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Karolinska Institutet, Stockholm, Sweden

**Diabetes during childhood and adolescence:  
Studies of insulin treatment, patient-reported  
outcomes, and evaluation of an empowerment-  
based education**

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# **Diabetes during childhood and adolescence: Studies of insulin treatment, patient-reported outcomes, and evaluation of an empowerment-based education**

## **THESIS FOR DOCTORAL DEGREE (PhD)**

This thesis will be defended on Friday, November 17, 2017, at 1:15 pm in Hall R 64, Karolinska University Hospital, Huddinge.

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‘Ibland måste man göra saker man  
inte vågar. Annars är man ingen  
människa utan bara en liten lort.’

*Astrid Lindgren*

## ABSTRACT

There is a lack of studies demonstrating positive effects on glycaemic control and HRQoL in children and adolescents starting CSII treatment. Guidelines recommend measuring perceived HRQoL routinely. It is important to have questionnaires, not overly comprehensive or time-consuming, to measure HRQoL in children and adolescents as well as their parents.

Structured and person-centred education has been emphasized as a key to successful self-management. Guided Self-Determination-Young (GSD-Y) is a person-centred communication and reflection method. The overall aim of this thesis was to increase the knowledge regarding glycaemic control, type of treatment, HRQoL, and a theory-based education among youth with type 1 diabetes.

**Study I** was a retrospective case-control study comparing children and adolescents starting CSII (n=216), with a control group treated with MDI (n=215). Children and adolescents who had started CSII showed improvement in glycaemic control, measured as HbA1c, during the first six months. For boys, this improvement could be identified throughout the first year.

**In Study II**, 197 parents and their children with type 1 diabetes completed the proxy and child versions of the questionnaires Check your Health and DISABKIDS to test the psychometric properties of Check your Health by proxy. The test of the reliability and validity of this questionnaire showed acceptable psychometric properties.

**Study III**, an RCT evaluating a GSD-Y education, included 71 adolescents starting CSII and their parents. The intervention group (n=37) attended seven group education sessions, lasting for about two hours each, using the GSD-Y method. The participants were followed for six months. The GSD-Y method showed a positive effect on glycaemic control, especially for participants with an HbA1c above 63 mmol/mol (n=48) at inclusion (p= 0.037); furthermore, readiness to change increased (p=0.037). A correlation was identified between HbA1c and goal achievement (rs=-0.475, p=0.001), and readiness to change (rs=-0.487, p=0.001). **In Study IV**, 13 adolescents were interviewed after the intervention with GSD-Y. From the qualitative analysis, two categories emerged: the importance of context, and growing in power through the group process. An overarching theme that emerged from the interviews was the importance of expert and referent power in growing awareness of the importance of self-management, as well as mitigating the loneliness of diabetes. Further, the findings showed that it is valuable for adolescents to meet other young people in the same situation, and to share their experiences from living with diabetes.

In conclusion the four studies showed, treatment with CSII may initially result in improved HbA1c. Group education with the GSD-Y method, for adolescents and their parents, has the potential to further improve HbA1c, mitigate the loneliness of diabetes, and contribute to conscious reflection about self-management. The Check your Health questionnaire by proxy has shown acceptable psychometric characteristics, and may be useful in both studies and clinical settings.

## LIST OF SCIENTIFIC PAPERS

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

- I. Brorsson AL, Viklund G, Örtqvist E, Lindholm Olinder A. Does treatment with an insulin pump improve glycaemic control in children and adolescents with type 1 diabetes? A retrospective case-control study. *Pediatr Diabetes*. 2015;16:546-553.
- II. Brorsson AL, Lindholm Olinder A, Wikblad K, Viklund G. Parent's perception of their children's health, quality of life and burden of diabetes: testing reliability and validity of 'Check your Health' by proxy. *Scand J Caring Sci*. 2016.
- III. Brorsson AL, Leksell J, Lindholm Olinder A. A person-centred education for adolescents with type 1 diabetes: Guided Self-Determination-Young - A randomized controlled trial. Submitted.
- IV. Brorsson AL, Lindholm Olinder A, Viklund G, Granström T, Leksell J. Adolescents' perceptions of participation in group education using the Guided Self-Determination-Young method: A qualitative study. Submitted.

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## LIST OF ABBREVIATIONS

BMI	Body Mass Index
BMI-SDS	Body Mass Index Standard Deviation Score
CBT	Cognitive Behavioural Therapy
CGM	Continuous Glucose Monitoring
CSII	Continuous Subcutaneous Insulin Infusion
DCCT	Diabetes Control and Complications Trial
DCGM-37	DISABKIDS Chronic Generic Module-37
DFCS	Diabetes family conflict scale
DSM-10	DISABKIDS Diabetes specific module
FGM	Flash Glucose Monitoring
GSD	Guided Self Determination
GSD-Y	Guided Self Determination-Young
HbA1c	Glycosylated Haemoglobin A1c
HRQoL	Health-Related Quality of Life
ISPAD	International Society for Pediatric and Adolescent Diabetes
MDI	Multiple Daily Injections
MI	Motivational Interviewing
NDR	The Swedish National Diabetes Register
PROs	Patient-Reported Outcomes
PROMs	Patient-Reported Outcome Measures
QoL	Quality of Life
RCT	Randomized Controlled Trial
SAP	Sensor-Augmented Pump Therapy
SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services
Swe-DES	Swedish Diabetes Empowerment Scale

# 1 PREFACE

I remember when I was new, as a nurse, at the children's diabetes outpatient department at Huddinge Hospital. When a patient – usually an adolescent – had unsatisfactory HbA1c (90-130 mmol/mol), the routine was that they were booked for frequent visits to the diabetes nurse, between their physician visits. What was I supposed to do? Check their HbA1c, of course, but what else? There was no possibility to download data from blood glucose meters or insulin pumps. I had limited and insufficient diabetes knowledge and skills, and further, perhaps most importantly, no knowledge in different communication methods. It was incredibly frustrating to meet these, usually very nice, teens and have nothing to offer them.

I have worked as a nurse since 1989. During my first years, I worked with premature children and children at the intensive care department. As a coincidence, I started working at the endocrinology outpatient department for children and adolescents at Huddinge Hospital. The diabetes nurse was my colleague, but diabetes seemed far too difficult and complicated for me. Just next to my workplace was the paediatric ward, which became my next workplace. There, I had to take care of children who were newly diagnosed with diabetes; it was at this point that my interest in this patient group was awakened, especially thanks to Dr Torun Torbjörnsdotter.

Working on wards with a great deal of technology, it was natural that I became interested in the technical aspects of diabetes care, insulin pumps, and continuous glucose monitoring (CGM). With great cooperation and much support from Dr Eva Örtqvist (who also introduced me to research), I had the opportunity to structure the insulin pump starts at the diabetes outpatient department at Astrid Lindgren Children's Hospital, and for this I received the Karoline Prize at Karolinska University Hospital.

Through my work, I met my supervisors Anna Lindholm Olinder and Gunnel Viklund, who led me into what this dissertation is about. Both, in different ways, had concluded in their dissertations that there was a need for improved education for adolescents and that this had to be done together with their parents. This fact, along with my interest in insulin pumps, was a natural step toward this dissertation addressing education and children and adolescents starting to use an insulin pump.

## 2 INTRODUCTION

In 2015 it was estimated that 542,100 children worldwide were living with type 1 diabetes and a further 86,000 children developed the disease annually, with Europe having the highest prevalence (1). In Sweden there are 7,310 children and adolescents living with type 1 diabetes; this prevalence has been stable since 2008. Treatment consists of either multiple daily injections of insulin (MDI) or continuous subcutaneous insulin infusion (CSII) (2); today, CSII is the most physiological way to deliver insulin (3, 4). In 2016, 60.9% of children and adolescents with type 1 diabetes in Sweden were treated with CSII (2), and in Europe this figure was 45.8% (5).

According to the International Society for Pediatric and Adolescent Diabetes (ISPAD) and International Diabetes Federation (IDF) Guidelines, the recommended glycaemic control, measured with HbA1c, for children and adolescents is <58 mmol/mol without an increase in the number of hypoglycaemic episodes (6, 7). The Swedish guideline for HbA1c has been lowered to 48 mmol/mol, which is consistent with recommendations from the National Institute for Care Excellence (NICE) in the UK (8, 9).

The Diabetes Control and Complications Trial (DCCT) and follow-up data clearly indicate that poor glycaemic control during adolescence and young adulthood increases the risks of micro- and macrovascular complications later in life (10, 11). In the same manner, 30 years after the DCCT study, the Epidemiology of Diabetes Interventions and Complications (EDIC) study showed that intensive diabetes treatment decreases the incidence of cardiovascular disease (12).

ISPAD recommends routinely measuring perceived Health-Related Quality of Life (HRQoL) (13). At the same time, it should be noted that there are few questionnaires available for doing so for children and adolescents in Swedish (14-16).

ISPAD emphasizes that education is the key to successful self-management. Adolescents have the right to receive a structured, person-centred and flexible education, which may strengthen them and their parents in taking control of their diabetes self-management (17).

## 3 BACKGROUND

### 3.1 THE HISTORY OF ILLNESS, DIABETES AND DIABETES EDUCATION

In the eighteenth century, the patient's experiences of living with an illness played a secondary role. The classification of disease shifted from being based on symptoms experienced and described by the patient to organic damage present in the dead body. The real disease could best be explored in the dead body. This view of the body stimulated a dramatic technological development. During the nineteenth century, technological advances such as the stethoscope and x-ray offered opportunities to 'anatomize' the living body. It is notable that modern medicine is mainly based not on the lived body, but rather the dead one (18).

In some situations, the patient is still treated as almost dead, for example at a physical examination when he/she is asked to lie down, silent and nearly naked, on a couch. This ritual might reduce the living body to something almost dead. However, it seems that there is gradually arising a quest for healthcare personnel to acquire a holistic view of human beings.

The philosopher Maurice Merleau-Ponty (1908-1961), along with other philosophers, coined the term 'the lived body' in reference to living bodies. The body is a unit, towards and with a perceived world, living together in relationships with other people, things, and the environment. Merleau-Ponty describes the lived body as intertwined – thinking and materiality are not separated (18). In meetings with young people with chronic illness such as diabetes, it is important not to treat them like a machine that works the same way as other machines. They are a 'lived body', everything in life is intertwined, and if you ask them for their story, you will hear about a part of the world in the way they embody it.

One way to describe and understand illness is that one feels un-homelike being-in-the-world. Here, un-homelike is the opposite of the normal meaning of healthy being-in-the-world, homelike. Living in our own bodies with illness is perceived as un-homelike. My body is experienced as an alien, but at the same time as myself, with biological processes that I, myself, have no control over. These are lived by me and belong to me. Merleau-Ponty describes how the body 'understands' and 'inhabits' the world. The body is not only a tool or a dwelling I live in; it is me. When illness has caused a sense of un-homelikeness, a person needs to be guided as far as possible in order to regain the feeling of homelikeness. The degree to which this is possible depends on healthcare professionals, family and friends, but mostly and finally, it depends on the person him/herself. It is possible to regain homelike being-in-the-body and being-in-the-world in dialogue with others, but it must happen in that person's own way (19). Adolescence is a period of development physically and mentally, which could mean that even a person without a chronic illness might not feel homelike in

his/her own body; thus, for adolescents with type 1 diabetes or any other illness, a feeling of un-homelikeness can arise in a double sense. Against this background, it is easier to understand when adolescents with type 1 diabetes express that they feel different, vulnerable and alone (20-23).

The period 1914-1936 is crucial in the history of diabetes nursing and education. During this period, most nurses had little or no education. In 1913, Dr Frederick Allen became the first to present a treatment that prolonged the life of persons with diabetes, in 'Studies concerning Glucosuria and Diabetes'. The treatment was a diet commonly called starvation therapy, for minimizing the risk of acidosis and uraemia. Dr Elliot P Joslin (1869-1962), one of the first diabetologists, working closely with the New England Deaconess Hospital School of Nursing in Massachusetts in the US, was a pioneer in several ways. He introduced the starvation therapy in practice, and the overall goal was to educate persons with diabetes to be able to manage themselves. He wanted, with the help of educated nurses, to empower patients to take care of their own diabetes. However, at the time nurses normally had little or no training, and he stressed the importance of educating them. In 1917, he stated that a diabetes-nursing specialty could be a new career for nurses and that 'a well-educated nurse was of more importance than the patient's doctor' (24).

In 1921, Frederick Banting and Charles Best discovered insulin. However, they worked in collaboration with Dr John James Rickard Macleod who had a medical laboratory. He was also the one who supported them, and presented their findings to the world. Furthermore, it was Frederick Banting and Dr Macleod who were awarded the Nobel Prize (24).

Dr Joslin and his nurses conducted the first trials regarding insulin treatment, and he developed an education programme to teach patients to inject insulin. On August 6, 1922, Dr Joslin and his co-workers administered the first injection to a 42-year-old nurse. After the discovery of insulin, most patients with diabetes were treated in outpatient clinics. In 1927, Dr Joslin initiated 'the wandering diabetes nurse' who should be ready to go wherever the diabetes patients needed her. Her task was to support parents after returning home from the hospital in achieving adequate self-care, e.g. learning to inject insulin and calculate carbohydrates, as well as test urine glucose and interpret the values; furthermore, she visited schools and provided diabetes camp instructions (24).

Even during the first years of insulin use, nurses continued to publish articles on the starvation diet; it was not until 1929 that the first article on insulin and nursing care was published. By 1936 the nursing care had developed into a diabetes-nursing specialty, with educators teaching patients to inject insulin, count carbohydrates, and measure urine glucose. Iris Langhart published the first article describing the diabetes education model and the diabetes nurse educator. She described individualized education, the objective of the education, the value of teaching in teams, and an effective education model (24).

## 3.2 DIABETES

For a person with type 1 diabetes it is a constant struggle – a lifelong project – to perform optimal self-management, have acceptable glycaemic control, have a good life, be able to do what you want and, in the short and long term, avoid complications. In everyday life, this includes assessing insulin doses, adjusting them if needed, and ‘continuously’ having control over your glucose level (25).

Glycosylated hemoglobin A1c (HbA1c) measures glycaemic control, and seems to reflect an average of the previous two to three months (26-28). The normal reference for children between six months and 18 years is 31-38.6 mmol/mol (5-5.7 DCCT %) (29).

In Sweden, the mean value for HbA1c has decreased in recent years in all paediatric age groups; in 2016 it was 56.9 mmol/mol. Among children and adolescents with type 1 diabetes there are clear age- and gender-related differences. After starting school (at 7 years of age) HbA1c tends to increase, and girls have more unsatisfactory glycaemic control than boys (2). Data from the Swedish National Diabetes Register SWEDIABKIDS showed that girls had higher HbA1c at diagnosis than boys, and that those who had HbA1c >78 mmol/mol during a specific period (2007) had remaining high HbA1c three years later (30). Moreover, among young adults, data from SWEDIABKIDS and NDR have shown a higher incidence of retinopathy among women compared with men (31).

The risk for a person with type 1 diabetes dying from any cause, including cardiovascular disease, is twice for well-controlled patients (HbA1c  $\leq$ 52) than that of a matched control group without diabetes, and increases with increased HbA1c (32). Furthermore, there is a risk for short-term complications such as hypoglycaemia and ketoacidosis, of which hypoglycaemia is the most common. The accepted definition of hypoglycaemia is a glucose value <3.6 mmol/l; however, in clinical practice a glucose value of <4 mmol/l is the recommended level to be treated. Hypoglycaemic events may be symptomatic or asymptomatic, and as these affect everyday life they may be barriers to achieving optimal glycaemic control (33). Ketoacidosis may be caused by a frequent absence of insulin doses, poor glycaemic control, previous episodes of ketoacidosis, and failure in CSII treatment. Unless this condition is corrected it is fatal; therefore, it is important to educate patients and their families about symptoms and in how to correct insulin deficiency (34).

### 3.2.1 Self-management and self-care

There are several definitions of ‘self-management’ and ‘self-care’ moreover, these concepts are widely used synonymously (35). The term reported in the following studies is the one used by the authors. Based on an analysis of 99 references, Schilling et al. suggested the following definition of self-management of diabetes in children and adolescents with type 1 diabetes: ‘Self-management of type 1 diabetes in children and adolescents is an active, daily, and flexible process in which youth and their parents share responsibility and decision-

making for achieving disease control, health, and well-being through a wide range of illness-related activities' (36, p. 92).

Pelicand et al. performed a review including 30 articles, with the objective of evaluating how 'self-care' is used in education interventions in patients with type 1 diabetes. Mostly, self-care is defined a series of disease-related actions, and these actions are mostly related to physical health. In children and adolescents, these are carried out individually or with help from their caregiver. When autonomy is included, this usually relates to the level necessary for performing daily technical self-care activities. It is rarely used with clear reference to psychosocial aspects. Furthermore, it is rarely used alone, but rather along with other terms like self-care behaviour, self-care management, or self-care activities (self-care activities are usually medical). Pelicand et al. have highlighted that the factors that most affect self-care in the family are cognitive and psychosocial. Cognitive factors include, notably, parents' level of knowledge and awareness as predictors of their ability to support self-care activities for their children. Psychosocial factors in the family, likely to affect self-care support for adolescents, are: family function, family stress, the occurrence of conflicts, how the youth and parent communicate, and type of parent support (35).

