Children and adolescents with diabetes, current state and future possibilities.

A study of factors affecting health-related quality of life, competences and treatment results in children and adolescents with type 1 diabetes.

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Dag Helge Frøisland, 121212

Innhold

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Dag Helge

Children and adolescents with diabetes, current state and future possibilities

A study of factors affecting Health-Related Quality of Life, competences and treatment results in children and adolescents with type 1 diabetes

Thesis for the Philosophiae Doctor (PhD) degree at the University of Oslo.

Summary

This thesis focuses on patient-reported outcome measurements. Through self-report questionnaires, quantitative and qualitative methods we have gained an insight into young people with type 1 diabetes' (T1D) self-perceived understanding of health-related quality of life and their experiences of own treatment.

Health-Related Quality of Life (HRQOL) of children and adolescents with type 1diabetes (T1D), and the association between HRQOL and mode of treatment, achievement of treatment goals and social situation, were assessed through questionnaires completed by the patients and one of their parents. Patients were recruited from 21 out of 27 paediatric clinics in Norway, and data obtained from the questionnaires were linked to data on diabetic control registered in the Norwegian Childhood Diabetes Registry (NCDR). To assess HRQOL, the European DISABKIDS Generic Module (DCGM-37) and Diabetes-Specific Module (DDM-10) were used after translation into Norwegian and validation against the Child Health Questionnaire 87 and its parent form, which have been widely used in Norway.

In addition, a group of adolescent patients' experiences with two different mobile phone applications used for diabetes care were evaluated in a qualitative study.

The psychometric properties of the DISABKIDS instruments were found to be valid and reliable in the Norwegian population (study 1). Through the second study, conducted in cooperation with the NCDR we were able to assess HRQOL measured by the DISABKIDS instruments in a large cohort of young people with T1D. Out of 1967 eligible patients, 937 (48%) responded. Boys experienced higher HRQOL than girls, but for both genders poor metabolic control was associated with impaired HRQOL. No association was found between HRQOL score and treatment modality (i.e. insulin pump versus multi-injections) in this

intensively treated population. Parents scored their children's HRQOL as poorer than the children themselves. Compared to similar studies elsewhere in Europe, the Norwegian children scored similarly on the DCGM-37, but considerable discrepancies were found when comparing the DDM-10 subscales. The low score on the DDM-10 treatment scale indicates that the Norwegian population is less adaptive to their treatment (i.e. carrying their equipment and planning their treatment).

Twelve adolescents participated in the qualitative study on the development of, and their experiences with, two mobile phone applications as a means of contact and guidance between themselves and the physician. The results suggest that the mobile phone-based diabetes diary gave the participants a new understanding of the cornerstones of treatment through visual impression.

The studies suggest that HRQOL issues are important both for psychosocial well-being and for achieving treatment goals, and therefore that assessment of HRQOL should be an integral part of clinical practice. The experience with the mobile phone application suggests that this method may be a way to further develop new educational and communication strategies for young people with diabetes and their health care providers. However, randomized intervention studies are needed to evaluate the applicability and potential benefits of such novel methods in clinical practice.

List of papers

Paper 1

Froisland DH, Markestad T, Wentzel-Larsen T, Skrivarhaug T, Dahl-Jørgensen K, Graue M. Reliability and validity of the Norwegian child and parent versions of the DISABKIDS Chronic Generic Module (DCGM-37) and Diabetes-Specific Module (DSM-10). Health Qual Life Outcomes 2012;10:19.

Paper 2

Froisland DH, Markestad T, Wentzel-Larsen T, Skrivarhaug T, Dahl-Graue M, Jørgensen K. Health-Related Quality of Life among Norwegian children and adolescents on intensive insulin treatment. A population-based study. (Submitted Pediatric Diabetes)

Paper 3

Frøisland D.H., Årsand E, Skarderud F. Improving diabetes care for young people with Type1 diabetes through visual learning on mobile phones. J Med Internet Res 2012.

Abbreviations

T1D, type 1 diabetes

T2D, type 2 diabetes

MDI, multiple daily injections

QOL, Quality of life

DCGM-37, 37 item DISABKIDS Chronic Generic Module

DDM-10, 10 item DISABKIDS Diabetes Specific Module

CHQ-CF87, 87 item Child Helath Questionnaire-Children Form

CHQ-PF, Child Helath Questionnaire-Parent Form

HbA1c, glycated haemoglobin

NCDR, Norwegian Childhood Diabetes Registry

ICT, information and communication technology

PROMs, Patient-Reported Outcome Measures

HRQOL, Health-Related Quality of Life

DSME, Diabetes Self-Management Education

SMBG, Self Monitoring Blood Glucose

WHO, World Health Organization

ADA, American Diabetes Association

ISPAD. International Society for Pediatric and Adolescent Diabetes

CRF, Case Report Form

SUS, System Usability Scale

SPSS, Statistical Package for the Social Sciences

DKA, diabetes ketoacidosis

EU, The European Union

SMS, Short Message System

1. Introduction

Theoretical framework and concepts

This introduction is intended to give the reader a general understanding of type 1 diabetes and the challenges people living with diabetes face in their everyday life as a background to the research questions of the present study. It will also introduce the reader to the concept of Patient-Reported Outcome Measures (PROMs), Health-Related Quality of Life (HRQOL) and elements of Diabetes Self-Management Education (DSME).

1.1. Diabetes mellitus

The term "diabetes mellitus" was introduced by Aretaeus the Cappadocian in Ancient Greek medicine around 200 AD. According to the physician, "diabetes" means "to flow through like a siphon", and "mellitus" means "honey". Aretaeus also described diabetes as a disease that "melts down the flesh and limbs into urine". According to Francis Adams' translation of 1856, Aretaeus' description of the disease runs: "Diabetes is a wonderful affection, not very frequent among men … The course is the common one, namely, the kidneys and the bladder; for the patients never stop making water, but the flow is incessant, as if from the opening of aqueducts. The nature of the disease, then, is chronic, and it takes a long period to form; but the patient is short-lived, if the constitution of the disease be completely established; for the melting is rapid, the death speedy. Moreover, life is disgusting and painful; thirst, unquenchable; excessive drinking, which, however, is disproportionate to the large quantity of urine, for more urine is passed; and one cannot stop them either from drinking or making water. Or if for a time they abstain from drinking, their mouth becomes parched and their body dry; the viscera seem as if scorched up; they are affected with nausea, restlessness, and a burning thirst; and at no distant term they expire. Thirst, as if scorched up with fire … Hence, the disease appears to me to have got the name diabetes as if from the Greek word "siapftrs" (which signifies a siphon), because the fluid does not remain in the body, but uses the man's

body as a ladder, whereby to leave it. They stand out for a certain time, though not very long, for they pass urine with pain, and the emaciation is dreadful; nor does any great portion of the drink get into the system, and many parts of the flesh pass out along with the urine" (1).

Type 1 Diabetes

The onset of diabetes mellitus is still dominated by the same symptoms as those described in this ancient text. Due to defective insulin production or defective insulin action it was traditionally divided into insulin-dependent diabetes mellitus (IDDM) or type 1 diabetes and non-insulin-dependent diabetes mellitus (NIDDM) or type 2 diabetes. A new classification system was introduced in 2003 eliminating the terms IDDM and NIDDM (2;3). The terms type 1 diabetes (T1D) and type 2 diabetes (T2D) have been retained. In this study we will concentrate only on people with T1D.

