be applied.

## Conclusions

In a prospective, randomized study, two different treatment regimens at T1DM diagnosis were compared. The treatment-as-usual regimen included support from the whole diabetes team except for the specific support of a psychologist-psychotherapist with special training in diabetes. Families in the intervention group were also provided with therapy sessions focusing on including both parents in the diabetes care of the child and supporting parental communication skills and age-appropriate expectations for the child.

To evaluate the intervention regarding HRQOL, the PedsQL 3.0 Diabetes Module was completed by the participants and validated. It was shown to be a useful tool, not only for research but also in a clinical setting, for identifying children and adolescents in need of additional psychological support. Furthermore, it proved useful in conversations with families concerning the diabetes management, as children's responses in the self-report questionnaire could be used to highlight their subjective view. Girls tended to report a lower HRQOL compared to boys, and adolescents reported a lower HRQOL compared to the younger children.

The family history before the onset of T1DM in a previously healthy child was a starting point for how the family dynamics developed subsequently. The psychological perspectives of the mothers and fathers differed, but both were equally important for the wellbeing of the family. The age, maturity, and psychological development of the siblings were of importance for how they handled the new family situation. Some families will need continuing psychological consultation for several years after the diagnosis.

Actively including both parents in the intervention had a positive impact on the children's and adolescents' reported HRQOL. Children and adolescents in the intervention group had better overall diabetes-related quality of life. Since the fathers were shown to have a significant effect even on the child's glycemic control, it is recommended to involve both parents, not only immediately after T1DM onset but also in the child's ongoing care. In addition, communication training within the family had a positive effect. Thus, offering psychological support to the whole family after onset of type 1 diabetes is essential.



## **Future perspectives**

The main study in this thesis evaluated a structured psychological intervention starting immediately after T1DM onset, with extended support in response to the associated crisis and with follow-up communication skills training sessions that included the family members of the child with diabetes. It was hypothesized that this family intervention could improve the children's HRQOL two years later. Overall, children and adolescents in the intervention group had a significantly better generic HRQOL even at six months after T1DM onset. The results suggest that offering early psychological support after diabetes onset to the whole family together could enable these children to adapt to living with this chronic disease and still perceive themselves as having a normal everyday life.

At 24 months, the children and adolescents in the intervention group gave higher ratings for their communication skills than they did at six months, whereas the control group indicated that their communication skills had decreased over time. The results are encouraging, since the intervention was to a large extent based on supporting communication skills within the family. Clearly this should be a major element of future family support programs integrated into the work of the diabetes team.

Furthermore, the children in the intervention group perceived themselves as having less worry than the control group at 24 months after T1DM onset. This might reflect the fact that they had an opportunity to verbalize their experiences of the diabetes-specific issues that worried them. The family intervention may also have helped them to communicate with their parents and the diabetes team about their diabetes management. Another recommended element of future family support programs is to use the responses in the self-report questionnaire of the PedsQL instrument to raise the parents' awareness of their child's subjective view when they are experiencing the family crisis of T1DM onset.

At 24 months, the fathers in the intervention group estimated their child's emotional functioning to be higher in comparison to the ratings by fathers of the control group children at 24 months. They also observed that their child had fewer diabetes symptoms and overall an improved HRQOL, as reported by the children themselves. Since the fathers were shown to have a significant effect on the child's glycemic control, it is recommended to involve both parents, not only in family support programs immediately after T1DM onset but also in the child's ongoing care. This study showed promising results and illustrates the need for family support from a psychologist after diabetes onset.



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Last but not least, to my wife **Lena** for past, present and future memories.

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