'Assuming responsibility for self-care' has been clarified through concept analyses by Hanna et al. and defined as 'a process specific to diabetes within the context of development. It is daily, gradual, individualized to person, and unique to task. The goal is ownership that involves autonomy in behaviours and decision-making' (37, p. 104).

### **3.2.2 Patient-reported outcomes (PROs)**

Patient-Reported Outcomes (PROs) provide patients' perspectives on treatment beyond medical parameters, which are often important to patients. This includes patients' experiences of their own health, QoL, or abilities associated with their current treatment or with the healthcare system. Patient-Reported Outcome Measures (PROMs) are included in PROs, and are measurements and/or tools used to report the PROs. The most common dimensions are general QoL and HRQoL, which have become increasingly important for capturing patients' feelings and experiences (38).

Aristoteles (384-322 BC) was one of the first to attempt to define QoL. He described that every person imagines 'the good life' or 'doing well' as equivalent to 'being happy'. However, some have expressed that a more correct description of the Greek word would be 'well-being', which Aristoteles denoted as both a feeling and a kind of activity. He stated (which is also relevant to discussions today) that QoL means different things to different people and that it varies depending on a person's current situation. Since then, QoL has been mentioned very rarely before the twentieth century (39). WHO defines QoL as 'an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns' (40, p.



361). However, there are several other definitions of QoL, often emphasizing components of happiness and satisfaction with life. HRQoL is used to distinguish between more general QoL and its use when related to clinical medicine or clinical trials (39). However, the definition by the Food and Drug Administration (FDA) is: ‘HRQoL is a multi-domain concept that represents the patient’s overall perception of the effect of an illness and its treatment on physical, psychological and social aspects of life’ (41, paragraph. 5.5).

The National Diabetes Register (NDR) of Sweden acts as a tool in clinical work, quality improvement, the assessment of diabetes care, and epidemiological research. As a first step the NDR has developed a new diabetes-specific PROM, and evidence has been established for face and content validity (42, 43).

For adolescents, there are no differences in HRQoL between those with diabetes and those without it. On the other hand, girls both with and without diabetes report poorer quality of life than boys do (44, 45).

HRQoL factors for adolescents with type 1 diabetes are associated with glycaemic control. (45, 46). Adolescents with unsatisfying glycaemic control have lower physical and mental health, and experience a higher burden of diabetes and lower empowerment (46).

Results from a study including adolescents and their parents indicate that fewer diabetes-specific family conflicts are associated with better psychosocial wellbeing and less depressive symptoms. Poorer glycaemic control is associated with living with a single parent, being a member of an ethnic minority, and lower wellbeing (47). Likewise, lower HRQoL is associated with diabetes-related conflicts and negative diabetes-related family communication. Further, higher levels of HRQoL are associated with collaborative parent involvement in diabetes care (48). Similarly, a study involving children and adolescents (aged 8-17 years) shows that diabetes-specific family conflicts are the only predictor of total QoL (49).

However, family structure, conflicts, and children’s moods are some factors that influence glycaemic control. The Risk Index for Poor Glycaemic Control (RI-PGC), a measure for predicting deteriorated glycaemic control, can be used by physicians and nurses. Unfortunately, it has not yet been translated into the Swedish language or validated (50).

For children and adolescents there are nine questionnaires measuring HRQoL, of which five are diabetes-specific (51). DISABKIDS Chronic Generic Module-37 (DCGM-37), including the diabetes-specific module (DSM-10) (14), and PedsQL (15) have been translated into Swedish and psychometrically tested. Both have a generic and a diabetes-specific part, totalling 50 and 51 items, respectively. For both questionnaires, there is a proxy version for parents (14, 15). The DCGM-37 and DSM-10 have been developed and pilot- and field-tested

with seven European countries (including Sweden) involved, which strengthens the questionnaire's cross-cultural validity (52-54).

Since a questionnaire's response rate is reduced when it is comprehensive and time-consuming to complete (55), Wikblad et al. developed the questionnaire Check your Health. It consists of four pages with one domain/item on each page, and measures perceived health, relationships, QoL, and burden of diabetes; the unique aspect of this instrument is that, while it is not comprehensive or time-consuming, it still measures these items (55, 56). Its psychometric properties have been tested for adults and adolescents (16, 56).

### **3.2.3 Insulin pump treatment and continuous glucose monitoring (CGM)**

#### *Insulin pump treatment - continuous subcutaneous insulin infusion (CSII)*

CSII was introduced 35 years ago in order to achieve long periods of near-normal glucose values in patients with type 1 diabetes (57, 58). The basal rate is automatically infused by the insulin pump in a pre-programmed pattern. For carbohydrate meals or when glucose levels are above the target, a bolus dose can be delivered manually (4). The Swedish national guidelines for initiating CSII treatment for children and adolescents are broad (59). However, treatment with CSII is associated with increased costs compared with MDI (60). Some studies have shown that CSII is cost-effective when it results in improved glycaemic control and Quality of Life (QoL) (61-63). These studies presume a greater effect on glycaemic control and/or reduced number of hypoglycaemic events when treated with CSII than is shown in recent studies (60). In Sweden, boys treated with CSII have a slightly higher HbA1c (0.6 mmol/mol) than boys treated with MDI, while there is no difference among girls (42). On the other hand, children and adolescents with type 1 diabetes in Europe have a higher HbA1c when treated with MDI, compared with those on CSII (5).

There are recently published studies showing positive effects of CSII on diabetes-related complications. A unique Swedish study with data from NDR included 18,168 persons with type 1 diabetes, of whom 2,441 were treated with CSII and 15,727 with MDI. All had been diagnosed with type 1 diabetes before the age of 30. The follow-up was at 6.8 years, and has shown that the adjusted hazard ratios were significantly lower for participants treated with CSII than for those treated with MDI: 0.58 for fatal cardiovascular disease (coronary heart disease or stroke) and 0.73 for all-cause mortality (64).

Furthermore, the incidence of microvascular complications was investigated, comparing CSII and MDI in an Australian study including 989 patients (12-20 years) with a diabetes duration of more than five years. There was no difference in HbA1c between patients treated with CSII (70 mmol/mol) and MDI (72 mmol/mol) ( $p=0.7$ ). However, CSII treatment was associated with a lower risk for retinopathy (OR 0.66, 95% CI 0.45–0.95,  $p=0.029$ ) and peripheral neuropathy (OR 0.63, 95% CI 0.42–0.95,  $p=0.026$ ) (65).

A report by the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) showed that there is a great lack of knowledge about the effects of CSII treatment compared with MDI for children and adolescents. The report's inclusion criteria were: studies involving an intervention with participants using CSII with analogue insulin and a control group on MDI using analogue insulin for meals. Exclusion criteria were intravenous insulin treatment and intraperitoneal insulin treatment. Additionally studies needed to have more than ten participants in each arm, and should be a randomized controlled trial (RCT) or clinical controlled trial (CCT) with a follow-up time of more than three months. Eleven articles were found that fulfilled the criteria for inclusion. However, only two studies with moderate or high quality included children and adolescents (60), and they had been newly diagnosed with type 1 diabetes (66, 67).

One of the studies included in the above report, a Swedish RCT study by Skogsberg et al., included a total of 72 children and adolescents (aged 7-17 years), randomized to CSII or MDI and they were followed for 24 months. There were no differences in glycaemic control between the treatment groups, but treatment satisfaction was higher in the CSII group (66). The second study was an RCT pilot trial comparing CSII with MDI treatment in 24 participants (aged 8-18 years). Five participants withdrew during the study period, which meant that by the end of the study only 19 participants remained. At six months an improvement was identified in the CSII group, but it was not significant ( $p=0.06$ ), and at 12 months there was no difference (67).

Using less strict approaches, there are several studies that have reported results that could be informative. Table 1 presents those published in approximately the past ten years (68-72).

Among adolescents treated with CSII, one explanation for deteriorated glycaemic control is omitted bolus doses before meals (73, 74). This is mainly explained by loss of focus, as children and adolescents sometimes forget to take their meal doses (75).

Results from a Danish study including children treated with CSII ( $n=296$ ) and MDI ( $n=404$ ) showed that those on CSII and with a diabetes duration of more than one year reported better HRQoL, especially regarding generic HRQoL (76), which is consistent with results in the study by Lukacs et al. (44). On the other hand, a Norwegian study showed no differences on HRQoL between children and adolescents treated with CSII ( $n=503$ ) and MDI ( $n=434$ ). However, lower scores on HRQoL were associated with poorer glycaemic control and being a girl (77).

**Table 1.** Studies comparing CSII treatment and MDI treatment.

Authors (publ year)	Design	Age (years)	Partici- pants (n)	Dur of study (months)	Result HbA1c		Treatment	
					CSII vs. MDI	0 vs.12 months p-value (difference in mmol/mol)		0 vs. end of study p-value (difference in mmol/mol)
Schiaffini et al. (2007) * (71)	RCT	9-18	<b>CSII:</b> 18 <b>MDI:</b> 18	24		<b>CSII:</b> NS, <b>MDI:</b> p<0.05 (-8.7)	<b>CSII:</b> <0.05 (-7.6) <b>MDI:</b> NS	<b>CSII:</b> Rapid-acting analogue insulin <b>MDI:</b> Glargine and human regular insulin
Jakisch et al. (2008) (69)	Case-control (register study)	8-14	<b>CSII:</b> 434 <b>MDI:</b> 434	36	<b>12 months:</b> p= 0.006 <b>24 and 36 months:</b> NS			Type of insulin not mentioned
Johannesen et al. (2008) (70)	Case-control	13-19	<b>CSII:</b> 30 <b>MDI:</b> 26	12		<b>CSII:</b> NS <b>MDI:</b> NS		<b>CSII:</b> Actrapid <b>MDI:</b> Actrapid and NPH
Johnson et al. (2013) (72)	Case-control	11.5 ± 3.7	<b>CSII:</b> 355 <b>MDI:</b> 355	60	<b>12, 36, 48 and 60 months:</b> p<0.05	<b>CSII:</b> p<0.05 <b>MDI:</b> NS	<b>CSII:</b> p<0.05 (-7.7) <b>MDI:</b> (+17.1)	<b>CSII:</b> Type of insulin not mentioned <b>MDI:</b> 37% Glargine, 63% NPH and human regular insulin
Fendler et al. (2012) (68)	Observational	10.8– 16.2	<b>CSII:</b> 223 <b>MDI:</b> 231	36.6 ± 16.8 (mean)	<b>End of study:</b> p=0.002		<b>MDI:</b> NS <b>CSII:</b> NS	<b>CSII:</b> 81% Analog, 19% Human insulin <b>MDI:</b> Long-acting analogues or NPH, short-acting analogues or human regular insulin

\* Inclusion criteria HbA1c > 64 mmol/mol (8 DCCT %)

### *Technical devices*

In recent years, the use of CGM and SAP (sensor-augmented pump therapy) has increased. In an RCT study including adults and children (age groups  $\geq 25$  years, 15-24 years, and 8-14 years), 165 of the participants were assigned to CGM and 157 to the control group. The duration of the study was 26 weeks. In the two groups including children and adolescents, there were no differences in glycaemic control between the group assigned to CGM and the one that was not. However, the proportion who used CGM for six days or more for a week was considerably lower among the children and adolescents compared with the adults ( $\geq 25$  years 85%, 15-24 years 30%, and 8-14 years 50%) (78). Furthermore, Bergenstal et al. included 485 patients aged 7-70 years (156 children aged 7-18 years) in an RCT study. Of these, 166 adults and 78 children were assigned to SAP and the control group continued with MDI. After 12 months, the children in the SAP group had decreased their HbA1c while the MDI group had increased slightly ( $p < 0.001$ ) (79).

Positive results have been shown when CGM is added to CSII treatment. HbA1c and time spent in hypoglycaemia decreased during the CGM period. Moreover, the amount of mealtime boluses increased when using CGM. For those who used CGM less than 70% of the time, the decrease in HbA1c was smaller (80). Furthermore, a recent review of CGM in children and adolescents concluded that CGM is safe and effective in this age group (81).

Parents of children and adolescents (1-17 years) reported that CSII was beneficial to both them and their children, while, CGM was of more advantage to the parents than to their children. Furthermore, the parents described that it was easier to reach the targets for glucose values with the help of technology (82). On the other hand, children and adolescents using SAP do not report better HRQoL; however, they do report better treatment satisfaction (83, 84).

For a few years, Flash Glucose Monitoring (FGM) has been available as an alternative to measuring glucose control by finger stick or with CGM. A small sensor is worn on the back of the arm. A scanner, which displays glucose values after scanning over the sensor, does not need to be close to the sensor, and are factory calibrated (do not require calibration). The scanner has no automatic alarms, but during scanning shows trend arrows, current glucose value, and eight-hour glucose history. In Sweden, FreeStyle Libre, an FGM system, became available to adults in 2014 and to children and adolescents in 2016. For children and adolescents, FGM has shown to be accurate, safe and user-friendly (85). A study involving adult patients showed a decrease in the time spent in hypoglycaemia for those using FGM, compared with the control group using self-monitoring of blood glucose (86).

### **3.3 LIFE WITH DIABETES**

#### **3.3.1 Adolescence and diabetes**

The way to adulthood is long, and fraught with many temptations and risks. Everyone must experiment to find their own way, trying different lifestyles to find their personality. The experiments involve success and mistakes, which lead to learning and development. This era is necessary in order to become an independent individual, to rely on oneself, and develop one's own identity. During this period, the adolescent has to develop a new relationship with his/her parents, be able to have close relationships with individuals outside the family, consider how to live life as an adult, develop a lifestyle and self-care, and plan a career. Simply put, adolescents need to learn to take care of themselves and their lives. Gradually, the cognitive ability to analyse and the imagination will be developed, both of importance in the development of one's identity (87, 88).

Adolescents have described constantly struggling with their diabetes self-management, dealing with hypoglycaemia and hyperglycaemia, as well as with the fear of complications later in life. They describe a fear of nocturnal hypoglycaemia, as well as anxiety about falling asleep and the risk of dying in their sleep. They are aware of diabetes as a chronic illness that will last forever; they have to live their life in a new way – a life with type 1 diabetes (25). A study has identified five trajectories of glycaemic control: 'stable on target, stable above target, volatile late peak, stable high, and inverted U'. Parents' social status and family structure differed in those groups with unsatisfied poor or divergent glycaemic control from the 'stable on target' group. Additional factors that distinguished the 'stable on target' group from the one with unsatisfactory glycaemic control were conflicts with friends, the quality of the communication, psychological distress, and self-care behaviour at study start (89, p. 5-7). In the same manner, a cross-sectional multicentre study has shown that factors shown to associate with satisfactory glucose control were high socioeconomic status, parents' educational level, usage of carbohydrate counting, usage of CSII continuously or for shorter periods, and BMI within the normal range. In a logistic regression analysis, the factors that could be demonstrated to be of significance for glycaemic control were socioeconomic status and years of education for the mother (90).

#### **3.3.2 Transition of responsibility**

Glycaemic control is worse during adolescence than during childhood (2). Children and adolescents with diabetes and their parents describe, in varying ways, that they want to be like everyone else (20-23, 25, 91). One stressor described by adolescents is worries about ineffective self-management during the period when taking over the responsibility (92). Low blood glucose values and self-care activities, including blood glucose tests and insulin administration, are described as challenging for adolescents (22). Parental involvement and shared diabetes self-management have shown to be important during adolescence (88, 93-96). In an interview study, young adults (20-22 years) in Sweden describe the importance of their parents, especially their mothers, during this period of crucial change (97).

Regarding adolescents' and their parents' experiences of living with diabetes, three stages have been identified: adapting to the diagnosis, learning to live with type 1 diabetes, and becoming independent. For teens, the key to developing self-management skills and independence was experimental learning. Parents and health professionals must create conditions that give adolescents the freedom to learn through trial and error (98). Furthermore, themes identified in communication between children and parents are frustration, fear, normalizing, trusting, and discounting (99).

Babler et al. defined normalization as 'the ability to integrate diabetes into one's daily life to make diabetes 'part of me', and identified six codes describing actions by adolescents during each phase (normalizing during each phase): remembering the journey (recognizing that life is changing), balancing blood sugar/preventing a crisis (taking action to prevent a crisis), integrating diabetes with the world outside the home (disclosing to engage support), moving the journey towards independence (taking on the burden of care), figuring it out (accepting the new normal), and helping others (hoping for a normal future). One of the most crucial periods is when the adolescents are 'moving the journey towards independence', taking more responsibility, having more conflicts with their parents, and realizing that diabetes self-care is a challenge. Gradually, they take full responsibility for the disease, 'taking on the burden of disease' (100, p. 650). Adolescents having difficulty moving into this phase may feel different and experience diabetes as a burden, which results in conflicts and unsatisfactory diabetes self-management. When they manage to figure out how to handle their diabetes they gain greater self-confidence, which means they can move on and help others learn how to manage their own diabetes (101).

Adolescents were asked to identify their top three stressors, rate them on a scale from 1-10, and describe what was stressful about them. The top three stressors were: school (82%), social life (49%), and diabetes (48%). Diabetes did not substantially contribute to school stress (6.7%) or social life stress (4.3%). When the text was qualitatively analysed, general life stressors were identified ('fitting in, having friends, balancing competing demands, living with family, and feeling pressure to do well'), as were diabetic specifics ('just having diabetes, dealing with emotions, and managing diabetes') (20) p. 137.

Parents and adolescents perceive the level of parental support equally. On the other hand, youth experience lower levels of shared responsibility. However, a higher level of support is associated with a higher level of shared responsibility (102). In the same manner, there is an association between shared responsibility and better psychosocial health, satisfying self-care, and acceptable glycaemic control (103).