T1D is one of the most common chronic illnesses affecting children and adolescents. Onset can occur at any age, but a peak in incidence is observed around puberty (4). It is a metabolic disorder characterized by chronic hyperglycaemia due to defective insulin production. There is a considerable geographical variation in incidence of T1D diabetes around the world, with low incidence in China and Venezuela ,- 0.1/100000 persons per year and a high incidence in Scandinavian countries (4;5). The incidence of diabetes in Norway ranks as one of the highest in the world with 32/100000 persons per year (6;7). In 2011, 2567 children and adolescents were registered in the Norwegian Childhood Diabetes Registry, of whom 99% had T1D. Intensified insulin treatment, i.e. multi-injection or insulin pump therapy, was used by 97.4 % of the population.

T1D is a disease with genetic susceptibility. It is considered to be an autoimmune disease, i.e. the body's defense system, for unknown reasons, attacks and destroys the insulin-producing cells of the pancreas, the beta cells (2;8). This specific T cell-mediated autoimmune

destruction of the insulin-producing beta cells results in a lack of the hormone insulin. With reduced endogenous insulin production the glucose will remain in the blood, resulting in high plasma glucose levels. The elevated level of blood glucose leads to spillage of glucose into urine, and the lack of glucose entry into the cells leads to incomplete metabolism. These disturbances lead to polyuria, polydipsia, weight loss, dehydration, electrolyte disturbance and ketoacidosis, and eventually coma and death if not treated with insulin. For thousands of years, T1D was a disease with a short and fulminant course and no cure. In 1916, Nicolae Paulescue published his reports on the discovery of what he called "pancreine" and his use of this purified substance in several animal tests to demonstrate its effect on carbohydrate metabolism (cited from 9). However, Banting and Best were awarded the Nobel Prize for the discovery of insulin following their reports of the discovery, purification and demonstration of insulin's physiological activity (10). In many ways the cure for diabetes had been found, and from then on extracts of animal insulin were utilized to treat the disease. The molecular structure of the hormone was disclosed during the 1960s and 1970s, and synthetic (human) insulin was approved for pharmaceutical use in 1982.

In 1986, results from the Oslo study indicated that near-normoglycaemia induced by insulin pumps (CSSI) or multiple daily injections (MDI) delayed the development of long-term complications (11). This was confirmed by the Diabetes Control and Complications Trial (DCCT) study which demonstrated significantly better long-term outcomes for intensive treatment given by multi-injections or insulin pumps than with more conservative treatment modalities, i.e. one or two daily injections (12). These studies also inspired the search for other and better types of insulin and the introduction of faster-acting insulin analogues in the 1990s and longer-acting insulin analogues in the 2000s. In Norway, intensified insulin regimens, which include a rapid-acting insulin analogue at each meal combined with long-

acting insulin analogues one-two times daily or continuous subcutaneous insulin infusion with insulin pumps, are now more the rule than the exception (13).

Diabetes as a systemic disease

Diabetes is not only a lack of insulin and high levels of plasma glucose, but also a systemic disease with major implications for patients who encounter serious short-term challenges including risks of acute complications, hypoglycaemia and diabetes ketoacidosis (DKA). The metabolic change that affects the whole body also includes long-term complications, including serious effects on the cardiovascular system. These changes in micro- and macro-vascular systems result in cardiovascular disease and premature death, severe visual impairments, including blindness, renal failure and neuropathy (14-22). These long-term complications can, to a large extent, be prevented by optimal blood glucose control (11).

1.2. Psychosocial aspects

The awareness of the psychosocial implications of diabetes is clearly presented in the International Society for Pediatric and Adolescent Diabetes (ISPAD) Consensus Guidelines from 2000: ‘‘Psychosocial factors are the most important influences affecting the care and management of diabetes” (23). A huge body of literature also highlights the importance of psychosocial factors (24-27). It is suggested that this might be due to the burden of daily treatment, and the fear of short- and long-term consequences (28-30). The disease has a great impact on daily life for the patients and their families, and it is known that psychological aspects and the total well-being affect the daily treatment of this chronic condition (24;29;31-36). Family structure, communication and relations within the family play major roles in the achievements of goals (27;35). Peer relations are also reported to have an impact on self-treatment routines (37).

It is common to have adjustment problems soon after the diagnosis, even though most children and adolescents resolve these problems. Those who do not, are at risk of poor metabolic control and continued psychosocial difficulties (38;39). Behavioural problems at diagnosis seem, however, to be associated with mental problems later in life (40). Psychosocial problems may counteract optimal diabetes care and achievement of treatment goals (24;38;41-43). The presence of diabetes-related complications and anxiety are correlated with lower physical and psychosocial functioning. Increased co-morbidity in terms of affective disorders and other psychological or mental difficulties are reported in young diabetics (44-48). In one of the first studies to look at the relationship between depression and adaptation to diabetes, Lernmark and co-workers concluded that the identification of the patients with depression is important in order to be able to increase their ability to deal with their diabetes (49). Studies have shown that paediatricians are highly specific, but have a poor sensitivity for detecting psychiatric co-morbidity among patients (50). It has therefore been suggested to apply routine screening for psychosocial implications of chronic diseases in paediatric care (38;51). One way to assess this is through instruments that measure HRQOL. De Wit et al. were the first to report from a randomized controlled study that monitoring and discussing HRQOL with young people with T1D improved psychosocial well-being and treatment satisfaction (52). Further, the same groups reported that the beneficial effect disappears after one year. This underlines the importance of routine evaluation and discussion of HRQOL in routine care (53). In this thesis we have assessed HRQOL among children and adolescents with T1D in Norway.

1.3. Glucose control and HBA1c

The intermittent self-monitoring of blood glucose (SMBG) determines the capillary glucose level at the moment when tests are performed. This method has revolutionized the management of diabetes. In 1978 a new measure of long term blood glucose control was introduced (54). Glucose is irreversibly attached to the haemoglobin molecules in the red

blood cells, forming glycated haemoglobin (HbA1c). The formation of HbA1c is proportional to the concentration of plasma glucose (55). The measured HbA1c therefore reflects glucose levels over the preceding 4-12 weeks and can be used as a test to evaluate metabolic control (56;57). It is also the only biological measure for which good data are available in relation to the development of micro- and macro-vascular complications (58). The international society of paediatric and adolescent diabetes (ISPAD) guidelines recommend a treatment goal of HbA1c< 7.5 %.

1.4. Diabetes treatment

Over the last 20 years there has been a radical change in the treatment of type 1 diabetes and today's treatment is tailored and based on self-management. The treatment goals are hard to achieve and come at a high price for young people, as they include rigorous daily routines where the main goal is to maintain healthy blood glucose levels. Treatment goals might be achieved by *tailoring the insulin dosages* to *blood glucose measurements* and actual *food intake* while taking into account *physical activity*. These four elements are described as the cornerstones of diabetes self-management. However, in spite of SMBG, new insulin analogues, insulin pens and pumps, and improved support from diabetes teams and patient organizations (59), patients and their carers struggle to achieve treatment goals, especially when the patients enter their teenage years. It is reported that more than 50% of patients internationally do not obtain adequate metabolic control (36). Less than 30% of Norwegian children and adolescents achieve treatment goals of HbA1c<7.5% (13;60). The relationships between metabolic control and development of competences to implement self-treatment involve many mediating variables. It is predictable that different competences both in the child itself and among their significant others affect diabetes self-management.

1.5. Competences

Competence used as a substantive comes from the Latin words *cum – together* and *petere – seeking out.* This makes sense in the diabetes setting, as both the patients and health -care providers need to seek out the various factors that affect insulin dosages and glucose measurements. Socrates described competent individuals as "those who manage well the circumstances which they encounter daily, and who possess judgment which is accurate in meeting occasions as they arise and rarely miss the expedient course of action" (61) p155).. Physiological and psychological variations, social interactions, as well as health-related quality of life, knowledge and skills are all variables that affect and mediate action in young people living with a chronic disease. The traditional understanding of competence is frequently seen as a combination of knowledge, skills, attitudes and behaviours that an individual is competent at; in other words, competence has traditionally been seen as an ability to deliver or perform tasks with relative ease and with a high level of predictability in terms of quality and timeliness (62). We know that modern diabetes self-care requires advanced knowledge and practical skills (58;63). However, the use of these competences is subject to negotiations according to the contexts of the everyday lives of people living with diabetes. It is important to remember that people visit their doctor three-four times a year for 30-45 minutes. The organization "Ungdiabetes" in Norway estimated the time left alone with your diabetes to be 99.97% of the year. This highlights the fact that health-care providers are also challenged by time in order to get to know their patients and it is pretentious to expect that these short meetings have a large effect on daily self-care. Furthermore, in almost no other chronic condition is the achievement of "competent self-management" so critical. We know that the adolescent phase as a transitional period in itself is a challenge for young people, and for their carers. An additonal chronic disease makes this period of adaptation an even greater challenge. Rigorous self-care is particularly difficult for children and adolescents who want an independent lifestyle like their peers (41). The parents are often in charge of

treatment during childhood, and the gradual transfer of daily responsibility and daily routines in late childhood seems to be important in order for the adolescents to be competent and capable of taking care of their own daily self-management (63).

Used in our context, competence is related to the attempts to master various tasks in different settings when living with type 1 diabetes. The *action competence* concept helps us to focus on children and young people as acting subjects in their daily life (64). While an "individualistic-mentalistic approach" to competence development considers this as a process situated *inside* the individual, the "situated learning approach" explains competence development as continuously ongoing processes situated in and affected by different socio-cultural contexts (65). "The action competences of children and youth develop dynamically over time. This development is complex and happens as a result of children's participation in and across different practices within different contexts" (66) (Figure 1). It is claimed that children and adolescents who experience social and/or health problems have a tendency to develop alternative strategies and practices to tackle their daily life. This may implement coping strategies and action competences which promote and/or maintain *dysfunctional behaviour* as an alternative way to reduce the outer and/or inner stressful complexity of their life (64).

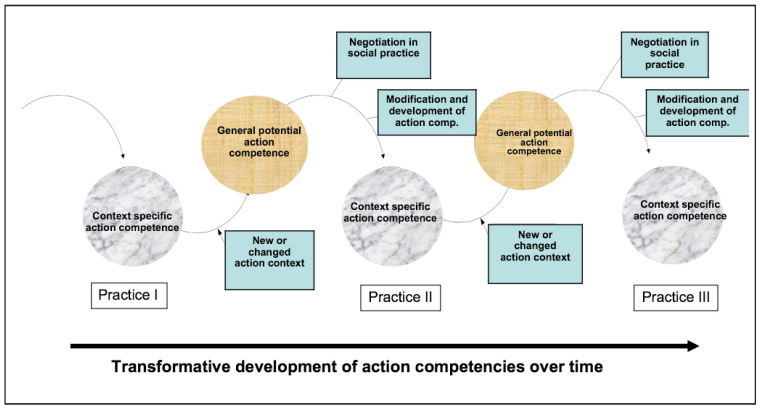

Figure 1: The ongoing transformation of action competencies, where the individual is confronted with new demands in new or changed contexts (from (65)). (Reproduced by permission.)

It might be beneficial when we do research on the psychosocial consequences of type 1 diabetes to be aware of action competences thought to be relevant in order to master tasks for living with type 1 diabetes. External conditions and social practices in different activities among family and friends, at home or school, in leisure activity or at work mutually affect young people with T1D and their action competencies. The Norwegian psychologist Jon Haug has suggested in his thesis that the most important competence for people living with diabetes is to acquire a mental, or rather psychological, need for insulin in order to replace the physiological beta cell response to carbohydrate intake (67). In order to facilitate such an integrated, psychological competence, we need to continuously search for factors and strategies that make this competence development possible.

The adolescent brain is "a work in progress". In child and adolescent medicine it might be useful to take into account the novel understanding from longitudinal studies on brain development through the child and adolescent phase using magnetic resonance imaging (MRI) (68;69) (Figure 2).

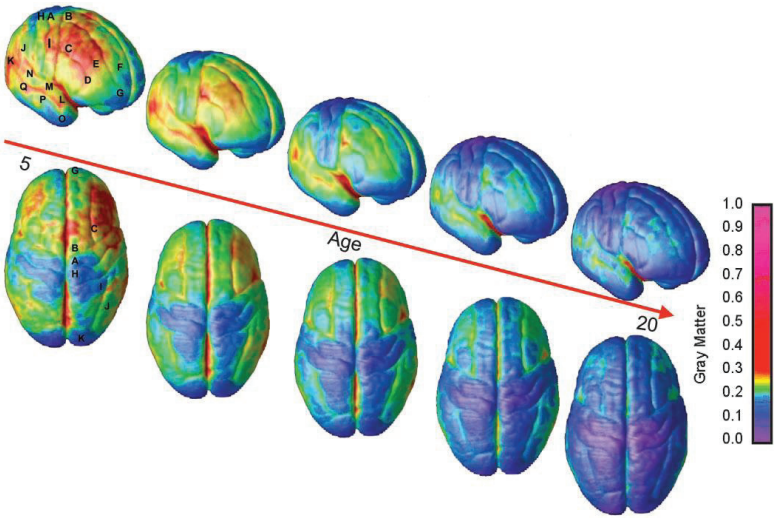

Figure 2: Right lateral and top views of the dynamic sequence of grey matter maturation over the cortical surface. The side bar shows a colour representation in units of grey matter volume. The initial frames depict regions of interest in the cortex (from Gogtay (69) (Reproduced by permission.)

Diabetes self-care is highly dependent on coordination of thoughts and behaviour, i.e. executive functions. The skills necessary for such coordination are ”selective attention, decision-making, voluntary response, inhibition and working memory (70)”. We now that motor and sensory brain areas mature first and especially that the occipital pole containing the primary visual cortex matures early, with later maturation in areas involved in executive functions (69). This might facilitate the use of modern technology making use of visual imaging in this particular patient group. Reports show that simple visual tools designed by young people in their own personal settings seem central to developing patients' comprehension, recall and adherence (71;72).