In a study, adolescents were divided into three HbA1c groups (ideal  $\leq 58.8$  mmol/mol, satisfactory 58.9 -69.4 mmol/mol, and poor  $>69.4$  mmol/mol). No differences in self-management were identified between the groups (104). On the other hand, results from a study by Scholes et al. describe how adolescents with non-satisfactory glycaemic control believed type 1 diabetes was curable, had negative experiences of receiving the diagnosis diabetes, neglected diabetes self-care, and had poor parental support. The participants with

more satisfactory glycaemic control knew diabetes could not be cured, had less negative experiences of being diagnosed, practiced good diabetes self-care, and received parental support (105).

### **3.3.3 Parental support**

It is known that relations between parents and adolescents are of great importance to diabetes self-management, and several studies indicate an association between family conflicts and glycaemic control (106-112). Both adolescents and parents describe that responsibility shifts from parent to adolescent as age increases (112, 113), and that diabetes-specific family conflicts are not associated with age (112). However, diabetes-specific family conflicts, older age of children, longer diabetes duration, insulin delivery via injections versus CSII, greater depressive symptoms, and ethnic minority predict poorer diabetes self-management and glycaemic control (109). Common reasons for conflicts are nagging (primarily about blood glucose testing), logging results, and meals (47, 114). Other reasons include parental anxiety and intrusive behaviours, including parents' lack of understanding as well as criticising behaviour (115). When there is discrepancy in the parents' and children's reported experiences of the frequency of communication, results from previous research indicate an association with poor glycaemic control and more conflicts. Parents usually feel they have frequent communication, while adolescents experience this less. Adolescents who experienced a more positive tone in conversations with their parents also had a better glycaemic control (107). Parents' ability to cooperate seems to affect family conflicts (116) and glycaemic control (117).

Adolescents with poor glycaemic control experience more conflicts with peers, more negative feelings about diabetes and fewer blood glucose tests, and miss clinic appointments more frequently (118). Symptoms of anxiety increase in families with a great deal of conflicts, which could have a negative effect on glycaemic control (108). It is known that family conflicts are associated with self-efficacy (119). On the other hand, the effect diabetes-related family conflicts have on glycaemic control might be mitigated by self-efficacy (120).

In a Norwegian study, adolescents with type 1 diabetes reported that their parents were more involved and controlling, compared with the reports of healthy and disabled adolescents. No association was found between glycaemic control and QoL (93). Research on the effect of parental involvement and care on glycaemic control shows divergent results. Some studies show that parental care, control, and involvement are not related to glycaemic control (93, 113). At the same time, research has shown that parental involvement is a predictor of the frequency of glucose monitoring (106). Agreement between parents and adolescents and fewer diabetes-related conflicts are predictors of glycaemic control (113, 121) and better HRQoL (121). This strengthens the results presented by Olinder et al. describing the need to clarify responsibility in order to avoid missed insulin doses (122). In a qualitative interview study, adolescents were divided into two groups according to their HbA1c levels (low group  $\leq 63.9$ , high group  $>63.9$ ). Adolescents in the low group described their parents' rules more positively, while adolescents in the high group were irritated by reminders and described



more diabetes-related conflicts with their parents (123). Adolescents with parents who were perceived to be over-involved in diabetes care have worse glycaemic control. The greater the disagreement between adolescent and parents regarding responsibility for diabetes self-management, the worse glycaemic control (124).

In families with parents living together, the adolescents have better glycaemic control than those in single-parent families (124, 125). On the other hand, Dashiff et al. indicate that conflicts or adherence have no association with self-care in different family structures, or whether or not the mother works (126).

In families with a warm and nurturing home environment with positive emotional support and communication, children and adolescents experienced higher levels of self-care and a lower impact of diabetes, had fewer worries about diabetes, and experienced greater life satisfaction, but no association was found with glycaemic control (127). Main et al. describe that parental support is associated with better diabetes self-management. Mothers reported an association between conflicts and inadequate diabetes self-management and more depressive symptoms. On the other hand, adolescents reported no correlation between conflicts with parents and diabetes self-care or depression (128). In families describing household chaos, a correlation with glycaemic control has been indicated (129).

From a long-term perspective, an authoritative parenting style seems to work the most effectively. It gives teens the space to develop in accordance with their needs and their sense of what they want. Experimentation can then take place under the safest conditions possible, in consultation with parents who put reasonable limits in place. Parents need to be able to justify prohibitions and requirements. This parenting style should not be confused with an authoritarian style, which can be compared with military-style parenting, whereby parents want to dictate how their teens behave (87). A study by Mlynarczyk et al. showed a difference in adherence between adolescents perceiving their parents as authoritative and those perceiving their parents as authoritarians, permissive, or neglectful. In families with an authoritative parenting style, better adherence and perceived QoL were identified. However, there was no difference in HbA1c between the parenting styles (130).

### **3.4 PATIENT EDUCATION**

Recommendations from ISPAD highlight that education for adolescents with type 1 diabetes should be structured, person-centred, and flexible. Education focusing on the acquisition of knowledge rarely leads to behavioural change. Consequently, educational interventions are most effective if they are based on psychoeducational theories, are integrated into clinical activities, have parental involvement, and use cognitive behavioural methods related to problem-solving, communication skills, assigning goals, dealing with family conflicts, coping skills, and stress (17).

The new Medical Research Council guidance recommends that available evidence and appropriate theories should be used when developing an intervention, and that a pilot study should be carried out (131). Ayling et al. have recently published a review evaluating the efficacy of theory-based RCT interventions aimed at behavioural change in young people with type 1 diabetes, published between July 1999 and November 2012 (132). Using the template for quality audit for systematic reviews according to AMSTAR (a measurement tool for assessing the methodological quality of systematic reviews), the review meets the basic requirements for quality (133). However, it includes studies with a wide range of interventions, with durations ranging from 1 hour to 15 months. The results show that 30% of included studies do not mention or describe any explicit use of theory. Overall, there was an effect on HbA1c for intervention participants, with an effect size of 0.16 (95% CI: 0.01-0.30), and for those explicit uses of theory there was a better effect of 0.22 (CI: 0.07-0.36). The results were moderately heterogeneous ( $I^2= 51.6\%$ ). For studies that mentioned or explicitly used theory, there was an effect on psychological outcomes (132).

However, there are some problems with meta-analysis, as the combined effect is not a reliable estimate of the 'true' effect. Firstly, it may be that the results included are not a representative sample, due to a problem known as publication bias. Usually, this means that the estimated effect is too large. Secondly, the results are based on studies that are not sufficiently similar to the others (normally called clinical heterogeneity), and may be presented in either an overestimation or underestimation of the 'true' effect (133).

### **3.4.1 Power and self-efficacy**

It is important to highlight the patient's own power to manage a lifelong chronic disease. According to Barrett, power in healthcare is 'the capacity to participate knowingly in change', and consists of four inseparable dimensions – awareness, choices, freedom to act intentionally, and involvement in creating change. Two forms of power that may play a role in education are empowerment and social power (134, p. 48).

One of the most widely used definitions of empowerment is the one defined by Funnell and Anderson: 'the discovery and development of one's inherent capacity to be responsible for one's own life' (135, 136, p. 454). 'Patients are empowered when they have knowledge, skills, attitudes, and self-awareness necessary to influence their own behaviour and that of others in order to improve the quality of their lives' (135, p. 38).

The most common description of social power is the one by French and Raven, who divided it into five forms, of which referent and expert power are relevant in this context. Referent power is defined as the ability of some individuals to be a reference and to have significant importance for others. They can induce changes in the attitudes, values, and decisions of others. A person with referent power is benevolent and caring. Expert power is knowledge from a person that results from experience or education (137, 138).

Self-efficacy is a person's feelings and thoughts about his/her own capability. How active a person is in his actions is linked to the strength of a person's self-efficacy. Those who expose

themselves to subjectively perceived threatening situations will gain experiences that enhance their self-efficacy and, gradually, their defensive posture (139).

### **3.4.2 Person-centred approach**

While it is difficult to describe what a person is, it could be based on four ethical concepts: *autonomy*, *dignity*, *integrity*, and *vulnerability*. *Autonomy* means being able to choose your own path in life. *Dignity* makes a connection to other people, a respect for others who have the same rights and obligations as you do. *Integrity* means not to hurt, harm or destroy other people's lives, but to protect the person in the context of life and his/her life history. Finally, *vulnerability* constitutes an essential determination of the human as a mortal being. It should not be interpreted as a weakness, but as the inherent structure of human finiteness (140).

According to Paul Ricœur, a human being is considered capable and can take responsibility for actions and decisions. He/she is capable of prioritizing and motivating decisions. Ricœur believes that ethics is superior morality, but that the ethical quest should be tested against moral norms. He sums up the meaning of ethics as a quest for a good life with and for others within the institutions of justice. Firstly, ethics ultimately concern what makes life worth living. Secondly, ethics entail a quest involving interpersonal dimensions 'with and for others'. A happy human needs friends. Mutuality in interpersonal relationships requires that you take the other seriously. The third part of the ethic quest is 'within the institutions of justice' (141). However, it is important to be aware that, during adolescence, cognitive ability develops from a limited capability for abstract thinking regarding understanding the consequences of actions to a more realistic analysis and view of the future (88).

Person-centred care includes patients being seen based on their context, strengths and future plans, and their rights being taken into account. Person-centred care highlights the importance of knowing the person behind the patient in order to engage the person as an active partner in his/her own care and treatment. The person's story is central and, in partnership with the medical staff, determines actions meeting the person's expectations and goals, which should be documented (142).

Many of our beliefs are collectively nurtured and maintained. A dialogue is a process that offers the opportunity to reflect on and change these self-imposed limits. According to Buber, dialogue is a prerequisite in meeting, whereby people can soften or release the obstacles between them, perhaps even defeat them, and achieve a real meeting (143). Dialogue is central in education programmes using conversations. To achieve dialogue, it is important for participants to understand each other's perspectives; through this, conditions are created that allow them to discover perspectives other than their own (144). However, at the same time, conflict is a prerequisite for action. There is no norm for what is right or wrong in a given situation, but a human being is able to take responsibility for his/her actions and decisions (141).

### **3.5 EDUCATIONAL INTERVENTIONS**

#### **3.5.1 Guided Self-Determination (GSD)**

Using grounded theory, Vibeke Zoffman explained barriers to empowerment that were seldom overcome by health professionals. Based on this, along with other theories, she developed a method she named Guided Self-Determination (GSD) (145). GSD is an empowerment-based, person-centred reflection and problem-solving method intended to guide the patient in becoming self-determined and developing life skills for managing difficulties in diabetes self-management (146). Life skills are defined by WHO as: ‘abilities for adaptive and positive behaviour, that enable individuals to deal effectively with the demands and challenges of everyday life’, and examples include ‘decision-making, the ability to solve problems, creative and critical thinking, communication, communication skills’ (40, p. 360). The definition of self-determination in GSD is: ‘Quality of human functioning that involves the experience of choice, in other words, an internal perceived locus of causality; Self-determination is the capacity to choose and to have those choices be the determinants of one’s action’ (145, p.8). GSD is a method intended to facilitate meaningful and effective problem-solving between patients and healthcare professionals. Both parties are guided by the method of using their inherent capacity, individually and together, in a process that promotes patient life skills (146-148).

To make the method clinically useful, Zoffmann added reflection worksheets based on several theories (145). By using the completed worksheets together with communication methods – mirroring, active listening, and value-clarifying responses – GSD helps the patient and the healthcare professional overcome barriers to empowerment. In mirroring, the group leader ‘mirrors’ (rather than interprets), repeating what the other has said or done. This gives the other person an opportunity to observe him/herself from outside. In active listening, the group leader usually concludes the mirroring and thereafter interprets the total message, asking if the interpretation is correct. Finally, in value clarification, values and aims are linked. The group leader expresses a response or question that encourages a reassessment of values. The person is encouraged to make informed choices (145-148). GSD has been effective in both individual and group training for adults with type 1 diabetes (149, 150). The method has been adapted for teenagers, in the GSD-Young (GSD-Y) in Denmark. In an RCT including 71 adolescents (aged 13-18 years), 37 received an intervention with GSD-Y. The results showed no significant reduction in HbA1c, but did show improvements in the patients’ motivation for diabetes self-management. Further, adolescents expressed growth in life skills, which to them meant new relationships with health professionals and their parents, and increased decision-making competence as well as personal maturity (151, 152).

#### **3.5.2 Empowerment based education**

Viklund et al. performed an RCT with an empowerment intervention for a six-month period including 32 adolescents (aged 12-17 years). The education programme consisted of six sessions (2 h) once a week. Each time, a topic was raised based on the empowerment

concept: life satisfaction and goal-setting, problem-solving, coping with emotions, coping with daily stress, social support, and motivation.

There was no difference in glycaemic control or empowerment between the intervention and control groups six months after intervention. For adolescents aged over 14 years, HbA1c was significantly higher six and 12 months after intervention, but had decreased to baseline after 18 months. All groups were offered an extra opportunity to invite their parents and inform them about the content of the education. Two invited their parents, two allowed the group leader to meet their parents, and two did not want to invite their parents. There were no differences in HbA1c in these groups at baseline; however, in the group whose parents were not invited, HbA1c had increased 12 months after the intervention. The group that invited their parents showed significant improvement in HbA1c 12 and 24 months after the intervention ( $p < 0.05$ ) (153). Two weeks after completing the empowerment education, the adolescents were interviewed in order to explore teenagers' perceptions of factors affecting decision-making competence in diabetes management. Five categories were revealed: cognitive maturity, personal qualities, experience, social network, and parent involvement. Furthermore, an overall theme was formulated: 'Teenagers deserve respect and support for their shortcomings during the maturity process' (95, p 3265).

### **3.5.3 Structured education**

The CASCADE (Child and Adolescent Structured Competencies Approach to Diabetes Education) is a comprehensive prospective multicentre RCT including 362 participants aged 8-16 years with type 1 diabetes, and their parents, involving 28 paediatric diabetes clinics in the UK. The participants, randomized to intervention or control, were followed for 24 months. The intervention consisted of four modules over four months. Each session lasted approximately two hours, and was held by paediatric diabetes specialist nurses and dietitians. In the sessions, two psychological approaches were used: motivational interviewing and solution-focused brief therapy. The intervention provided both structured education and a model in order to motivate the participants and their parents to reflect on their own self-management approach.

The results showed that, of the included participants, only 30% attended all sessions in the intervention group, 53% attended at least one session, and 68% of the possible groups were carried out. Some staff described that they found it difficult to manage the psychological techniques, and experienced it as burdensome to organize the groups. The participants experienced the intervention as positive and as resulting in: improved relationships in the family, increased knowledge and understanding of diabetes, increased security, and increased motivation to perform self-management. The results of the study showed no differences in HbA1c between the groups at 12 or 24 months (154).

### **3.5.4 Self-management education**

Cai et al. describe the development and pilot test of an education programme involving a self-management approach including 22 children and adolescents aged 8-16 years and their

parents. The participants were divided into seven groups based on the youth's age. The intervention consisted of a whole day workshop focusing on the overall management of blood glucose management and the challenges of diabetes in everyday life. The participants found the day with the workshop useful and enjoyable. The parents appreciated listening to the youth's experiences. Both parents and the youth appreciated meeting others and sharing their experiences of living with diabetes. Although many had a high level of diabetic knowledge, they experienced that they had learned new things. As this was a feasibility study, including only 22 participants, no statistical analyses have been performed. However, HbA1c levels were about the same before and after the intervention:  $66 \pm 12$  mmol/mol before and  $65 \pm 13$  mmol/mol after (6-12 months) (155).

### **3.5.5 Coping skills training**

Coping-skills training has been carried out in RCT interventions involving pre-adolescent children. Ambrosino et al. and Grey et al. reported on a study with 111 children and adolescents aged 8-12 years, and Holmes et al. (2014) on one with 226 adolescents (aged 11-14 years). Neither of these had a proven effect on glycaemic control (156-158). Grey et al. reported positive effects for both the intervention group (receiving coping-skills training) and control group (receiving general diabetes education) on diabetes impact, coping skills, self-efficacy, depressive symptoms, and parental control (159). In the study by Holmes et al., the intervention group received coping-skills training and the control group received diabetes education as a supplement to quarterly visits. Both groups prevented deterioration in diabetes care and improved QoL in children and parents, including indicators of more effective communication. Adherence barriers decreased without increasing diabetes-related conflicts (158).

### **3.5.6 Cognitive behavioural therapy (CBT) and motivational interviewing (MI)**

A systematic review was performed in 2009 by the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), regarding education for adults with diabetes. For persons with type 1 diabetes, the report showed insufficient scientific evidence regarding the efficacy on HbA1c or QoL of interventions with CBT, both individual and group-based, and no difference in effect on glycaemic control when using motivational interviewing (MI) compared with usual care (160). There are no studies on children and adolescents with results regarding interventions with CBT.

Channon et al. performed a multicentre RCT comparing MI with support visits in 66 adolescents (aged 14-17 years). The intervention lasted for 12 months, and follow-up data were collected 6, 12 and 24 months after baseline. There was a significantly lower HbA1c in the intervention group at 12 months, and this was maintained at follow-up 24 months after start (161). Fifty-four adolescents (aged 12-18 years) were included in an RCT using MI with a control group receiving structured diabetes education (SDE). The intervention lasted three months. In the results of this study, the SDE group showed significantly better HbA1c than the MI group at nine months after study start (162).