1.6. Diabetes education

Recommendations on diabetes treatment highlight the importance of diabetes self-management education (DSME). National standards for DSME have been designed by the American Diabetes Association (ADA) to define quality diabetes self-management education and to assist diabetes educators to provide evidence-based education (73). A definition of diabetes education has been suggested as "*the process of providing the person with the knowledge and skills needed to perform diabetes self-care, manage crises and to make lifestyle changes to successfully manage the disease"* (74). However, despite recommendations and widespread use of educational programmes there is little scientific evidence of the effect of and development of self-care support programmes among children and adolescents (75-77). Various practices both in dietary intake and health-care providers' approach to insulin self-treatment in different clinics and countries make studies difficult to compare (78). Reviews, call for well-designed, standardized DSME interventional trials that involve parents and children and are developmentally appropriate and feasible for inclusion in daily health care (75;79).

It is clear from group discussions with young people that education using new technologies might be attractive, but there is little evidence to support this notion (80). In their article

"Diabetes education in children and adolescents – what do adolescents want?", Chaney et al. highlight that interventional programmes need to be designed in collaboration with adolescents and their families (81). Further, they conclude that follow-up post-education presents a challenge to health care practitioners as the adolescents participating in the study only wished to communicate by text message (81). The literature seems to agree that there is still a long way to go to find the best DSME and that future programmes need to be developed in collaboration with the end-users and their families if we are to get closer to successful management of diabetes.

1.7. Patient-reported outcome

In recent decades there has been a shift in focus to involve patients in treatment decisions. This is reflected in international treatment recommendations and national strategies (51;82;83). "Patient-Reported Outcome Measures (PROMs) are tools we use to gain insight from the perspective of the patient, into how aspects of their health and the impact of their disease and its treatment are perceived to be having on their lifestyle and subsequently their quality of life (QOL). They are typically self-completed questionnaires" (84). In addition, patient-reported outcome could also be assessed by exploring patients' experiences and perceptions in a systematic manner. Despite international initiatives and national policy, to our experience and according to unpublished reports from NCDR, the inclusion of formal validated questionnaires in routine clinical work in Norwegian diabetes outpatient clinics is rare or non-existent. Patient-reported outcome measures can guide health-care personnel in making treatment decisions; they can be used to monitor outcome and are suitable for providing a baseline assessment of self-perceived health status, quality of life, etc. (84). Further, they are useful for communicating health-care needs to health-care practitioners (85;86). In both research and clinical work it is recommend that PROMs are selected based on content, psychometric properties and alignment with the issues we aspire to understand better (87).

1.8. Quality of life (QOL) as a construct

Quality of life is a broad concept, with no universal definition, making it difficult to comprehend, and not least difficult to utilize as a joint working instrument in clinical and scientific work. It is a hypothetical construct and therefore cannot be observed. When dealing with the QOL concept a lot of different macro and micro systems and various perspectives and variables are discussed. QOL models that incorporate different academic traditions have been suggested, implementing sociological, economical, psychological, philosophical and ethical aspects of a person's life. The measures of QOL should therefore be viewed as indicators of underlying characteristics often referred to as a latent trait or process (88). Theoretical concept models with respect to global quality of life have been suggested. These models traditionally incorporate five wide-ranging domains: the biological, psychological, interpersonal, social and economic experiences of a person. Mattejat and colleagues presented the basic concepts of QOL in children and adolescents (Mattejat 1998) and this was later developed into a figure by Jozefiak (Figure 3) (87 p16).

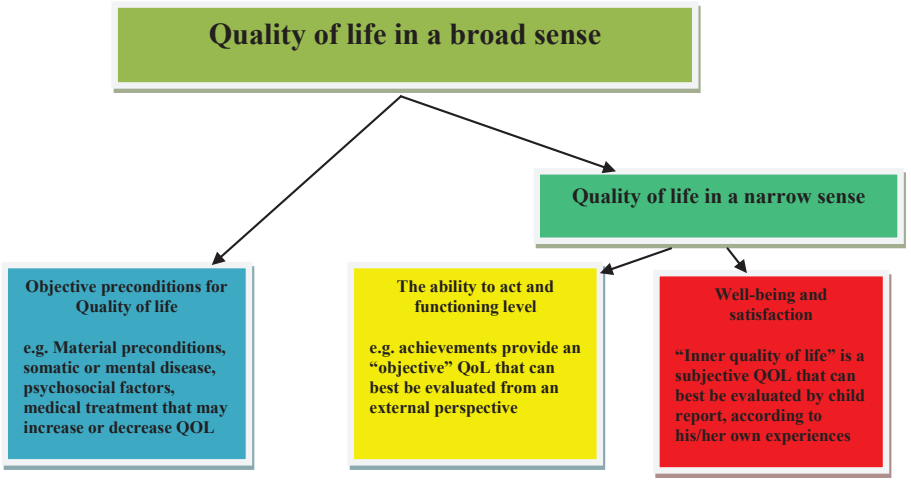

Figure 3: Basic aspects of quality of life. (Reproduced by permission.)

Most models of quality of life emphasize the distinction between the experience of life and life conditions, and social researcher and head of department in the Department of Social Policy and Social Work at the University of Manchester Beverley Hughes has suggested another conceptual model of quality of life and highlights the interacting system of factors which together define and assess quality of life (Figure 4) (89).

Figure 4. A conceptual model of quality of life (after Hughes (89) p55). (Reproduced by permission.)

While it is obvious that experiences are subjective, life conditions are more objective parameters. Integration of both subjective and objective elements into the concept of QOL increases the complexity of the construct. It is also emphasized that general measures of QOL are useful for comparison across populations, but it is questioned whether they are sensitive to unique aspects of particular diseases (90). Further, the health system does not have instruments to affect all the elements implemented in the broader QOL construct. In an attempt to constrict the concept of QOL into a patient-reported measure, some researchers have suggested the concept of health-related quality of life (91;92).

1.9. Health-Related Quality of Life (HRQOL)

HRQOL is a construct designed to capture essential aspects of psychosocial outcome in people with chronic health conditions (92). HRQOL is seen as a multidimensional construct

and is defined by referring to "the physical, psychological and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations and perceptions" (93). The World Health Organization (WHO) declared in 1948 that health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (94). In 1993, the WHO published recommendations important for HRQOL measurements among children and adolescents (95). Most HRQOL instruments tailored for young people therefore comprise the physical, mental and social domains. HRQOL indicates the impact of a medical condition or disease on an individual's physical, emotional and contextual well-being (96;97).

1.10. Developing test instruments, conceptual background, validity and reliability

Designing and developing instruments to be used in HRQOL studies is a complex process (98;99). As already mentioned, most HRQOL instruments are based on a definition of HRQOL that includes mental, social and physical components, making this a relatively broad psychosocial construct. HRQOL instruments are available both as generic and disease-specific instruments, as well as for both general populations and people with chronic diseases.

The use of HRQOL measure has to a large extent focused on adults. However, there has been a growing interest in assessing HRQOL in children and adolescents over the last few decades (99;100). It is important that such instruments are age and developmental appropriate, and they should be adapted culturally to the population targeted (95). The European Union (EU)-initiated DISABKIDS instrument is the only HRQOL instrument developed across cultures for children with chronic diseases, and it has been developed in a bottom-up process including focus groups and field testing among European children and adolescents with chronic diseases (98;101). To a large extent, therefore, this EU-initiated project has taken into consideration the criticism raised in literature towards the lack of cross-cultural HRQOL instruments for children with chronic conditions. The EU-initiated DISABKIDS project

followed a rigorous methodology (Table 1) that emphasizes the subjective evaluation of symptoms. It is unique in its cross-cultural development, the modular system and the combination of specific and generic aspects, as well as the wide age range and the representation of parents' and children's views (98).

Table 1: Overview of the methodology in the DISABKIDS project.

Litterature review
Focus groups
Item development
Translation
Pilot testing
Field testing
Implementation study
Final report manual

This methodology also ensured the validity and reliability issues related to such instrument development as described in the DISABKIDS handbook. Concerns on cultural variations are important in every step from the conceptual and construction level through cross-cultural focus groups, pilot and field testing and final implementation. Further, when applying cross-culturally developed instruments to new populations, we nevertheless have to deal with the items through the translation phase and the psychometric testing phase, to ensure that the instruments to be used really assess what they intend to measure and that this really mirrors the underlying constructs. Guidelines have been published to ensure this process (102). These international guidelines were the basis for the translation and validation procedures of the Norwegian version and also included convergent validation against a valid and widely used HRQOL instrument, the Child Health Questionnaire CHQ-87 and the Child Health Questionnaire Parent Form CHQ-PF (article1).

The DISABKIDS GENERIC INSTRUMENT - DCGM-37

The basic structure of domains of the DISABKIDS generic instrument as an HRQOL measurer is summarized in Figure 5.

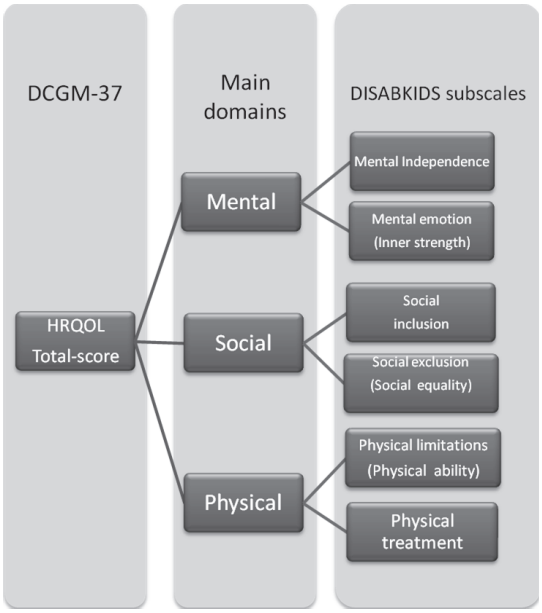

Figure 5: The structure of the DISABKIDS Chronic Generic Module 37 (DCGM-37), including rephrased, positive subscales (in parenthesis) (98;103).

However, in order to comprehend the concept of HRQOL and the DCGM-37 in particular, we need to be aware that all responses to questions in such instruments will also be affected by other factors and life conditions beyond health alone. In Figure 6, we have implemented some of these factors to display the other aspects thought to affect the responses to questions in an HRQOL instrument like DISABKIDS.

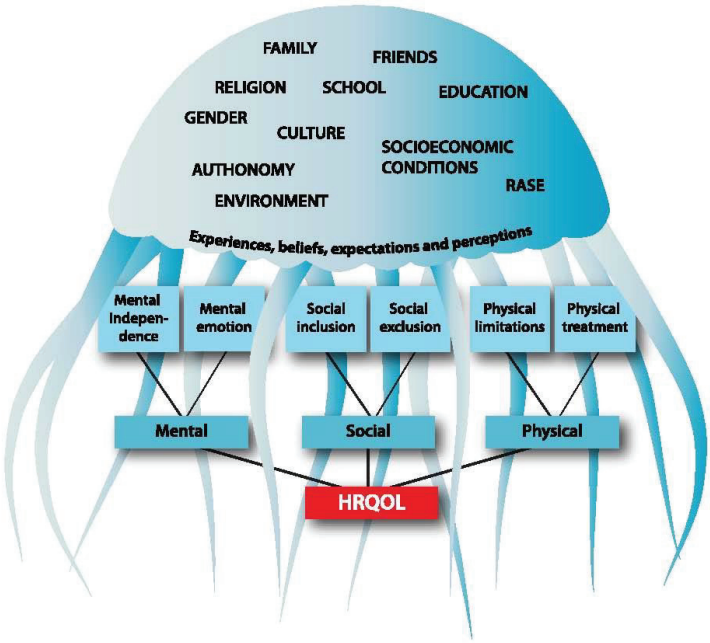

Figure 6: The DISABKIDS generic instrument (original version) placed in and surrounded by the "tentacles" of general life conditional factors that to a larger or lesser extent influence experiences, beliefs, expectations and perceptions and through this the individual HRQOL score.(Frøisland 2012)

The DISABKIDS Diabetes instrument DDM-10

The diabetes specific instrument DDM-10 (Figure 10) is more directly focused on the impact (acceptance) and treatment of the disease, making the responses on these scales less dependent on general life conditions. Nevertheless, it is important to be aware that individual responses are affected by the total life conditions of the respondents.

1.11. Information and communication technology and electronic health

There has been a rapid development in information and communication technology (ICT) in recent decades. This development applies to the health-care area as it is thought to ease the flow of information between the health care workers and their patients (104;105). Health-care providers recognize that these new technologies might be useful in preventing, diagnosing, monitoring and treating chronic diseases (106). Technologies apllied include the Internet, email and mobile phone applications, and are frequently referred to as "electronic health" or "eHealth" (107).

The use of ICT to facilitate health care has over the last twenty years been dominated by computer technology using personal computers (PCs) (105). Many ICT studies report overall positive results and there are evidence that ICT-based interventions improve health care utilization, health behaviours, attitudes, skills and knowledge (105). Over the last decade, studies involving mobile phones in relation to health care have been published (106;108-111). Few studies have been carried out among children and adolescents with type 1 diabetes.

When developing a new ICT system, user-involved design of patient-operated systems is advocated in order to forward useful applications (112). Wagner's Chronic Care Model suggests that the patient-provider interaction should ensure "behaviourally sophisticated self-management support that gives priority to increasing patients' confidence and skills so that they can be the ultimate manager of their illness" (113). Based on this philosophy, the Norwegian Centre for Integrated Care and Telemedicine has developed and tested several mobile applications based on user-participatory design processes.

2. Aims and objectives

Aim of study 1: To test and validate the DISABKIDS HRQOL instruments for the Norwegian child and adolescent diabetes population.

Aims of study II: To investigate psychosocial well-being measured by the DISABKIDS health-related quality of life instruments in children and adolescents with type 1 diabetes and to test the associations between total HRQOL score and level of metabolic control (HbA1c), frequency of acute complications, and socio-demographic factors. Finally, we wanted to examine whether there are detectable differences in HRQOL scores between those using an insulin pump and those on multiple daily injections.