DEPICTED (the Development and Evaluation of a Psychosocial Intervention in Children and Teenagers Experiencing Diabetes) is an MI-inspired programme in which patient and personnel set the agenda together and use different communication methods. The programme involved 693 young persons (359 intervention) aged 4-15 years from 26 centres. For the intervention, 79 healthcare workers from 13 centres were trained in the method. These healthcare workers were trained to put the patient in the centre through more constructive consultations, in order to achieve behavioural changes. Despite this, there were increases in HbA1c in both groups at follow-up after one year. Mean HbA1c (SD) at baseline vs. follow-up were 9.2 (1.8) vs. 9.5 (1.7) for the control group and 9.4 (1.7) vs. 9.7 (1.7) for the intervention group (163).

## **4 GENERAL AND SPECIFIC AIMS**

### **4.1 GENERAL AIM**

The overall aim of this thesis was to increase the knowledge regarding glycaemic control, type of treatment, HRQoL, and a theory-based education among youth with type 1 diabetes.

### **4.2 SPECIFIC AIMS**

- To investigate long-term effect on glycaemic control, ketoacidosis, serious hypoglycaemic events, insulin requirements, and body mass index standard deviation scores (BMI-SDS) in children and adolescents with type 1 diabetes starting on continuous subcutaneous insulin infusion (CSII) compared with children and adolescents treated with multiple daily injections (MDI) (Paper I).
- To test the validity and reliability of the Check your Health by proxy instrument in parents to children (aged 8-17 years) with diabetes (Paper II).
- To evaluate whether an intervention using Guided Self-Determination-Young in groups of adolescents starting on continuous subcutaneous insulin infusion and their parents leads to improved glycaemic control, increased perceived health and HRQoL, fewer diabetes-related family conflicts, and improved self-efficacy (Paper III).
- To describe adolescents' perceptions of participation in group education with the Guided Self-Determination-Young method together with parents, in connection with the introduction of continuous subcutaneous insulin infusion (Paper IV)



## 5 METHOD AND PARTICIPANTS

### 5.1 STUDY DESIGNS

In this thesis, both quantitative and qualitative methods have been used. An overview of the studies is presented in Table 2.

**Table 2.** Overview of designs, data collection year, participants, data collection, and analyses.

<b>Paper</b>	<b>Design</b>	<b>Data collection (years)</b>	<b>Participants</b>	<b>Data collection</b>	<b>Analyses</b>
<b>I</b>	Retrospective descriptive study	2005-2011	Starting CSII (n=216) Control MDI (n=215)	Gender, age, HbA1c, insulin requirement, BMI, BMI-SDS, ketoacidosis, and serious hypoglycaemic events.	Descriptive rANOVA Independent and dependent t-test
<b>II</b>	Psychometric properties of evaluation instrument	2011-2014	197 parents and their children	Proxy and child versions of Check your Health and DISABKIDS	Spearman's rank correlation Mann-Whitney U-test Wilcoxon signed rank test
<b>III</b>	Randomized controlled multicentre study	2012-2017	71 patients (11.5-18.1 years) starting CSII and their parents	At start, 6 and 12* months: HbA1c, height, weight, Check your Health, DISABKIDS, DFCS, Swe-DES, 23, and usage of FGM or CGM. At 6 and 12* months usage of CSII	Spearman's rank correlation Mann-Whitney U-test Wilcoxon signed rank test Multiple linear regression analysis
<b>IV</b>	Qualitative interview study	2015-2016	13 adolescents (12-20 years) from the intervention group in Paper III	Individual interviews	Qualitative content analysis

\* The analyses for 12 months are not included in this thesis.

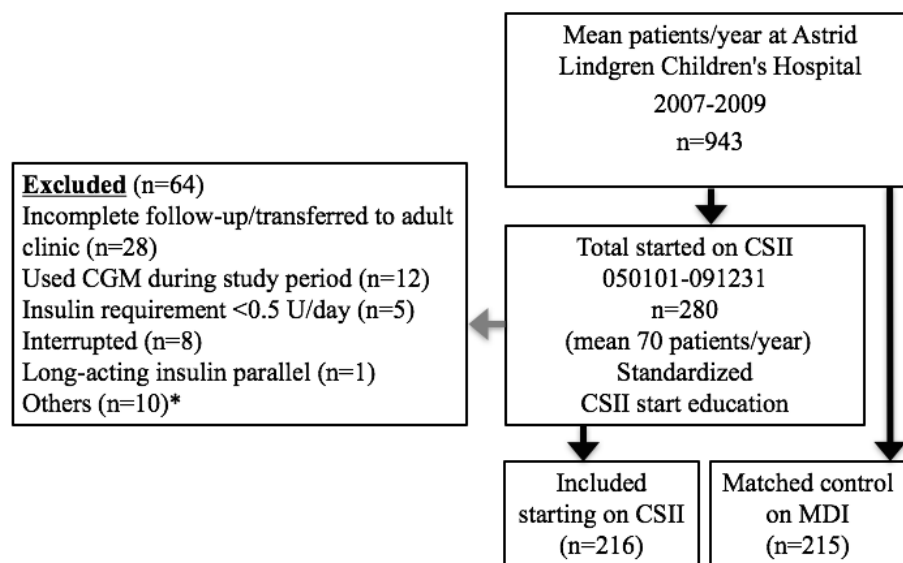
### 5.2 PARTICIPANTS AND SETTING

#### Paper I

This was a retrospective study collecting data from a total of 431 children and adolescents at Karolinska University Hospital, Astrid Lindgren Children's Hospital, Stockholm, Sweden. Of those, 216 were starting CSII during the period 1 January 2005 to 31 December 2009.

Inclusion criteria were insulin requirement of more than 0.5 u/kg/day to exclude the effects of own residual insulin secretion (164). Patients with incomplete follow-up data, use of CGM during the entire period, or long-acting insulin together with CSII were excluded. Each

patient was matched for age, sex, and HbA1c levels to one control on MDI with direct-acting insulin analogues; in total, 215 controls were included. The control group was collected from SWEDIABKIDS at the same hospital (Figure 1).



\* Patients who started CSII at a branch of Astrid Lindgren Children's Hospital who did not have the same routines at start of CSII or introduced carbohydrate counting during the study period.

**Figure 1.** Flowchart for eligible, excluded, and included participants in Paper I.

## Paper II

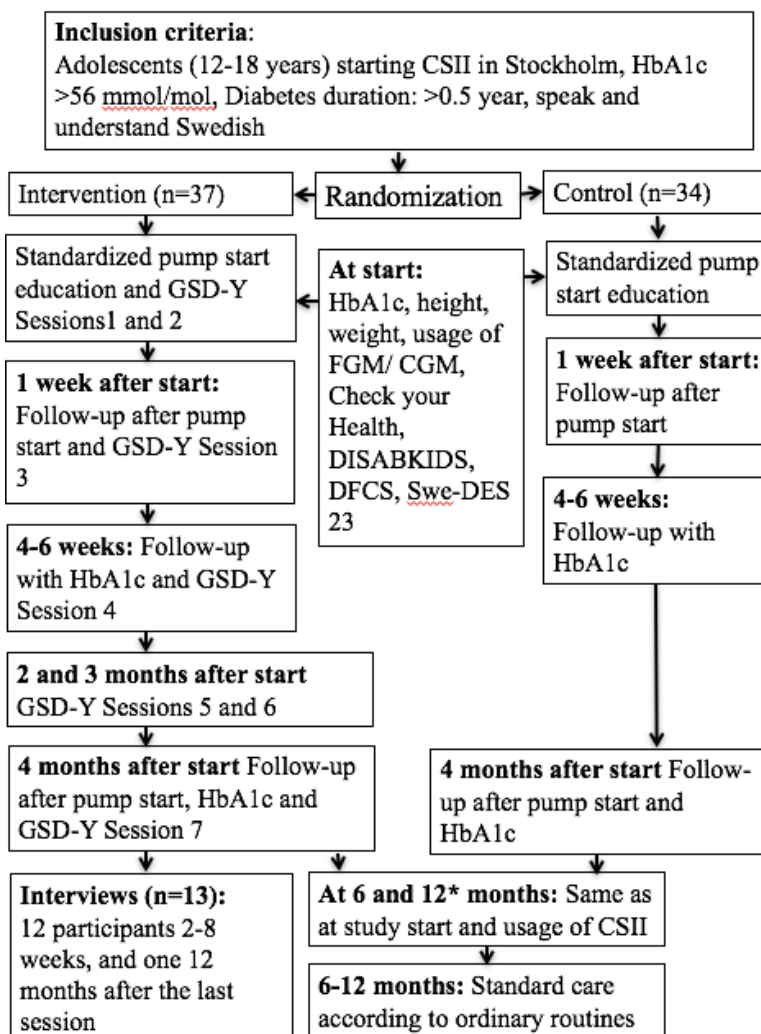
Parents (n=197) and their children with type 1 diabetes were consecutively recruited from Karolinska University Hospital, Astrid Lindgren Children's Hospital, Stockholm, Sweden, and Sachs' Children and Youth Hospital, Södersjukhuset, Stockholm, Sweden, during visits to the diabetes clinic. Inclusion criteria were children aged 8-17 years with a duration of type 1 diabetes of more than six months, and one of their parents. Both children and parents understood written Swedish.

## Papers III and IV

Recruited participants were aged between 11.5 and 18.1 years and starting CSII at Sachs' Children and Youth Hospital, Södersjukhuset, Stockholm, Sweden, and Astrid Lindgren's Children's Hospital, Karolinska University Hospital, Stockholm, Sweden. At study start, inclusion criteria were: diagnosed with type 1 diabetes for more than 12 months, HbA1c >63, insulin requirement >0.5 U/kg, not using CGM at start of CSII, and able to speak and understand the Swedish language (both the adolescents and their parents). Power calculation (power 80% and alpha 0.05) indicated that, to show a difference of 6 mmol/mol in HbA1c (SD:  $\pm 9.1$ ), each group had to contain at least 37 participants. At study start 160 patients at the clinics in question fulfilled the inclusion criteria, and from these mean HbA1c and standard deviation (SD) were calculated:  $74.2 \pm 9.1$  mmol/mol.

During the inclusion period of November 2012 to November 2016, levels of HbA1c have significantly improved and the use of CGM/FGM has increased at the clinics in question (2), resulting in difficulty recruiting participants. In addition, the Swedish guidelines' recommendation for HbA1c has been lowered to 48 mmol/mol, which is consistent with recommendations by the National Institute for Care Excellence in the UK (NICE) (8, 9). Therefore, the HbA1c level for inclusion was lowered to >56 mmol/mol and the use of CGM/FGM was accepted. Furthermore, the criteria for diabetes duration were lowered to six months or more. In total, 71 youths were included during the inclusion period (Figure 2).

Of the 37 youths completing the intervention, 14 (7 boys and 7 girls 12-20 years) were asked to participate in an interview study. Of these, one girl declined participation (Figure 2). Purposeful sampling was used with maximum variation was used to select the participants. Purposeful sampling is widely used in qualitative research for the identification and selection of information-rich cases related to the phenomenon of interest (165).



\* Results from 12 months analyses are not presented in this thesis.

**Figure 2.** Flowchart of Papers III and IV.

## **5.3 INTERVENTION**

### **Paper I**

The start of CSII described in Paper I was performed in groups consisting of three to six children and at least one of their parents (preferably both). All the participants starting CSII received a structured theoretical and practical education, including knowledge related to using the insulin pump, and education in hyperglycaemia, ketoacidosis and hypoglycaemic events. At the clinic, a checklist had been developed and was used to ensure the quality. Education at the start of CSII was mainly conducted by the diabetes nurse. A physician (specialized in paediatrics and endocrinology) was responsible for the calculation and correction of doses, and for the education about ketoacidosis and hypoglycaemic episodes. The start included a full day (6 hours) and two half days (3 hours each) education. One week after start of CSII, the group met for follow-up and evaluation of insulin doses. Four to six weeks after the follow-up visit, the patients were individually booked with their parents to visit a physician. Thereafter, they received standard care according to ordinary routines, which meant visits to a nurse or physician at three-month intervals.

### **Paper III and paper IV**

All adolescents and their parents attended a standard insulin pump introduction programme, offering education and practical training in areas including technical skills and how to use carbohydrate counting with CSII. In addition, one parent for each child was offered the possibility to voluntarily simulate diabetes by wearing an insulin pump containing saline and test their glucose values before the child started the insulin pump treatment. After this, the control group received standard care according to ordinary routines.

The intervention group attended seven group education sessions using the GSD-Y method (146, 147). Each session lasted about two hours, and was led by two group leaders (two diabetes nurses, or one diabetes nurse and one dietician). All group leaders had received education in the method from its creator, Vibeke Zoffmann. Three of the sessions were held in connection with the start of CSII, and thereafter about once a month for the remaining four. Before each session, the participants completed a specific reflection worksheet i.e. one worksheet per session. The first worksheet was sent to the participants before their first session. For subsequent sessions, the worksheet for the next meeting was distributed at the current one (Table 3). The parents completed reflection worksheets at Sessions 3, 4 (room for diabetes in your life), 5, and 7. To support patients in the dialogue at each session to allow them to express and consider difficult issues that emerged when using the reflection worksheets, the group leader used various communication methods (mirroring, active listening, and value-clarifying responses) (146).

**Table 3.** Overview of content of the reflection worksheets used at the GSD-Y sessions.

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Session 1 (Start CSII)	<b>Your life with diabetes from the beginning to now</b> <ul style="list-style-type: none"><li>• Written invitation to work together in a new way</li><li>• Two ways of looking at HbA1c</li><li>• Agreement on things to work on</li></ul>
Session 2 (Start CSII)	<b>Your life with diabetes from the beginning to now</b> <ul style="list-style-type: none"><li>• Important events and periods in your life</li><li>• What do you find difficult at present living with your diabetes?</li><li>• Your plans for changing your way of life</li></ul>
Session 3 (Start CSII)	<b>Values and opportunities</b> <ul style="list-style-type: none"><li>• Unfinished sentences: needs, values, experiences and opportunities?</li></ul>
Session 4	<b>Diabetes in your life</b> <ul style="list-style-type: none"><li>• A picture or expression describing your life with diabetes</li><li>• Room for diabetes in your life</li><li>• Shared responsibility between adolescent and parent(s) for diabetes in daily life</li><li>• Common name for a difficulty in your life with diabetes</li><li>• Agreement on things to work on until next visit</li></ul>
Session 5	<b>Problem identification and problem-solving</b> <ul style="list-style-type: none"><li>• Current and dynamic problem-solving</li><li>• Agreement on things to work on until next visit</li></ul>
Session 6	<b>Different ways of looking at numbers</b> <ul style="list-style-type: none"><li>• Blood glucose tests and your reasons for checking</li><li>• Actual numbers of blood glucose tests and wishes</li><li>• Your plan for blood glucose regulation in the short and long run</li><li>• Common name for a difficulty in your life with diabetes</li><li>• Agreement on things to work on until next visit</li></ul>
Session 7	<b>Problem identification and problem-solving</b> <ul style="list-style-type: none"><li>• Current and dynamic problem-solving</li><li>• Solved problems and subjects to continue working on</li></ul>

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## 5.4 DATA COLLECTION

### 5.4.1 HbA1c

In Paper I, HbA1c values were collected from the patient's medical record or SWEDIABKIDS. HbA1c levels were measured using high-performance liquid chromatography on filter paper or the DCA 2000 apparatus (Siemens Medical Solution Diagnostics, Mölndal, Sweden). All values collected before 2011 were converted to Swedish Mono-S standard (Mono-S gives an approximately 1% lower result than DCCT's HbA1c units). A consensus on a global standardization of the HbA1c measurement was approved in 2007, recommending that HbA1c level should be reported in IFCC units (mmol/mol) (166). Therefore, our results in Mono-S (%) were converted to IFCC (mmol/mol) and to DCCT (%) values (167).

In paper II and III HbA1c values were collected at clinical visits or from the medical record. HbA1c was analysed using DCA Vantage (Siemens Healthcare Diagnostics AB, Upplands Väsby, Sweden).

The grouping for HbA1c used in Paper II was based on ISPAD guidelines 2014 (<58 mmol/mol, 58-75 mmol/mol and >75 mmol/mol) (7).

#### **5.4.2 BMI-SDS**

Body Mass Index (BMI, kg/m<sup>2</sup>) is an objective way to measure weight status. In children and adolescents there is age-related variation; therefore, reference values and tables have been developed for mean and standard deviation score (SDS) of BMI (BMI-SDS) (168).

In Papers I and III, BMI-SDS was collected from the patient's medical record and SWEDIABKIDS.

#### **5.4.3 Psychometric measures**

*DISABKIDS generic (DCGM-37) and diabetes-specific (DSM-10) questionnaire*

In Paper II, the DCGM-37 and DSM-10, both the child and proxy versions were used when validating Check your Health by proxy and in Paper III to measure HRQoL.