Aims of study III: To evaluate by mixed methods; i.e. qualitative interviews, metabolic control (HbA1c), a system usability scale (SUS) and diabetes knowledge tests the usability of and experiences with two different mobile phone applications applied by adolescents with type 1 diabetes when involved in a three-month trial. Further, the aim was to explore how applications for mobile phones can be used in follow-ups on adolescents with type 1 diabetes, and to use the findings to guide further development of the applications.

The general aim of this project was to lend an ear to the real experts, the people living with the disease, to explore and report on their own experiences, and pass this on to a broader public. We report on the present state in relation to HRQOL among Norwegian children and adolescents with diabetes as well as describing future options and possibilities in order to affect competence, applied knowledge and treatment behaviour and possibly affect future HRQOL among children and adolescents living with diabetes.

3. Material and methods

The collection of data and range of scientific methods used in this study vary according to the aim of each sub-study (table 2). In order to uncover a broader understanding of competences, experiences, challenges and associations in relation to young people living with diabetes we utilized both quantitative and qualitative data and research methods.

Three separate studies were performed. The first collected data from three different outpatient clinic populations in South Eastern Norway. Data were collected through paper-based HRQOL questionnaires. Scores from the HRQOL questionnaires were merged with biophysical variables from the NCDR. In the second study, questionnaires were distributed to all participating centres in the NCDR. Paper-based questionnaires were returned to the registry, and the data from this study were merged with variables from the annual case report forms reported to NCDR in 2010. In the third study, a mixed-methods design was applied, i.e. interviews, two different questionnaires and metabolic control measured by HbA1c. An overview of methods, participants and samples according to the different studies carried out is described in article 1, 2 and 3 respectively.

Table 2: Overview of the research methods, populations and data collection in the three different studies.

Study	Method	Participants	Data collection period	Data collection method
Study I	Quantitative	Children and adolescents from 3 different hospitals in South-Eastern Norway Regional Health organization (N103)	2009	Self-completed questionnaires. Clinical variables from the Norwegian Childhood Diabetes Registry (Barnediabetesregisteret)
Study II	Quantitative	Patients >8<20 years of age registered in the Norwegian Childhood Diabetes Registry (Barnediabetesregisteret)(N937) and their parents .	2010-2011	Self-completed questionnaires. Clinical variables from the Norwegian Childhood Diabetes Registry (Barnediabetesregisteret)
Study III	Qualitative	Children and adolescents from 2 different outpatient clinics in Innlandet Hospital trust (N 12)	2010	Semi-structured interviews. System Usability Scale and knowledge tests. Clinical parameters collected from the two hospitals.

3.1. Participants

The Norwegian Childhood Diabetes Registry (NCDR) is a population-based, nationwide registry covering all paediatric departments in Norway. Since 2009, all departments in Norway have participated in this registry. In 2010, 95% of all children and adolescents with diabetes treated by paediatricians were included in the registry (13). The registry has collected data through the case record form (CRF) translated and modified from the WHO Basic Information Sheet for children and adolescents (114). It contains detailed reports on biophysical parameters as reported in Table 3. Since the year 2000 the participating centres have reported a CRF for each participant from an annual visit to NCDR. The registry punch paper-based data into coded files and associated studies can apply through the board to acquire data from the registry. In study 1 and 2, such data were provided by NCDR. Paper-based instruments for HRQOL data were scanned using Tele Form and merged with the biophysical data from NCDR.

Table 3: Variables collected as quality indicators and benchmark variables in case report form in the Norwegian Childhood Diabetes Registry.

Standardized HBA1c measurement	Treatment modality	Amount and type of insulin per day
Number of blood glucose measurements per week (4-week recall period)	Number of consultations last year	Number of injections per day (4-week recall period)
Number of events of hypoglycaemia with seizures or unconsciousness last year	Number of events of hypoglycaemia with the need of help (4-week recall period)	Number of days in hospital due to diabetes (last year)
Number of events of ketoacidosis with hospitalization last year	Contact with dietician (last year)	Familiar diabetes onset or cardiovascular event last year
Eye examination	Retinopathy	Treatment of eye complications (laser)
Urine albumin	Medical treatment due to high blood pressure or epilepsy	Blood lipids
Nerve examination	Other autoimmune disorders (i.e. celiac, thyroid and Addison's disease)	Examination of insulin injection sites
Height and weight	Pubertal status	Smoking status

Biophysical data from the registry for participants aged above eight years participating in the NCDR are used as background data in studies 1 and 2.

Study 1

The study population in regard to study 1 (article 1) is shown in Figure 7. A relatively large proportion of the total eligible child-parent dyads did not want to participate or were never approached for participation.

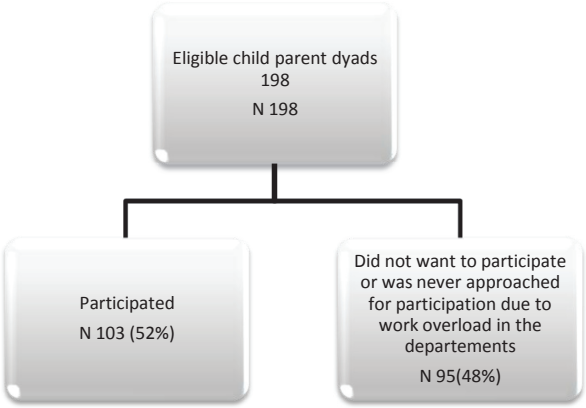

Figure 7: The study population in regard to article 1 is as shown in Figure 1.

Study 2

The study population in regard to study 2 (article 2) is shown in Figure 8. In our reports we have used a calculated response rate from the total number of eligible children and adolescents at each centre when calculating our response rate. We requested the participating centre to report the exact number of patients not approached, but due to the complexity of our study design, the workload in the clinics and the substantial numbers of health-care personnel involved in these reports, only 14 centres reported this number, and the reported data were suboptimal. In our paper (paper2) we therefore calculate our participation rate based on the

total number of eligible child-parent dyads at the 21 participating centres. However, in Figure 8, the report of 255 child-parent pairs not approached is shown. This is further discussed on page 48.

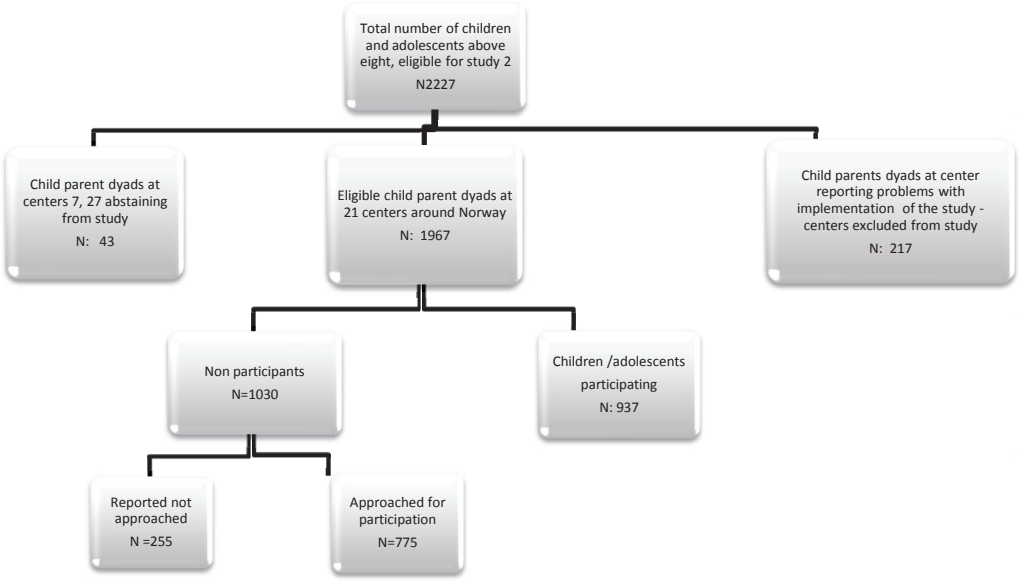

FIGURE 8: Flow chart of total eligible population and non-participants versus participants in study 2.

Study 3

The study population in regard to article 3 was recruited from two different outpatient clinic populations in Eastern Norway (Gjøvik and Lillehammer) (n 12).

3.2. Data procedures

Study 1

Instruments used were patient self-report on paper copies of DCGM-37, DDM-10 and CHQ-CF87. Proxy report by one of the participants' parents were obtained on the parent versions of DCGM-37, DDM-10 and CHQ-PF. In study 1 and 2 a standard manual detailing the data collection was distributed to each of the participating centers (Appendix 1) and a information brochure was sent by post prior to one of the patients consultations (Appendix 2).

Study 2

Instruments used were patient self-report on paper copies of DCGM-37and DDM-10. Proxy reports by one or both of the parents were obtained on parent versions of DCGM-37, DDM-10 and response on questionnaire regarding socioeconomic parameters.

Study 3

Data collection was through semi-structured interviews. In order to apply a broader view, triangulation of methods was used and three additional measurements were applied: change in metabolic control, measured by HbA1c before and after the intervention period, the System Usability Scale after, and knowledge tests before and after the 12-week period.

3.3. Questionnaires

DISABKIDS Instruments (Study 1, 2)

As previously reported, the DISABKIDS questionnaire was used in studies 1 and 2. The DCGM-37 questionnaire contains 37 items which explore six dimensions of HRQOL (115;116) (Figures 5), Appendix 3, 4 (child/adolescent version), Appendix 5, 6 (parent version).

"Mental independence assesses whether the child feels confident about the future and is able to live an autonomous life without impairments caused by the condition; Mental emotion (Inner strength) addresses emotional reactions, such as worries, concerns, anger and problems caused by the child's condition; Social exclusion (Social equality) deals with the feeling of being left out and stigmatized; Social inclusion focuses on positive social relationships and the understanding of others; Physical limitation (Physical ability) refers to somatic limitations due to the condition; and Physical treatment assesses the impact of taking medication, receiving injections, etc" (98;103).

Due to the fact that the instruments are based on both positive and negative statements, the scales original names are also phrased in the same manner. Since scales for negatively worded items are reversed, higher scores will indicate less impact of the disease on all domains. It is difficult to comprehend how someone may present a high score on both social inclusion and social exclusion subscales, and it has been claimed that this makes the presentation of HRQOL results difficult to transfer into clinical relevance (117). Osobo et al. have therefore suggested that HRQOL results would be more meaningful if negative domains were reconceptualised to positive statements (118;119). In this thesis, therefore, similar to the presentation of the results of DISABKIDS from Sweden (119) as well as in our own studies, "Mental emotion" is rephrased as "Inner strength", "Social exclusion" as "Social equality", and "Physical limitations" as "Physical ability". In DDM-10, the "Diabetes impact" scale is renamed "Diabetes acceptance" (119).

"Each item in DCGM-37 and DDM-10 is scored on five-point Likert scale indicating frequency of behaviours or feelings as 1 = never, 2 = seldom, 3 = quite often, 4 = very often, 5 = always. According to the manual, the scales for negatively worded items are reversed. In computation of sum scores, missing values are substituted by the mean of the non-missing items if only one item of the domain is missing. If more than one item is left out the domain is

not scored. The sum score of each domain is the sum of the single-item scores. This raw score is transformed to a sum score for each domain ranging from 0 to100. From these a total score may be computed with a range from 0 to 100 with higher scores indicating higher self-perceived HRQOL" (103).

DISABKIDS Diabetes Module 10

The diabetes specific instrument (DDM-10) consists of an "Impact" scale ("Acceptance") and a "Treatment" scale (Figure 10).

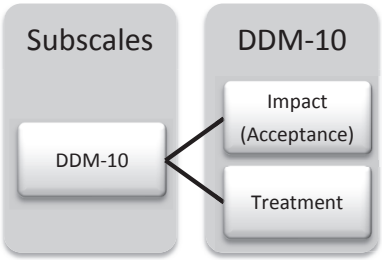

Figure 10: The structure of the DISABKIDS Diabetes Module 10 (DDM-10).

"The "Impact scale" ("Acceptance") deals with emotional reactions to blood glucose control and adhering to diets in everyday life, and the "Treatment scale" deals with emotional reactions to the planning of treatment and the burden of carrying equipment" (120).

In line with international scientific translation procedure recommendations, our group forward and backward translated the DCGM-37 and DDM-10 forms from English to Norwegian (98). The goal of this process was to keep the original meaning of the questions and simultaneously to find the most appropriate terms in the new language. The final versions were approved by the DISABKIDS research group.

Child Health Questionnaires (Study 1)

Child Health Questionnaire 87/Child Health Questionnaire Parent Form

In addition to the DISABKIDS questionnaires, the children and adolescents also filled in the Child Health Questionnaire Form 87 (CHQ-CF87) (Appendix 7), and their parents the Child Health Questionnaire Parent Form 50 (CHQ-PF) (Appendix 8). The CHQ-CF87 is a generic HRQOL questionnaire designed to measure physical, emotional, behavioural and social well-being (121). CHQ-CF87 is recommended for independent response by children above 10 years of age, while the questions could be read to younger children (122;123).

The effect that health implies is assessed over several domains (103;124). The responses are indicated on four- to six-point Likert items describing frequency of behavior or feelings ranging from "very often" to "not at all". The items form scales and responses on items within each subscale are summed into raw scores and transformed to a score between 0 and 100. Higher scores indicate better functional health and well-being. "Extensive studies on the psychometric properties of the CHQ-CF87 and CHQ-PF50 suggest strong internal consistency, content validity and construct validity. Translation into Norwegian had been carried out previously, and the instruments have been used in several Norwegian patient cohorts (25;125;126). Except for the "Change in health" and "Family cohesion" items, which refer to last year, and the "General health" scale, which has no recall period, a four-week recall period is used for each scale" (103).