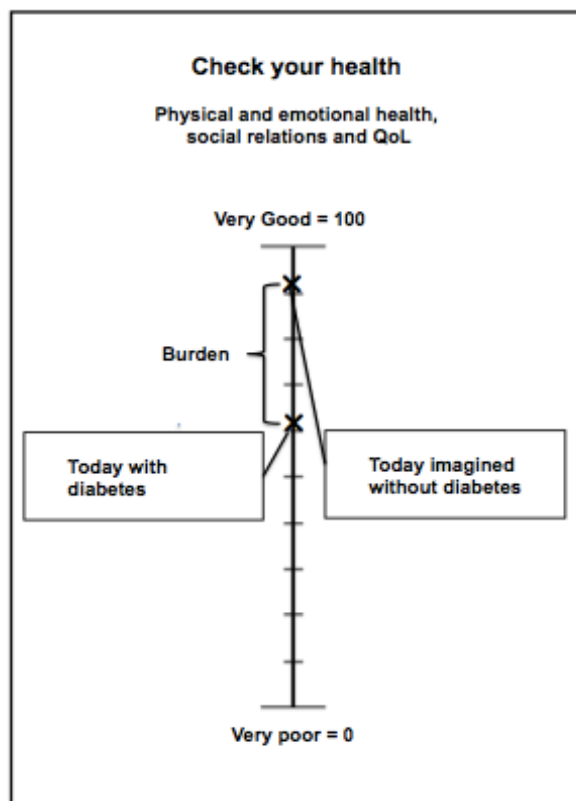
DISABKIDS (DCGM-37) is a generic instrument for measuring HRQoL in children and adolescents with a chronic disease. The development of the instrument took place in seven European countries, including Sweden. After a pilot (53) and a field study were conducted, a final generic version emerged, the DCGM-37, containing 37 items (52, 54). The items are divided into six subscales with six to seven items in each domain: Independence, emotion (inner strength), social inclusion, social exclusion (equality), physical limitation (physical ability) and medication (treatment). The original domains are a mixture of positive and negative expressions; therefore, the negative ones were changed to positive and are described in brackets. Each item is rated on a five-point Likert scale (14, 52). The DCGM-37 has demonstrated acceptable reliability (Cronbach's alpha) (53, 54), good content validity (53) and acceptable construct validity (52-54). Schmidt et al. demonstrated a moderate effect size (ES) (0.33-0.72) (sensitivity) by comparing the different diagnosis groups (52).

Parallel to the DCGM-37, seven disease-specific modules were developed, among them one for diabetes (DSM-10) (169). The DSM-10 consists of ten items and is divided into two domains: impact (acceptance) and treatment (14). In psychometric tests of the DCGM-37 and the disease-specific module for children with type 1 diabetes in Sweden and Norway, an acceptable convergent and discriminant validity has been demonstrated (14, 170). Frøisand et al. have shown acceptable reliability for the DCGM-37 and DSM-10 in Norway (170). However, reliability has not been tested on the Swedish population (14). For both DSGM-37 and DSM-10, a proxy version for parents is available (54, 169).

*Check your Health*

In Paper II psychometric tests were conducted on Check your Health by proxy for parents, and in Paper III it is used to measure perceived health, social relations, general QoL, and burden of diabetes.

Check your Health, developed by Wikblad et al., is a measure that is short and easy to complete. It consists of four pages with one domain/item on each page. On each page there is a vertical scale (0-100). On the left side of the scale, there is a question regarding perceived physical and emotional health, social relations and general QoL today with diabetes. On the opposite side of the scale there is the same question, but ‘how you would imagine it without diabetes’. From each question, a line is drawn to the vertical scale (Figure 3) (56). Diabetes burden is the difference between the two lines. The limit values for no (0), low (1-10), high (11-29) or very high (>30) burden in Paper II are arbitrary.



**Figure 3.** Description of the measure Check your Health.

#### *Diabetes family conflict scale (DFCS)*

In Paper III, the DFCS was used to measure how the adolescents perceived diabetes family conflicts (110). Sand et al. have translated and assessed the psychometric properties of the revised DFCS for children with type 1 diabetes and their parents in Sweden. It consists of 19 items on diabetes management tasks, with each item rated on a three-point Likert scale (1=never arguing, 2=sometimes arguing, and 3= always arguing). The items are divided into two domains: around direct management (9 items) and around indirect management (10 items). The total score can range between 19 (no conflicts) and 57 (highest degree of conflicts). The DFCS has shown acceptable reliability and validity for children, mothers and fathers (111).

### *Swedish Diabetes Empowerment Scale (Swe-DES 23)*

In Paper III, the Swe-DES was used to measure the psychosocial self-efficacy of people with diabetes. It consists of 23 items divided into four subscales: goal achievement, self-awareness, managing stress, and readiness to change. Each item is rated on a five-point Likert scale ranging from strongly disagree (1) to strongly agree (5). It has been validated in Swedish for adults, and demonstrates acceptable internal consistency (Cronbach's  $\alpha$  for subscales: 0.68-0.91 and Cronbach's  $\alpha$  for total scores 0.91) (171).

#### **5.4.4 Interviews**

For Paper IV, an interview guide was designed according to the study aim. Semi-structured questions were asked about the group (e.g. what comes to mind when you think of the group sessions? What do you think was good about the sessions?), the parents (e.g. Can you tell me what it was like having your parents in the group? Can you tell me what things are like at home – has anything changed?), and diabetes self-management (e.g. Can you tell me what you think about having diabetes after having been involved in this programme?). Furthermore, probing questions were used. The adolescents were asked to describe their experiences as fully as possible. The interview guide was pilot-tested on three adolescents, and no major changes were made.

For practical reasons, the interviews in Paper IV were conducted by two researchers. For consistency, the two researchers conducted the first three interviews together, with one performing the interview and the other serving as an observer, asking additional questions if needed. All interviews were recorded, and a secretary transcribed them verbatim.

## **5.5 PROCEDURES**

### **Paper I**

The patients were followed for 24 months, and data collection was done by review in the medical record system and the National Diabetes Register – SWEDIABKIDS. The collected variables are presented in Table 4. In addition, reported events of ketoacidosis (hospitalized) and severe hypoglycaemia (hospitalized or reported by patient) during the 24-month study period were collected.

**Table 4.** Data collection in Paper I.

<b>At baseline and 6, 12, and 24 months</b>	<ul style="list-style-type: none"><li>• Gender and age (only at baseline)</li><li>• HbA1c, insulin requirements, BMI, and BMI-SDS</li></ul>
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## **Paper II**

The participants, pairs of a parent along with their child with type 1 diabetes, were asked to participate in the study at an ordinary visit to the clinic. They completed the Check your Health, DCGM-37 and DSM-10 proxy and child versions before or directly after visiting the clinic. To test reliability, the questionnaires were sent two weeks later to 45 of the 197 participants. Furthermore, current diabetes treatment and HbA1c were collected.

## **Paper III and IV**

In Paper III, those adolescents and parents who were positive to participate were consecutively divided into groups and randomized to either intervention or control. The data collection is described in Figure 2.

The participants in Paper IV, the interview study, were asked to participate at their last visit in the GSD-Y intervention or by telephone. The interview guide was pilot-tested on three adolescents two months (two participants) and one year (one participant) after completion of the intervention. These adolescents remembered a great deal from the intervention, and the interviews were rich in information; however, they found it difficult to remember details from their work with the reflection worksheets. To increase the possibility that they would remember this information, the remaining interviews were conducted two to six weeks after completion of the intervention (10 participants). Interviews with the adolescents were conducted individually. Twelve were interviewed face-to-face, and one by telephone. All interviews were recorded. The adolescents were asked to describe their experiences as fully as possible. Ten interviews were conducted in a room outside the paediatric diabetes department at the children's hospital, two in the participants' homes, and one by telephone. The decision to conduct interviews in the participants' homes or by telephone was made according to the participants' wishes.

## **5.6 QUANTITATIVE DATA ANALYSES**

In Papers I and II, data were analysed using the Statistical Package for Social Sciences (SPSS, version 21; IBM, Stockholm, Sweden). In Paper III, SPSS version 23 was used. The level of statistical significance was  $p < 0.05$ .

### **Paper I**

In Paper I, descriptive statistics were used for baseline characteristics. The numbers of reported ketoacidosis and severe hypoglycaemic episodes are presented as episodes per 100 person-years.

When comparing HbA1c, insulin requirements and BMI-SDS over time and between CSII and MDI groups, repeated ANOVA (rANOVA) were used. Further, post hoc tests using independent (un-paired) Student's t-test (two-tailed) were conducted to identify differences

between groups at different times (at baseline, 6, 12 and 24 months). Changes within groups (over time) between baseline and follow-up were calculated using dependent (paired) t-tests. The study population was divided into subgroups, and thereafter the same analyses were conducted as for the whole group: age 0–<7, 7–<12, and 12–18 years; gender; and participants with baseline HbA1c values above 70 mmol/mol.

## **Paper II**

In Paper II data on age, HbA1c, and diabetes duration were distributed normally; therefore, mean values (95% CI) have been used. However, results from Check your Health had a non-normal distribution and therefore median values (range) were used.

Floor (0) and ceiling effects (100) have been calculated, and are presented in the percentage scoring as either 0 or 100. Reliability and convergent validity were analysed using Spearman's rank correlation. The Mann-Whitney U-test was used to analyse differences in independent (unpaired) samples, and the Wilcoxon signed rank test to compare dependent (paired) samples (child-parent pairs). Reliability was calculated through test-retest correlation, and convergent validity was calculated by analysing the correlation between Check your Health by proxy and DCGM-37 by proxy. In this thesis, the strength of a correlation <0.4 is regarded as low, 0.4–0.74 as good, and >0.74 as excellent (172).

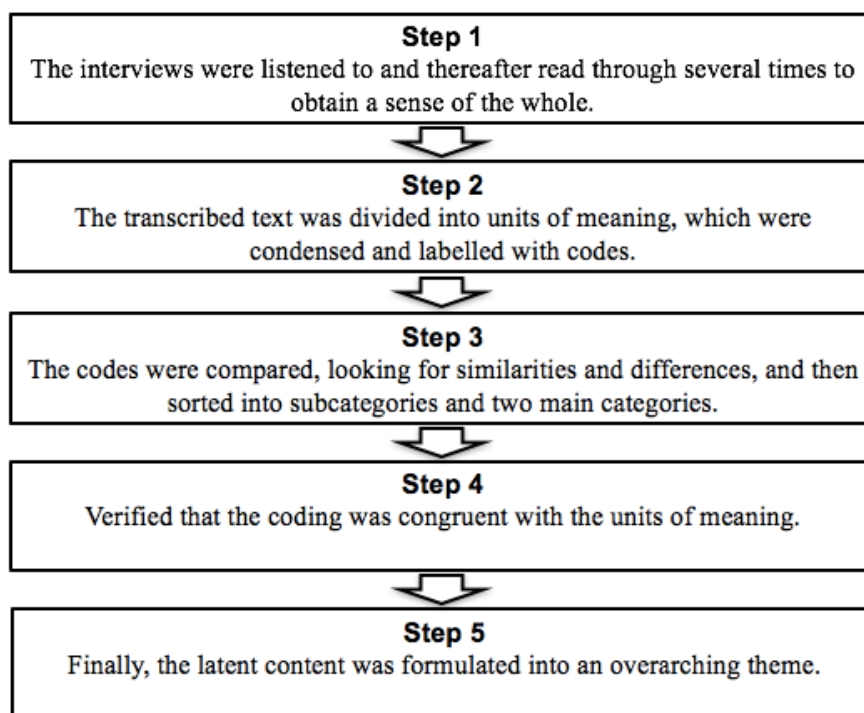
## **Paper III**

Analysis in Paper III was done based on intention to treat. A non-normal distribution was found for all variables, and therefore median values (range) were used.

Correlation was analysed using Spearman's rank correlation. The Mann-Whitney U-test was used to analyse differences in independent (unpaired) samples, and the Wilcoxon signed rank test to compare dependent (paired) samples. Multiple linear regression analysis was used to examine which variable contributed the most to glycaemic control at six months. A model was created with forward stepwise regression; the model was validated for normally distributed error terms, homoscedasticity, linear function, independent error terms, outlier observations, and multicollinearity.

## **5.7 QUALITATIVE DATA ANALYSES**

In Paper IV, qualitative content analysis inspired by Krippendorff was used in the inductive analyses (173). Content analysis is a general term for the identification, organization, and categorization of narrative text, and detects patterns and themes (165). The analysis was performed as described in Figure 4.



**Figure 4.** Description of the qualitative content analysis process.

The categories were carefully assessed based on internal homogeneity (data belonging to the same category belongs together in a meaningful way) and external heterogeneity (the difference between the categories is clear) (165). The analysis was based on a manifest interpretation of the text. When all authors made a latent interpretation of the content, an overarching theme was revealed.

We have strived to achieve trustworthiness (credibility, dependability, confirmability, and transferability) by describing the analytical process in detail, providing quotations from the interviews (Paper IV), involving several researchers in the analyses, and describing the sample and context in as much detail as possible. The different intervals between intervention and interviews may have increased trustworthiness; the results were consistent despite the varying intervals (165, 174).

## 5.8 ETHICAL CONSIDERATIONS

The Ethical Review Board in Stockholm, Sweden, has approved all studies (I, 2010/234-31/1, II, 2011/762-31/4, III and IV, 2011/762-31/4 and 2012/2124-32), which were carried out in accordance with the Declaration of Helsinki. The participants received oral and written information about the studies when they were asked to participate. Information was given that participation was voluntary, that they could discontinue whenever they wanted, that all collected data would be kept safe, and that it will not be possible for any information to be linked to any person. Written consent was obtained from the participants

(children/adolescents and parents in Papers II and III). In Paper IV, written consent was also obtained from a parent for those under 15 years (175).

None of these studies can be expected to present any risk or possible complication for the participants. In studies involving children and adolescents, it is important to be aware of the feeling of disadvantage that young people may experience in relation to adults. In Paper IV we were aware of this, especially during the first three interviews, in which two researchers participated. Therefore, we chose to start the interviews with everyday talk to create a good environment to encourage a meeting on equal terms. At the interviews, the participants were once again asked if they minded that the interview would be recorded, and if they were aware that the material would be transcribed verbatim. The results of the studies will be presented to the participants in the form of the Swedish summary of this thesis.

## 6 RESULTS

### 6.1 GLYCAEMIC CONTROL

#### Paper I

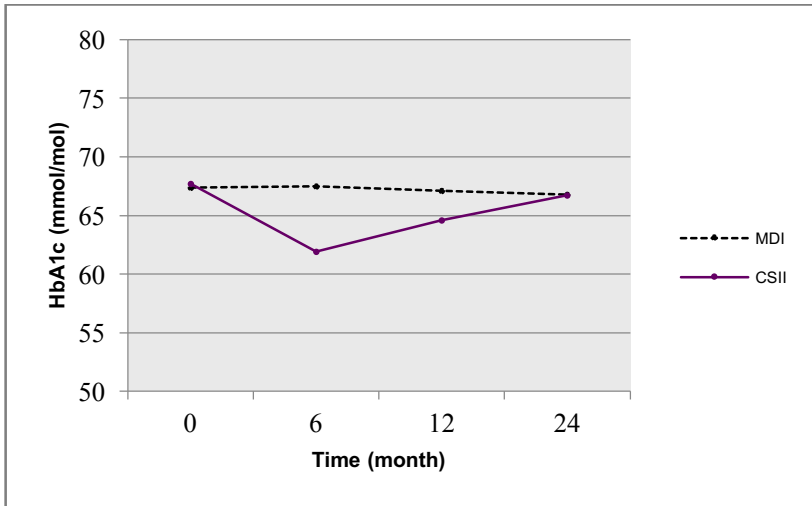
In the study in Paper I, data were collected from 431 participants aged 1.1-17 years. Of these, 216 children and adolescents started CSII treatment and 215 were recruited to the control group on MDI, matched for age, gender, and HbA1c (Table 5). In the CSII and MDI groups, the patients used rapid-acting analogue insulin (Insulin Lispro or Insulin Aspart); further, 91% of the participants in the MDI group used long-acting insulin analogue (Insulin Glagine and Insulin Detemir), and during the study period 4% changed to long-acting insulin analogues.

**Table 5.** Baseline characteristics of the CSII and MDI group, presented as mean (95% CI) for age, diabetes duration, and HbA1c.

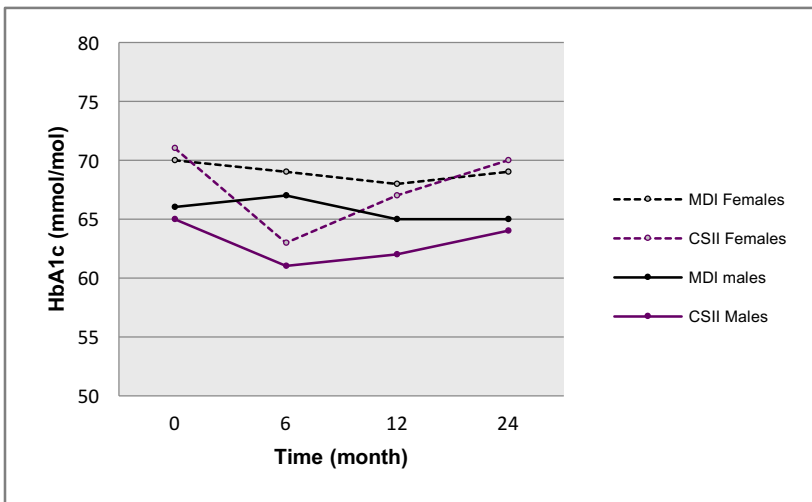
Characteristics	CSII (n=216)	MDI (n=215)	p-value
Female sex, n (%)	103 (48)	103 (47)	
0-6.99 y, n (%)	41 (19)	38 (18)	
7-11.99 y, n (%)	82 (39)	81 (38)	
>12 y, n (%)	93 (43)	96 (44)	
HbA1c $\geq$ 70, n (%)	83 (38)	84 (39)	
<b>Age</b> (range)	10.7 (1.9-17)	10.8 (1.1-16.9)	NS
Female	11.1 (2.6-17)	11.2 (1.1-16.9)	NS
Male	10.3 (1.9-16.8)	10.4 (2.5-16.9)	NS
<b>Diabetes duration</b> (Year)	4.6 (0.1-15.3)	4.1 (0.3-12.4)	NS
Female	4.8 (0.3-15.3)	4.3 (0.3-12.4)	NS
Male	4.5 (0.1-12.2)	4.0 (0.3-12.1)	NS
<b>HbA1c</b> (mmol/mol)	68 (66, 70)	68 (66,70)	NS
Female, mean (95% CI)	71 (67, 74)	70 (66, 73)	NS
Male, mean (95% CI)	65 (63, 68)	66 (63, 68)	NS

In the analysis, differences between the groups were identified at six and 12 months ( $p < 0.001$  and  $0.03$ , respectively) (Figure 5). In respect to changes over time (rANOVA), it was only for boys that a difference was identified ( $p = 0.035$ ) (Figure 6). For boys and girls, individually, a difference could be identified in both groups at six months, but it was only for boys that it remained at 12 months ( $p = 0.023$ ) (Figure 6).

When the study population was divided into age groups ( $< 7$  years, 7-11.99 years and  $\geq 12$  years), it was only at six months that a difference in HbA1c could be identified for participants older than 12 years ( $p < 0.001$ ). For those with HbA1c over 70 mmol/mol at study start, a difference was found at six months between the groups in favour of the CSII group ( $p < 0.0001$ ).



**Figure 5.** HbA1c levels in the CSII and MDI groups.



**Figure 6.** HbA1c levels for boys and girls.

In comparison with baseline, an improvement in HbA1c could be identified in the CSII group after both six and 12 months ( $p < 0.001$ ), while no changes could be identified in the MDI group. Likewise, this could be seen in boys and girls separately. When the study population was divided into age groups, no differences were found in the group with the youngest children ( $< 7$  years). For those in the CSII group aged 7-11.99 years, a difference was detected after six months ( $p < 0.001$ ). For the oldest participants (12-18 years) in the CSII group, improvements were detected after six and 12 months ( $p < 0.001$ ), and in the MDI group after 12 months ( $p < 0.05$ ). For those with HbA1c over 70 mmol/mol at study start, improvements were detected in both groups after six months (CSII:  $p < 0.001$ , MDI:  $p < 0.05$ ) 12 and 24 months ( $p < 0.001$ ).

The numbers of reported ketoacidosis were 2.8 episodes/100 person-years in the CSII group and 0.5 in the MDI group ( $p<0.01$ ). The incidence rates of severe hypoglycaemic episodes per 100 person-years were 3 in the CSII group and 6 in the MDI group ( $p<0.05$ ).

### Paper III

The results presented in this thesis are from six-month follow-up. The data collection from the 12-month results will be completed at the end of 2017, and will therefore be analysed and published later. Seventy-one participants, aged between 11.5 and 18.1 (median 14.9) and starting CSII at the participating hospitals, were recruited. One participant was excluded after the start of CSII due to a diagnosis of MODY-3 diabetes and has not been included in the analyses. Median duration of diabetes was 4.2 years (0.5-14.8). HbA1c and BMI-SDS did not differ between the groups at inclusion. Descriptions of the participants at inclusion are presented in Table 6.

**Table 6.** Baseline characteristics of the-intervention and control groups

Characteristics	All (n=70)	Intervention (n=37)	Control (n=33)	Mann-Whitney U-test, p-value
Female sex, n (%)	42 (60)	20 (54.1)	22 (67)	
Age	14.9 (11.5-18.1)	14.8 (11.5-18.1)	15.3 (11.9-18.1)	NS
Female (n=42)	15.0 (11.8-18.1)	15.0 (11.8-18.1)	15.0 (11.9-18.1)	NS
Male (n=28)	14.8 (11.5-17.6)	14.8 (11.5-17.6)	15.6 (13.1-17.4)	NS
Diabetes duration, yrs	4.2 (0.5-14.8)	4.1 (0.5-12.5)	4.4 (0.9-14.8)	NS
Female	5.2 (0.7-14.8)	4.5 (0.7-12.5)	6.0 (1.0-14.8)	NS
Male	3.1 (0.5-13.5)	3.4 (0.5-12.2)	3.0 (0.9-13.5)	NS
HbA1c* mmol/mol	68 (52-130)	67 (52-101)	69 (56-130)	NS
DCCT %	8.4 (6.9-14)	8.3 (6.9-11.4)	8.5 (7.3-14)	
Female mmol/mol	71 (52-130)	66 (53-82)	72 (56-130)	NS
DCCT %	8.6 (6.9-14)	8.2 (7-9.7)	8.7 (7.3-14)	
Male mmol/mol	67 (52-103)	67 (52-101)	67 (60-103)	NS
DCCT %	8.3 (6.9-11.6)	8.3 (6.9-11.4)	8.3 (7.6-11.6)	
BMI-SDS	0.60 (-2.94-3.14)	0.52 (-1.29-3.24)	0.76 (-2.94-2.89)	NS
Female	0.76 (-2.94-3.14)	0.46 (-1.29-3.14)	1.34 (-2.94-2.89)	NS
Male	0.42 (-1.15-2.51)	0.52 (-1.15-2.51)	0.33 (-0.67-2.4)	NS

\*At inclusion

Of the participants in the intervention group (n=37), 16 participated (43%) in seven sessions, 11 (30%) in six sessions, five (13.5%) in five sessions and five (13.5%) in four sessions. Forty-eight patients (69%) had HbA1c >63 mmol/mol at inclusion, 23 (62%) in the intervention group (median 75, range 64-101), and 25 (76%) in the control group (median 72, range 66-130).

A total of four participants (5.7%) – three in the control group (9.1%) and one in the intervention group (2.7%) – had stopped using CSII and restarted MDI at six months. Twenty patients (28.6%) – 11 in the control group (33.3%) and nine in the intervention group (24.3%)

– used CGM/FGM at baseline, as did 30 (42.9%) at six-month follow-up – 14 in the control group (42.4%), and 16 (43.2%) in the intervention group.

Among all participants there was a decrease in HbA1c after six months with CSII ( $p < 0.001$ ). There were no differences between the intervention and control groups at inclusion or at six months. Among the participants with HbA1c above 63 mmol/mol ( $n=48$ ) at inclusion, there was no difference between the groups at inclusion but there was at six months ( $p = 0.037$ ) (Table 7).

**Table 7.** HbA1c of the intervention and control groups at inclusion and 6 months.

Characteristics	All (n=70)	Intervention	Control	p-value
<b>HbA1c mmol/mol</b>				
Inclusion	68	67 (n=37)	69 (n=34)	NS
6 months	60*	58 (n=37) *	64 (n=32) *	NS
<b>HbA1c &gt;63 mmol/mol (n=48)</b>				
Inclusion	73	75 (n=23)	72 (n=25)	NS
6 months	61*	57 (n=23) *	66 (n=25) *	0.037

\*  $p < 0.01$  compared with study start

There was no difference in HbA1c between those who used CGM at baseline and those who did not (CGM: 64 mmol/mol vs. no CGM: 71 mmol/mol,  $p=0.439$ ), or between those who used CGM at six months and those who did not (CGM: 60 mmol/mol vs. no CGM: 60 mmol/mol,  $p=0.78$ ).

HbA1c did not correlate with HRQoL, measured with DISABKIDS (self and proxy versions) at inclusion. At six months, there was a weak correlation between HbA1c and diabetes acceptance ( $r_s = -0.307$ ,  $p=0.043$ ).

Measuring HRQoL with Check your Health, no correlations were found between HbA1c and the children's perceived HRQoL at baseline. At six months, there were weak correlations between HbA1c and the children's perceived physical health ( $r_s = -0.305$ ,  $p=0.037$ ) and physical burden ( $r_s = 0.374$ ,  $p=0.01$ ).

There were no correlations between HbA1c and DFCS at baseline. The difference in HbA1c between baseline and six months correlated with the difference in DFCS between baseline and six months ( $r_s = 0.479$ ,  $p=0.002$ ). At six months, there was a weak correlation between HbA1c and DFCSdir ( $r_s = 0.311$ ,  $p=0.045$ ).

There was no correlation between HbA1c and the Swe-DES total or any domain at baseline. However, for total Swe-DES a correlation was detected at six months ( $r_s = -0.439$ ,  $p=0.003$ ). Furthermore, there were correlations between HbA1c and goal achievement ( $r_s = -0.475$ ,  $p=0.001$ ) and between HbA1c and readiness to change ( $r_s = -0.487$ ,  $p=0.001$ ).

Multiple linear regression analysis showed that the variations in HbA1c at six months could be explained by participation in the intervention group ( $p=0.001$ ) and total score on the Swe-DES ( $p < 0.001$ ) when adjusted for sex ( $R^2 = 0.45$ ,  $p < 0.001$ ).



## 6.2 HEALTH RELATED QUALITY OF LIFE

### Psychometric test of Check your Health by proxy (Paper II)

We evaluated questionnaires from 197 parent-child pairs to test the psychometric properties of Check your Health by proxy. Characteristics of the children are presented in Table 8.

**Table 8.** Characteristics of the children, presented as mean (95% CI), for age, diabetes duration and HbA1c.

Variables	All (n=197)	Girls (n=95)	Boys (n=102)
Age, years	12.9 (12.6, 13.3)	12.8 (12.3, 13.3)	13.0 (12.6, 13.5)
Diabetes duration, years	5.6 (5.1, 6.2)	5.8 (5.1, 5.6)	5.4 (4.7, 6.2)
HbA1c, mmol/mol	64 (63, 66)	66 (64, 69)	62 (60, 65)

The test-retest (reliability) for Check your Health by proxy for parents was moderate to strong: Physical and emotional health, social relations and QoL with diabetes (0.49–0.54), and burden of diabetes (0.48–0.74). The convergent validity between Check your Health by proxy and DCGM-37 by proxy was low to good (0.15–0.49).

Our hypothesis for discriminant validity was: Parents estimate their children's general QoL lower than the children do; and further, that higher HbA1c and more serious disease are associated with lower self-reported health and higher diabetes burden. This hypothesis was based on results from previous studies (14-16, 170, 176, 177).

The results showed that the parents reported lower scores than the children on emotional health and social relations. Further, the parents estimated a higher burden of diabetes on physical and emotional health and QoL. There was no correlation between HbA1c and self-reported health or burden of diabetes. Poorer social relationships and QoL were associated with higher severity of disease. The diabetes burden domain of Check your Health by proxy (emotional health, social relations and QoL) showed discriminant validity on perceived severity of diabetes.

### HRQoL in an intervention with GSD-Y (Paper III)

When analyses were performed for all children, no differences were identified from baseline to six months in HRQoL or burden of diabetes. At baseline, there were differences between the groups in the domains of equality ( $p=0.008$ ) and physical ability ( $p=0.005$ ) in DISABKIDS (DCGM-37). Furthermore, a difference in physical burden at baseline, measured with Check your Health, was identified between the intervention and control groups ( $p=0.026$ ). In the intervention group, an increase in physical ability was detected from baseline to six months ( $p=0.011$ ).

## Diabetes-related family conflicts and self-efficacy in an intervention with GSD-Y (Paper III)

The degree of family conflicts varied between 19 and 37 with a median of 24 at baseline, and between 19 and 44 (median 24) at six months. At baseline, the intervention group perceived more diabetes-related family conflicts (intervention 25 vs. control 22,  $p=0.037$ ). The degree of conflicts decreased in the intervention group and increased in the control group, but the difference at six months was not statistically significant (intervention 24 vs. control 23,  $p=0.113$ ).

The DFCS scores correlated with those on the Swe-DES, at both baseline ( $r_s=-0.421$ ,  $p=0.002$ ) and six months ( $r_s=-0.54$ ,  $p<0.001$ ).

For total scores on the Swe-DES, there were no differences between the groups at baseline ( $p=0.298$ ) or at six months ( $p=0.265$ ). However, the intervention group perceived a lower degree of readiness to change at study start ( $p=0.026$ ). This difference was reduced after six months, as readiness to change increased in the intervention group ( $p=0.008$ ) and remained unchanged in the control group ( $p=0.772$ ) (Table 9).

**Table 9.** Data of Swe-DES: total, goal achievement, self-awareness, managing stress and readiness to change at study start and 6 months reported as median (range).

Characteristics		Intervention	Control	p-value
<b>Total score</b>	Study start	3.65 (3.0-5.0) (n=28)	3.87 (2.4-4.5) (n=26)	NS
	6 months	3.56 (2.9-4.9) (n=22)	4.0 (2.2-5.0) (n=23)	NS
<b>Goal achievement</b>	Study start	3.7 (2.10-5.0) (n=33)	3.8 (2.3-4.8) (n=27)	NS
	6 months	3.6 (2.5-5.0) (n=22)	3.9 (1.8-5.5) (n=24)	NS
<b>Self-awareness</b>	Study start	4.0 (2.8-5.0) (n=33)	4.0 (2.8-5.0) (n=27)	NS
	6 months	4.0 (2.9-5.0) (n=23)	4.5 (1.8-5.0) (n=24)	NS
<b>Managing stress</b>	Study start	3.75 (2.2-5.0) (n=35)	3.62 (2.5-5.0) (n=28)	NS
	6 months	3.5 (2.2-5.0) (n=23)	4.0 (1.0-5.0) (n=24)	NS
<b>Readiness to change</b>	Study start	3.6 (2.6-4.8) (n=30)	4.0 (1.4-5.0) (n=29)	0.026
	6 months	4.0* (2.4-5.0) (n=22)	3.8 (3.2-5.0) (n=23)	NS

\*  $p=0.008$  compared with study start.

## Parents' perspective of HRQoL in an intervention with GSD-Y (Paper III)

The parents' scoring on DISABKIDS and Check Your Health correlated with the children's scoring. However, the fathers' scoring of burden of diabetes did not correlate in the domains of emotional burden at six months and burden on quality of life at baseline and six months. The fathers perceived the children's burden as lower than the children themselves did, especially in the control group.

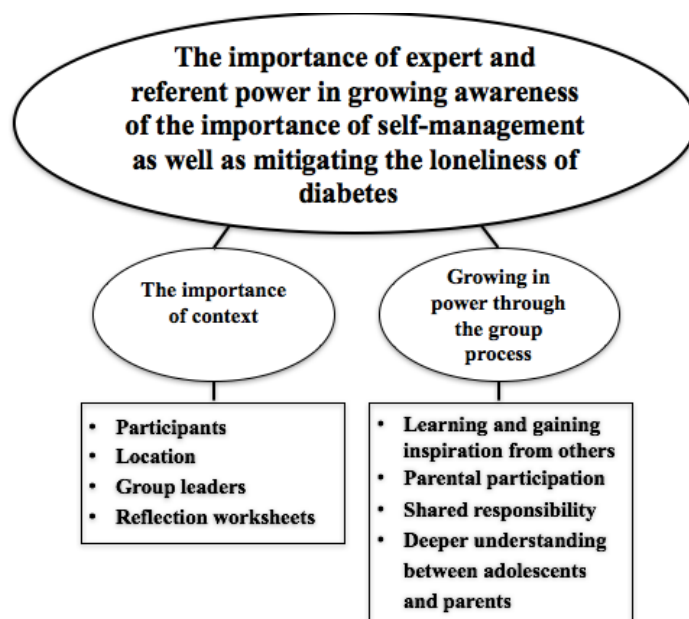
Differences between the groups among the fathers were detected at baseline in the domains of physical ability (intervention 69 vs. control 79,  $p=0.012$ ) and treatment (intervention 62 vs. control 75,  $p=0.034$ ); these differences had disappeared at six months (physical ability, intervention 73 vs. control 73,  $p=0.683$  and treatment, intervention 67 vs. control 71,

p=0.312). Mothers reported a difference in general QoL at baseline, measured with Check your Health (intervention 77 vs. control 84, p=0.037), and this difference had also disappeared at six months (intervention 83 vs. control 89, p=0.463). Among the fathers, a correlation between HbA1c and perceived emotional health at baseline was found, measured with DISABKIDS (rs=-0.393, p=0.005).

### 6.3 QUALITATIVE EVALUATION OF AN INTERVENTION WITH GSD-Y

In Paper IV, 13 out of 37 adolescents who had completed their education sessions with GSD-Y were interviewed.

From the analysis, two categories were revealed – the importance of context, and growing in power through the group process. Meeting others in the same situation is important; it creates a sense of belonging, and mitigates the feeling of loneliness. Sharing thoughts and experiences gives adolescents new ideas and tools for self-managing their diabetes in daily life. An overarching theme that emerged from the interviews was the importance of expert and referent power in growing awareness of the importance of self-management, as well as mitigating the loneliness of diabetes (Figure 7).



**Figure 7.** Description of the overarching theme, main categories, and subcategories emerging in the analysis.

## **The importance of the context**

### *Participants*

The participants reported that meeting others with diabetes in their age group and situation was a positive and enjoyable experience. They experienced both advantages and disadvantages regarding the age distribution. Older adolescents expressed concern that the experience could be difficult as well as exciting and/or instructive for the younger participants, while younger participants described experiencing no barriers between the different age groups

### *Location*

The adolescents found that having the sessions in the hospital was beneficial. Moreover, the groups were mixed and consisted of participants from all the clinics included in the study. Those who attended education sessions in a clinic they did not usually visit perceived this to be a positive aspect of the programme.

### *Group leaders*

Participants emphasized the importance of the role of the group leader, and valued a positive and permissive atmosphere. It was positive that the group leaders were not the same people they usually met at their diabetes clinics. The leaders were therefore perceived as neutral – people with whom they could reflect on their experiences, rather than people whose job it was to take care of them.

### *Reflection worksheets*

Overall, participants reported that the reflection worksheets used in the conversations were useful because they resulted in deeper reflection and allowed them to express themselves in different ways. They helped address issues they would not otherwise have discussed. Many of the younger participants needed help from their parents, both in completing the worksheets and during reflection work in the group. They perceived the reflection worksheets as too long, sometimes difficult to understand, and too time-consuming to fill in.

In one session, the aim of the worksheet was to visually describe the participants' images and thoughts regarding living with diabetes. This was appreciated and described as fruitful by the participants. Furthermore, they expressed that the activity required creativity and made for a pleasurable learning experience, and did not see it as a hard task that had to be completed. When they expressed themselves visually, thoughts and feelings surfaced that would have been difficult to express in words. However, it should be noted that the session involving the visual expression of thoughts and feelings was not considered suitable for all participants.

## **Growing in power through the group process**

### *Learning and gaining inspiration from others*

The importance of meeting other young people in the same situation and sharing experiences of living with diabetes was highlighted by most of the participants. These factors fostered a sense of belonging that could counteract the loneliness of living with diabetes.

Differences in diabetes self-management led to conversations that resulted in the sharing of ideas, knowledge, and advice among participants. In this same manner, participants stated that it felt good to hear how others thought, and to understand that their differences were not always so significant. Similarly, most of the participants perceived the participation in group conversations as worthwhile, inspiring, and encouraging. Several of them described how they had learned to make changes in their diabetes self-management and gained insight into the importance of taking care of themselves based on the group discussions.

Some of the adolescents expressed having felt that their human dignity was based on blood sugar values before the programme; however, after the intervention, blood sugar levels were no longer perceived as a determinant of value.

On one occasion the group was divided into adolescents and parents (session 3). The adolescents found the discussion very fruitful when the group was divided, and described that this separation gave them the opportunity to reflect on subjects they did not wish to discuss in their parents' presence, or on issues linked to their parents.

### *Parental participation*

The adolescents expressed that parental participation in diabetes self-management was important and worthwhile. Further, they believed it was beneficial for parents to share their experiences with other parents of children with diabetes. Several adolescents stated that they perceived that their parents were calmer and more relaxed after participating in the GSD-Y intervention, compared to their demeanour before the intervention. However, the importance of having conversations and sharing experiences with one's parents was also strongly emphasized.

The adolescents stated that their feelings of loneliness decreased after the intervention, and that they noticed the same effect on their parents.

### *Shared responsibility*

After the intervention, the adolescents found that parental responsibility and support became more balanced and transparent. They felt that their parents trusted them more and felt more confident in their abilities, and that the effect on the distribution of responsibilities varied; in some cases it had increased or decreased while in others it was unchanged. Parental support was viewed as relevant, based on the adolescents' responses. Parents are a source of security, advice and support, and the adolescents expressed that they would feel alone without this

support. A young person's need for support and cooperation with his/her parents is of the utmost importance. However, the adolescents had difficulty describing the ways their families distributed responsibility.

*Deeper understanding between adolescents and parents*

The adolescents expressed that they had gained a better understanding of their parents' anxiety and behaviour after having listened to their thoughts and experiences. They also described the benefits of hearing the experiences of the parents of other adolescents. Consequently, relationships and communication between adolescents and parents had changed, resulting in less nagging and fewer conflicts. The adolescents experienced an improved level of understanding from their parents regarding how young people think about diabetes. Some of the adolescents described that their diabetes self-management had previously been handled in the way their parents wanted, which had led to conflicts. After participating in the education programme, however, the adolescents' autonomy had increased and their parents supported this.

One clear result that emerged was that nagging takes on another dimension once you understand the reasons behind it. This understanding also resulted in experiences of fewer conflicts.

## 7 DISCUSSION

The overall aim of this thesis was to increase the knowledge regarding glycaemic control, type of treatment, HRQoL, and a theory-based education among youth with type 1 diabetes.

The main results initially show an improvement in glycaemic control for patients using CSII compared with MDI treatment. GSD-Y in connection with the start of CSII has the potential to further improve glycaemic control. Furthermore, GSD-Y increases the readiness to change, mitigates experiences of loneliness, and contributes to conscious reflections about self-management in the group (referent power) together with the group leader (expert power). For children and adolescents, it is important to have possibilities to measure HRQoL from the perspective of both the youths and their parents, and Check your Health may be useful in doing this, in both studies and clinical settings.

### 7.1 GLYCAEMIC CONTROL

There are few studies comparing CSII and MDI for a period of more than one year and using analogue insulin for both groups (66, 67). The study by Jakish et al. is consistent with Paper I: an improvement in HbA1c was initially identified, but thereafter subsequently deteriorated. However, information about type of insulin is not reported in this study (69). It may be of interest to consider whether it is the start of CSII, the education, or the fact that the participants' sense of importance due to involvement in a study that has the effect. Johannesen et al. gave a brush-up course to all participants before the start of the study. In both groups, a non-significant reduction in HbA1c was identified (70). In the same manner, Weintrob et al. offered a diabetes course three months before study to motivate participants to maintain a strict practice of blood glucose tests and adjust their insulin doses. The HbA1c levels at study start were significantly lower than before the course. There were no significant improvements in HbA1c during the study (178). At any rate, it should be emphasized that regardless of glycaemic control when being treated with CSII, it seems to have a long-term effect on the risk of microvascular complications as well as morbidity and mortality in cardiovascular disease (64, 65).

Further, it is important to reflect on the results of the study performed by Johnson et al., in which the participants in the whole group sustained their improved HbA1c for the whole follow-up period of seven years. Like the study presented in Paper I, this was a 'real-world' study. The authors describe that the team considered the patients' suitability for pump therapy before a decision was taken; however, it is difficult to say whether this was the reason for the sustained improved HbA1c during the long follow-up (72).

In Paper I, a gender difference was identified from baseline to the end of the study. In this case, the education cannot be the reason for the difference, since it was the same for

everyone. However, a gender difference is also presented in SWEDIABKIDS (2). In Sweden, a gender difference has been identified already at the diagnosis of type 1 diabetes (30). Undoubtedly, boys can maintain improved HbA1c longer than girls can. One conclusion we can draw from this is that girls and boys, different individuals, may need different types of education. Diabetes-related education needs to be more person-centred, which is consistent with recommendations by ISPAD (17).

In line with the above, a multicentre prospective RCT was performed, aimed at evaluating an intervention with GSD-Y in groups of adolescents starting CSII and their parents (Paper III). We found that the GSD-Y intervention – slightly but not significantly – improved HbA1c; however, among those with HbA1c above 63 mmol/mol at inclusion, a significant difference was detected between the groups favouring the intervention. Higher HbA1c is a significant risk factor for late complications (10, 11), and if an intervention with GSD-Y in connection with the start of CSII has the ability to decrease HbA1c and maintain this reduction for more than six months, it is a highly promising tool. There have been several studies carried out using different psychosocial education methods that have not been able to demonstrate an improvement in glycaemic control. The number of visits to the clinic could be a factor that affects glycaemic control; however, results from other studies have shown that the number of visits does not seem to have significance for glycaemic control (152-158, 162, 163).

In the study in Paper III the attendance was high, with 73% of participants attending more than five of the seven sessions. The CASCADE study involved 28 centres, and the intervention consisted of four sessions. Of its included participants only 30% attended all sessions in the intervention group, and 53% attended at least one session (154). Our first three sessions were held in connection with starting CSII, and the study involved only three centres in the same area. Further, the families perceived that starting CSII treatment and education were a coherent concept. Families usually experience starting CSII as a positive event, and it may be easier to carry out an educational intervention and achieve higher attendance for this in connection with other changes, when there already exists a ‘window of opportunity’. It is difficult to conclude whether the level of participation had any effect on glycaemic control. Unfortunately, sociodemographic data were not collected; therefore, it is not possible to draw any conclusions as to whether there was an association between participation and parents’ education or family structure.

While it could be expected that the use of CGM should decrease HbA1c values, the current study was not able to show any differences between the use and no use of CGM. One explanation for this could be that having high HbA1c was an indication for the use of CGM; another could be that those who used CGM had not received the correct support or information for its use (82).



## **7.2 HEALTH-RELATED QUALITY OF LIFE**

Viklund et al. showed that the lower the HbA1c, the better the perceived physical health and the lower the burden of diabetes (16). Studies measuring HRQoL before and after the start of CSII have shown divergent results. Some have shown an increase in HRQoL (179) while some have not (178, 180). Other studies have shown correlations between HbA1c and family conflicts (106-108, 111, 112, 121, 181, 182). The study in Paper III showed a correlation between the difference in HbA1c between baseline and six months, and the difference in perceived family conflicts during the same time. There was also a weak correlation between HbA1c and family conflicts at six months. The degree of reported family conflicts was rather low from the start, which might explain the difference in results compared with other studies. At baseline the intervention group perceived more diabetes-related family conflicts, but the degree of conflicts decreased in the intervention group whilst it increased in the control group; however, the difference at six months was not statistically significant. The GSD intervention may have had an impact on the perceived conflicts.

The degree of perceived diabetes-related conflicts correlated with self-efficacy measured with the Swe-DES, which is consistent with the results of previous research (119). The degree of self-efficacy seems to be important for achieving recommended glycaemic control (120). The intervention group increased their degree of readiness to change, which has previously been demonstrated in an empowerment-based education programme for adolescents (153). In the study by Husted et al., in which GSD-Y was used individually, the intervention group increased their motivation (152).

The parents' scoring of their children's HRQoL in Paper III correlated to the children's own scoring, which was also shown in Paper II. However, the respective scoring of the burden of diabetes in Paper III did not correlate between the fathers and the children. The fathers perceived the children's burden as lower than did the children themselves. The opposite was found in Paper II, with the parents scoring a higher burden than the children. This was mainly noticed in the control group in Paper III; perhaps the fathers in the intervention group had had the possibility to learn more about how their children perceived their disease burden.

## **7.3 PERCEPTIONS OF AN INTERVENTION WITH GSD-Y**

Our analysis in Paper IV revealed one overall theme to describe adolescents' perceptions and experience of participation in a group-based GSD-Y education. The theme is formulated as follows: the importance of expert and referent power in growing awareness of the importance of self-management as well as mitigating the loneliness of diabetes.

In order to, interpret and understand the results in Paper IV, we have used theoretical frameworks based on Barrett, and French and Raven (134, 137, 138). Barrett defines power in healthcare as 'the capacity to participate knowingly in change', including four interrelated dimensions – awareness, choices, freedom to act intentionally, and involvement in creating

change (134, p. 148). Another dimension of the concept is social power, described by French and Raven (1959), who divide it into five forms. Two of the forms – referent and expert power – are relevant in the context of this paper. Referent power is defined as the ability of some individuals to be a reference for others; they can induce changes in the attitudes, values, and decisions of others. Expert power is knowledge resulting from experience or education (137, 138).

The adolescents in Paper IV highlighted the need to meet others in the same situation as themselves and to share experiences, which has also been shown in previous studies including adolescents and their parents as well as adults (155, 183, 184). Participants emphasized that meeting others offers space for reflection and conversations about both concrete, everyday issues such as feelings and thoughts, and for taking responsibility for one's diabetes self-management. In our analysis, based upon the theoretical framework, it became clear that this is of importance for increasing referent power. A prerequisite for creating space regarding referent power in a group is the group leaders' competence and approach, i.e. expert power. This is in line with the GSD method, which highlights the group leaders' role in guiding the participants to reflect in a way that leads to decisions (147). Similarly, Lowes et al. describe that good communication with healthcare professionals made the visit more valuable (23).

The adolescents appreciated the reflection worksheets and found them to be a valuable tool in conversations. The worksheets highlighted things that otherwise would not have been mentioned, and helped in a structured way to deepen the dialogue, leading to clarifications about current, real problems experienced when living with diabetes. These results confirm that the reflection worksheets are tools that can help in overcoming barriers, as described in previous research (146, 151). Lowes et al. have shown that young people feel positive about preparing for the visits using pre-formulated questions. They wanted to know what they were expected to talk about (23).

The analysis in Paper IV revealed an additional success factor of the GSD-Y, when participants were invited to describe their thoughts about a life with diabetes through words or images (Table 3, Session 4). Several of the adolescents experienced visually describing things as liberating and creative. In this context, it was a new, positive way to prepare their reflections. They felt it was undemanding, and led to new ideas. These results are consistent with the study by Piana et al. that described how adolescents experienced describing their diabetes in words as stressful, but at the same time found that verbally describing their thoughts was liberating and that their self-image and relationships with others and the disease benefited from it (185). Buber argues that humans want to create, and that this is a natural way to 'learn'. Visually expressing themselves without expectations creates a natural way for humans to express themselves and, because of this, allows them to reflect and learn (144).

A common factor among participants that emerged in our study was a feeling of loneliness, likewise difficulty handling diabetes self-management in everyday life. In the analysis, according to referent power and Barrett's theory (134, 137, 138), we interpret that reflections

and dialogues – including giving advice to each other – create an arena for making choices about what changes they want to make, supporting them in the freedom to choose whether they want to do this and, thereafter do it intentionally. In general, the analysis showed that these factors were of importance in mitigating loneliness and increasing awareness of self-management. Consequently, through referent power and expert power, a person may get support to become empowered, and create prerequisites for achieving increased self-efficacy. Perceived self-efficacy, defined by Bandura, is ‘people’s beliefs about their capabilities to produce designated levels of performance that will have influence on events that affect their lives. Self-efficacy affects how people feel, think, motivate themselves, and behave’ (186, p. 71-81).

Parents were considered to have become more aware of the adolescents’ viewpoints and experiences, and the adolescents perceived positive changes in their parents’ demeanour after participating in GSD-Y. Previous research has shown that parents are worried about their adolescents’ futures and the possibility of developing complications (187). The adolescents appreciated parental participation and found it valuable, which led to an increase in their mutual respect for and understanding of each other and improved communication, resulting in a modified distribution of responsibilities, which reduced nagging and conflicts. Adolescents with greater diabetes-related responsibilities and more conflicts take fewer blood glucose tests and have poorer blood glucose control (112). Constructive communication between parents and adolescents seems to be an important component in diabetes self-management (95, 188). This emphasizes the importance of parental involvement and constructive parental support (95, 96, 122, 188). As a contrast, a study of a group education programme not involving parents had no effect on glycaemic control or empowerment outcomes (153).

In conclusion, GSD-Y has, in different ways, facilitated experiences of loneliness and contributed to conscious reflection about self-management in the group (referent power) together with the group leader (expert power). Overall, this highlights the benefits of group education, and the GSD method emphasizes the person-centred approach.

## **7.4 METHODOLOGICAL CONSIDERATIONS**

### **Paper I**

In Paper I, all children and adolescents who started CSII treatment during the entire study period were included, which resulted in a relatively large number of participants. The types of insulin for the participants in the control group on MID were: direct-acting insulin analogues for meals, and a majority with long-acting analogues once or twice a day. Comparing results between studies of similar design can be discussed, as the treatment is not equivalent or clear regarding the type of insulin (69, 72).

Even though this was not an RCT, which is the gold standard, and power calculations were not performed, the study population was 431 individuals and therefore the results are relevant for the whole group. However, when divided into different subgroups they were too small for any difference to be detected.

## **Paper II**

Check your Health has four domains with only one item each, measuring physical and emotional health, social relations, and QoL. The respondents decide how to interpret the single item in each domain. Further, in the DCGM-37, there are six to seven items in each domain. It could be discussed whether these two highly different ways of design are comparable. On the other hand, there are very few measures that have been translated and validated for youth with type 1 diabetes in Sweden (14, 15).

In Paper II the physical domain has the weakest correlation; however, the same was detected when psychometric properties were evaluated for Check your Health on adolescents (16). When the questionnaire was validated on adults, good consistency was identified; however, in that study the physical domain in Check your Health was compared with one item in the SF-36 ('How is your general health today?'), and this item may be closer to the one in Check your Health (56). It is unusual for children and adolescents with diabetes to experience major physical problems (14, 16). They rarely have long-term complications due to diabetes. Therefore, some questions may be perceived as irrelevant if they can run around as they wish, or if they sleep well. In Sweden, young persons with type 1 diabetes manage a great deal of their diabetes self-management themselves and rarely need help. One reason for the weak correlation of convergent validity may be that Check your Health likely measures health more generally than the DCGM-37. The results in Paper II are consistent with previous research, except regarding emotional health, whereby the children and adolescents in Paper II scored higher (16). However, this may be because they were younger in the present study.

As mentioned, a limitation of this study was the shortage of questionnaires validated and translated into Swedish. Therefore, it was difficult to find a suitable questionnaire to analyse convergent validity. Further, Check your Health is only available in Swedish and it is therefore not possible to make any comparisons with studies from other countries. The test-retest reliability may have been affected by the circumstances that the questionnaires were completed at the hospital and the re-test was completed in the participants' homes.

## **Paper III**

One of the foremost strengths of this study was the RCT design, which ensures that the two groups (intervention and control) are comparable regarding age, sex, and diabetes-related data such as duration since diagnosis and HbA1c. As the dropout rate was negligible, the risk of selection bias was greatly reduced. The choice of research design creates the prerequisite for the outcome to be generalized to young people starting CSII treatment and receiving a GSD-Y education.

However, there are critical considerations that may have affected the results. In general, there are pros and cons to clinical studies. A difficulty encountered in this study was that there were changes in the diabetes care – e.g., a national project including all clinics working with children and adolescents with diabetes resulting in changed treatment goals, increased use of carbohydrate counting and CGM – resulting in the recruitment of participants over a long period of time, which may have affected the result. Further, there were several who were positive to participate in the study, but declined before the randomization. Power calculation indicated that each group had to contain at least 37 participants. Due to the mentioned factors and the reliability of the result we decided to close the study inclusion in November 2016 even though we did not reach the desired number of participants.

In addition, we did not ask the participants about specific events (such as those related to school, family, or individual life events, etc.) that occurred during the intervention period that could have affected the results, and we did not collect demographic data such as parents' education level or socioeconomic status.

Major psychological and physiological changes occur during adolescence, which may have affected the outcome. On the other hand, the age distribution was similar in both groups, which would indicate that these types of changes would be equivalent in the two groups.

Although we used validated questionnaires, bias might be observed from pre- to post-test, simply due to the nature of the instrument. There is also a risk of regression to the mean, which means a tendency for participants whose scores lie at either extreme to score nearer the mean when measured a second time. While we have collected data on family conflicts from the adolescents there is no collected data on this subject from the parents, which might have provided additional interesting information for the results.

## **Paper IV**

In Paper IV, as we wanted to explore whether there was a pattern in adolescents' experiences of participation in the intervention, we chose qualitative content analysis (165, 174). One of the highlighted advantages of qualitative content analysis is that it is sensitive to the content and flexible in design, and is today an established method (189).

We have strived to achieve trustworthiness (credibility, dependability, confirmability, and transferability) by describing the analytical process in detail, providing quotations from the interviews (Paper IV), involving several researchers in the analyses, and describing the sample and context in as much detail as possible (165, 174). As the study was small-scale, the potential transferability of the findings may be limited. However, previous research using the GSD model has shown promising results (146, 151).

While most of the interviews were conducted in close proximity to the intervention – within a few months – one participant was interviewed after a year. This could be a weakness, but none of the researchers involved in the analyses noted any major differences. The different intervals between intervention and interviews may have increased trustworthiness; the results

were consistent despite the varying intervals. Further, the parents were not interviewed; if they had been, this might have increased the trustworthiness of the results.

When participants were selected, we used purposeful sampling with maximum variation. The interviewed adolescents were distributed equally according to gender, and there was a variation in age.

A weakness was that participants' demographic data were not collected; this could have been interesting to add to the results. Another limitation of the study was that the participants were aware of the researchers' involvement in the intervention, which may have affected the results.

Two researchers conducted the first three interviews. While they got the impression that this did not affect the adolescents, having two adults present could have hindered the adolescents in expressing their perspectives. None of the researchers who conducted the interviews had a close relationship with the adolescents.

## 8 CONCLUSIONS AND CLINICAL IMPLICATIONS

- Treatment with CSII may initially result in improved HbA1c and a decreased number of severe hypoglycaemic events; however, the frequency of ketoacidosis can increase.
- The Guided Self-Determination-Young method have the potential to be a useful tool for adolescents starting CSII treatment in group together with their parents for improving HbA1c, mitigating the loneliness of diabetes, and contributing to conscious reflection about self-management.
- The instrument Check your Health by proxy is a reliable and valuable tool for measuring perceived physical and emotional health, social relations, and general QoL and burden of diabetes. This PROM could be valuable to use in future studies, and may also be useful in a clinical context as it is not time-consuming to complete and is easy to interpret.

## 9 FUTURE STUDIES

- It is of great interest to evaluate whether the positive results of Paper III will remain at the 12-month follow-up. The final data will be collected at the end of 2017, and will thereafter be analysed and published.
- Alternative ways to offer education with the GSD-Y would be of great interest, as many young persons have difficulty prioritizing hospital visits. Therefore, it would be great interest to test the method virtually.
- It would be of interest to further investigate the level of empowerment (measured with Swe-DES) and its correlation with glycaemic control in youths with type 1 diabetes.
- Further studies are needed to investigate factors contributing to loneliness in adolescents living with diabetes and explore whether young people with type 1 diabetes feel more lonely than young people without diabetes.

# 10 SVENSK SAMMANFATTNING

## Bakgrund

För en person med typ 1-diabetes är det en ständig kamp, ett livslångt projekt att uppnå en optimal egenvård, acceptabel glukoskontroll, leva ett bra liv och på kort och lång sikt undvika komplikationer. Egenvården inkluderar att ta beslut om måltidsdoser, justera höga blodsocker och ständigt ha kontroll över glukosnivån.

Det finns 7310 (2016) barn och ungdomar (0-18 år) med diabetes i Sverige. Behandling med insulin ges med insulininjektioner flera gånger per dag eller med insulinpump. Vid insulinpumpbehandling tillförs insulinet kontinuerligt, vanligtvis via en plastkanyl som sitter i underhuds fettet. För måltider eller när blodsockret ligger för högt programmeras en dos manuellt. År 2016 behandlades 60,9 % av barn och ungdomar med typ 1-diabetes i Sverige med insulinpump.

HbA1c är ett sätt att mäta hur glukoskontrollen varit under två till tre månader. Internationella rekommendationer för barn och ungdomar är HbA1c <58 mmol/mol. Under de senaste åren har rekommendationerna i Sverige sänkts till HbA1c ≤48 mmol/mol (normalreferens 31–38,6 mmol/mol). Flera studier visar att höga glukosnivåer under tonåren ökar risken för komplikationer senare i livet. Utöver detta finns risk för akuta komplikationer som hypoglykemi (lågt blodsocker) och ketoacidosis (syraförgiftning), där hypoglykemi är vanligast. Hypoglykemier påverkar vardagen och är en begränsande faktor för att nå optimal glukoskontroll. Ketoacidosis är ett livshotande tillstånd och orsakas av insulinbrist. Orsaken kan vara uteblivna insulin doser eller fel som uppstått vid insulinpumpbehandling.

Trots stora tekniska framsteg inom diabetesbehandlingen, når mindre än en tredjedel av ungdomar ≥12 år med typ 1-diabetes den rekommenderade glukosnivån (HbA1c ≤48 mmol/mol). Hos ungdomar med insulinpumpbehandling är uteblivna måltidsdoser en anledning till bristande glukoskontroll. Därutöver är diabetesrelaterade konflikter inom familjen en känd riskfaktor för höga glukosvärden. Ansvarsfördelningen för diabetes egenvården mellan ungdomar och föräldrar är ofta oklar och behöver tydliggöras. Föräldramedverkan och konstruktiv kommunikation under tonårstiden ökar sannolikheten att den unge med diabetes att uppnå god glukoskontroll.

Utbildning till barn och ungdomar med typ 1-diabetes är nyckeln till framgång i diabetes egenvården. Den bör vara strukturerad, personcentrerad och flexibel. Personcentrerad vård framhåller vikten av att lära känna personen bakom patienten och att engagera denne i sin egen vård och behandling.

I patientutbildning med personer som har en kronisk sjukdom är det viktigt att lyfta fram personens egen inneboende kraft, 'power', definierat som 'förmågan att medvetet delta i förändring'. Två former av power som kan vara av betydelse i patientutbildning är empowerment och social power. Inom diabetesvården är den vanligaste definitionen av empowerment: 'Att upptäcka och använda sin inneboende förmåga för att ta kontrollen över



sitt liv' (Funnell och Anderson). Två former av social power är referent power och expert power. Referent power är förmågan att vara en referens och ha avgörande betydelse för andra, vilket kan medföra förändringar i attityder, värderingar och andra beslut. Expert power är kunskap från en person som har erfarenhet eller utbildning.

Guided Self-Determination (guide till självbestämmande, GSD) är en empowermentbaserad, personcentrerad, reflektions och problemlösande utbildningsmetod avsedd att guida patienten till självbestämmande och utvecklande av livskunskap för att hantera svårigheter i diabetesseguvården. I metoden används arbetsblad och kommunikationsmetoder (spegling, aktiv lyssning och värderingsförklaring). GSD är en hjälp för patienten och vårdpersonalen att övervinna hinder till empowerment. Metoden finns anpassad för ungdomar (GSD-Y). I en studie individuellt med ungdomar och deras föräldrar gav GSD-Y ingen minskning av HbA1c. GSD-Y förbättrade dock motivationen till diabetesseguvården och gav ökad livskunskap, vilket innebar en ny relation till vårdpersonalen och föräldrarna, ökad förmåga till att ta beslut och personlig mognad.

Det övergripande syftet med denna avhandling var att öka kunskapen om glukoskontroll, olika typer av diabetesbehandling, hälsorelaterad livskvalitet och en teoribaserad utbildning för ungdomar med typ 1-diabetes. För detta genomfördes fyra delstudier

I **studie I** undersöktes långsiktig effekt på glukoskontroll, ketoacidosis, allvarliga hypoglykemiska episoder, insulinbehov och BMI-SDS hos barn och ungdomar med typ 1-diabetes som startat behandling med insulinpump jämfört med barn och ungdomar som behandlas med insulininjektioner. Data samlades in från 216 barn och ungdomar som startat insulinpumpbehandling. Dessa matchades för ålder, kön och HbA1c med en kontrollgrupp med 215 deltagare som behandlades med insulininjektioner.

Resultatet visade att efter sex och 12 månader fanns en skillnad mellan grupperna till fördel för dem som startat insulinpumpbehandling. När gruppen delades in i kön kunde en skillnad ses för både flickor och pojkar efter sex månader, men det var bara för pojkarna en skillnad kunde ses efter 12 månader. När gruppen delades in i olika åldersgrupper (<7 år, 7-<12 år och ≥12 år) var det bara efter sex månader en skillnad i HbA1c kunde ses för deltagare 12 år och äldre. Antalet ketoacidoser var fler i insulinpumpsgruppen än i injektionsgruppen (2,8 vs. 0,5 episoder/100 personår). Förekomsten av svåra hypoglykemier var färre i insulinpumpsgruppen 3 vs. 6 episoder/100 personår).

I **Studie II** testades validiteten (giltigheten, mäter frågeformuläret det som är avsett att mäta) och reliabiliteten (tillförlitligheten) hos frågeformuläret 'Ta tempen på din hälsa' (föräldraversionen) på föräldrar till barn och ungdomar med diabetes. Frågeformulär från 197 föräldrar och deras barn utvärderades. Reliabiliteten var måttlig till stark. När validiteten testades visade resultaten att föräldrarna rapporterade lägre än barnen på känslomässigt välbefinnande och sociala relationer. Föräldrarna skattade en högre diabetesbörda på fysisk hälsa, känslomässigt välbefinnande och generell livskvalitet än barnen. Tidigare studier har

också visat att föräldrar skattar sina barns hälsa och livskvalitet lägre än barnen själva vilket stärker validiteten av 'Ta tempen på din hälsa' (föräldraversionen).

I **studie III** utvärderade om en utbildning med metoden GSD-Y i grupper med tonåringar som startar insulinpumpbehandling och deras föräldrar leder till förbättrad glukoskontroll, ökad upplevd hälsa och hälsorelaterad livskvalitet, färre diabetesrelaterade familjekonflikter och förbättrad tilltro till egen förmåga.

I studien deltog 71 ungdomar som startade insulinpumpbehandling tillsammans med sina föräldrar. De delades in i grupper med tre till fem ungdomar och deras föräldrar i varje grupp. Därefter lottades de till att delta i en utbildning med metoden GSD-Y eller till kontrollgrupp som följdes enligt ordinarie rutiner. Av dessa hade 48 ungdomar (69 %) HbA1c över 63 mmol/mol, 23 (62 %) i utbildningsgruppen och 25 (76 %) i kontrollgruppen.

Utbildningsgruppen träffades för GSD-Y samtal i anslutning till start av insulinpumpbehandling (tre tillfällen) och vid fyra tillfällen de första fyra månaderna därefter. Före varje GSD-Y samtal fyllde deltagarna i olika reflektionsblad anpassade för varje utbildningstillfälle. Dessa användes som samtalsunderlag i utbildningen.

HbA1c värdet vid sex månader kunde till 45 % förklaras av deltagande i utbildningsgrupp (deltagande gav lägre HbA1c) och tilltro till egen förmåga (bättre tilltro till egen förmåga gav lägre HbA1c). Bland deltagarna med HbA1c över 63 mmol/mol vid studiestart hade utbildningsgruppen ett lägre HbA1c än kontrollgruppen efter sex månader, 57 mmol/mol hos utbildningsgruppen jämfört med kontrollgruppens 66 mmol/mol.

Poängbedömningen av diabetesrelaterade familjekonflikter kan variera mellan 19 (inga konflikter) och 57 (högsta grad av konflikter). I denna studie varierade konflikterna mellan 19 och 37 vid studiestart och 19 och 44 vid 6 månader. Vid studiestart fanns en skillnad mellan grupperna med en median på 25 i utbildningsgruppen jämfört med 22 i kontrollgruppen. I utbildningsgruppen minskade konflikterna och i kontrollgruppen ökade de, vid sex månader kunde ingen statistisk skillnad ses mellan grupperna.

I denna studie mättes även tilltro till egen förmåga med frågeformuläret Swe-DES. Vid sex månader kunde ett samband ses mellan HbA1c-värde och tilltro till egen förmåga. Dessutom kunde ett samband ses mellan HbA1c och förmåga att identifiera och lösa problem samt mellan HbA1c och förändringsbenägenhet.

Vid studiestart beskrev utbildningsgruppen en lägre grad av förändringsbenägenhet än kontrollgruppen. Efter sex månader hade förändringsbenägenheten ökat i utbildningsgruppen, men var oförändrad i kontrollgruppen.

I **studie IV** intervjuades 13 ungdomar som deltagit i utbildningsgruppen i studie III. Syftet var att beskriva ungdomars uppfattningar om deltagande i grupputbildning med metoden GSD-Y tillsammans med föräldrar i samband med start av insulinpumpbehandling.

I resultatet framkom två kategorier – ‘vikten av sammanhang’ och ‘växande power’ genom grupprocessen (figur 6 tidigare i avhandlingen). Att träffa andra i samma situation är viktigt; det skapar en känsla av tillhörighet och lindrar känslan av ensamhet. Att dela tankar och erfarenheter leder till nya idéer och verktyg för att hantera sin diabetes i det dagliga livet. Ett övergripande tema som framkom var ‘vikten av expert (gruppledarna) och referent (övriga deltagare) ‘power’ för ökad medvetenhet av betydelsen av egenvård, samt för att mildra ensamhetskänslan vid diabetes’.

Deltagarna betonade vikten av gruppledarens roll och uppskattade en positiv och tillåtande atmosfär. Arbetsbladen som användes i samtalen var användbara eftersom de ledde till en djupare reflektion. De hjälpte till att ta upp frågor som de inte annars skulle ha diskuterat. Vid ett tillfälle var syftet att beskriva bilder och tankar om att leva med diabetes. Detta uppskattades och beskrevs som värdefullt av deltagarna. När de uttryckte sig med bilder och text uppkom tankar och känslor som hade varit svåra att uttrycka verbalt.

Ungdomarna uttryckte att föräldrarnas delaktighet i diabetesegenvården var viktig och värdefull. Dessutom trodde de att det var värdefullt för föräldrarna att dela sina erfarenheter med andra föräldrar till barn med diabetes. Flera ungdomar beskrev att de upplevde sina föräldrar lugnare och mer avslappnade efter att ha deltagit i utbildningen med GSD-Y.

Efter utbildningen upplevde ungdomarna att ansvarsfördelningen och föräldrarnas stöd blev mer balanserat och transparent. De upplevde att föräldrarna litade på dem vilket ledde till ökad tilltro till sin förmåga. Ungdomarna uttryckte att de hade fått bättre förståelse för föräldrarnas oro och beteende efter att ha hört deras tankar och upplevelser.

Relationen och kommunikation mellan ungdomar och föräldrar, förändrades under utbildningen, vilket resulterade i mindre tjat och färre konflikter. Ungdomarna upplevde en bättre förståelse från sina föräldrar om hur ungdomar tänker om diabetes. Ett tydligt resultat som framkom var att tjat får en annan dimension när du förstår orsakerna bakom tjtet. Denna förståelse resulterade också i erfarenheter av färre konflikter.

Sammanfattningsvis har resultaten i denna avhandling visat att behandling med insulinpump initialt kan resultera i förbättrat HbA1c. GSD-Y kan vara ett användbart verktyg för ungdomar som startar insulinpumpbehandling i grupp tillsammans med sina föräldrar för att förbättra HbA1c, mildra ensamhetskänslan vid diabetes och bidra till medveten reflektion om egenvården.

Frågeformuläret ‘Ta tempen på din hälsa’ (föräldraversionen) är tillförlitligt och säkert för att mäta upplevd fysisk hälsa, känslomässigt välbefinnande, sociala relationer, generell livskvalitet och diabetesbörda. Det kan vara värdefullt att använda i framtida studier och kan också vara användbart i ett kliniskt sammanhang eftersom det inte är tidskrävande att fylla i och är lätt att tolka.

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