Additional parameters (Study 1, 2)

As described above (under study 1), the DCGM-37 and DDM-10 questionnaires were used to partly assess psychosocial factors thought to influence daily HRQOL in children and adolescents living with diabetes. In addition to the NCDR annual collection of data we also collected socio-demographic background factors from the responding parents and used these

in our analyses. Children from 8 to 10 years were asked to respond to the DISABKIDS instruments only. Children and adolescents above 11 were asked to respond to a larger instrument panel, as will be analysed later. Parents were also asked to respond to the extended instrument package as well as socio-demographic factors.

3.4. Quantitative data analyses

The completed questionnaires were scanned using TeleForm (Cardiff Software, Vista, CA) and 10% randomly selected and checked for scanning errors. All the scanned data are stored in the research database at Oslo University Hospital, Ullevål. Scoring data are reported as means, with one standard deviation (SD); significance was defined as $P < .05$. Floor and ceiling are reported in numbers and/or in percentage of the total participants. We used IBM's statistical package for the social sciences (SPSS) version 18.0 (IBM Corporation, Somers, NY, USA) for the analyses.

Study 1

For the DISABKIDS questionnaires, reliability was assessed by tests of internal consistency of each of the subscales and the overall sum score. Cronbach's alpha coefficients above 0.70 are generally viewed as sufficient when instruments are used for group-level analysis (99;127). The two DISABKIDS instruments consist of short scales with less than 10 items in each scale; literature suggests that reporting on mean inter-item correlations in such cases might be more appropriate than the Cronbach's alpha. Upper and lower limits of mean inter-item correlations are a matter for discussion (103). Some authors claim that values between 0.2 and 0.4 are optimal (128), while others argue that a mean inter-item correlation consistently above 0.70 may indicate redundancy (129). We therefore considered mean inter-item correlations between 0.2 and 0.7 as satisfactory.

Convergent and divergent validity of the DISABKIDS questionnaire was assessed with reference to the CHQ-87 and CHQ-PF respectively using Pearson correlations adjusted for age and gender. A coefficient above 0.5 was considered high, between 0.3 and 0.5 as moderate convergence, while the measures were considered not to relate if the coefficient was lower than 0.3 (99;103). The DISABKIDS instruments' discriminant validity was assessed by multiple regression analyses (103).

Study 2

The same procedures as described under study 1 were applied to calculate total scores on the DISABKIDS instruments, and results were reported as mean with one SD. Floor and ceiling values were reported as percentages. As appropriate, independent sample t-tests were used for continuous variables and chi-square tests for dichotomous variables when comparing background variables of participants and non-participants. Paired sample t-tests were applied to compare children's/adolescents' score with that of their respective parents. We used multiple regression analyses to assess the different factors thought to affect HRQOL among children and adolescents. Statistically significant findings have been reported as unadjusted and adjusted scores for each of the factors, with p-values in parenthesis.

Study 3

In this study the main findings were based on qualitative methods, and primarily statistical methods were not found to be appropriate. However, we report briefly on statistical data in regard to participants: metabolic control was measured by HbA1c; the score on the System Usability Scale was calculated according to the manual; absolute score is reported, as is the statistical mean with SD. Scores on the theoretical knowledge tests were calculated manually. Pre and post results were compared by paired sample t-tests. SPSS version 18.0 (SPSS IBM, NY, USA) was used for all statistical analyses.

3.5. Qualitative analyses

A semi-structured interview guide was developed (study 3) (Appendix 11), trying to elicit topics described in the aims of the pilot study. The guide emphasized questions regarding different experiences with the implemented technology. The interviews were recorded and then repeatedly listened to. Interviews were transcribed verbatim, and non-verbal aspects of the communication, like pauses and laughter, were included. Field notes based on mind maps were written during the interviews and used as an supplementary data source. Two different authors analysed and coded the texts. Main themes were extracted and interpretations, codes and themes discussed until consensus was reached (130).

3.6. Ethical considerations

All the children and adolescents and their parents gave written consent according to Norwegian requirements. All three studies were approved by the Regional Committee on Medical Research Ethics (Ref. 2009/773b).

The collected paper-based data are stored in fire safes according to regulations. The anonymous scanned data are stored in the scientific database at Oslo University Hospital as appropriate.

4. Results

4.1. Reliability and validity of the Norwegian child and parent versions of the DISABKIDS Chronic Generic Module (DCGM-37) and Diabetes-Specific Module (DSM-10)

The aim of the first study (paper 1) was to examine the reliability and validity of the Norwegian versions of the DCGM-37 and DDM-10 questionnaires when assessing HRQOL among children and adolescents with type 1 diabetes based on their own report and that of their parents. We conclude that the instruments are valid and reliable in a Norwegian population.

Most scales in the Norwegian version had a Cronbach's alpha similar to the European validation study, but the "Social inclusion" and the "Physical limitation" subscales had an alpha less than 0.7 in our material (Table 4). These findings are modified to only one scale, "Physical ability", when using mean inter-item correlations.

Further, our study reports convergent validity using the established HRQOL instruments, the CHQ-87 and CHQ-PF, respectively. Finally, we report that the DISABKIDS instruments have the ability to discriminate between groups, in a regression model, with significant differences in HRQOL score in relation to age and HbA1C. Higher age and increasing HbA1c were associated with lower HRQOL scale scores. We also found trends towards lower HRQOL among girls versus boys and of higher HRQOL among insulin pump users versus those on multi-injections. (The discussion of these results follows in chapter 5.)

4.2. Health-Related Quality of Life among Norwegian children and adolescents on intensive insulin treatment. A population-based study

The aims of the second study (article 2) were 1) to assess HRQOL among Norwegian children and adolescents with T1D in intensive therapy based on their own report and that of one of their parents by using the DCGM-37 and DDM-10, 2) to examine associations between

HRQOL scores and demographic and disease-related variables, and 3) due to the high percentage of intensively treated patients, to examine whether there are detectable differences in HRQOL scores between those on continuous subcutaneous insulin infusion and those on multiple daily injections (MDI).

DCGM-37

Mean self-reported DCGM-37 subscale scores were in the range 76 to 84, and the mean total score was 78 (SD=14). In a regression model we found that low DCGM-37 total scores and most subscale scores were significantly associated with high HbA1c, being a girl, and reports on DKA. We did not find a significant association between self-reported total score and different modes of insulin delivery in this intensively treated population. Parents' total HRQOL score was lower than that of their offspring and this difference was considerable on the Social inclusion scale. Fathers' scores were generally higher than those of mothers.

DDM-10

We found that low scores on the Impact and Treatment scales of the DDM-10 were associated with being a girl and high HbA1c values, while increasing age was associated with lower scores on the Treatment scale. We did not find any significant association between modes of insulin delivery or any of the DDM-10 scales. Parents scored lower than their offspring on Diabetes Acceptance, but higher on the Diabetes Treatment scale. (The discussion of these results follows in chapter 5.

4.3. Improving diabetes care for young people with type 1 diabetes through visual learning on mobile phones: mixed-methods study.

The third study (article 3) is a qualitative study, piloting two different mobile phone applications among adolescents with diabetes: a picture-based diabetes diary utilizing the camera in the mobile phone (Fig. 11) and an encrypted Internet-based Short Message System

(SMS) solution. Mixed methods were applied through measurement of HbA1c, theoretical knowledge tests and the SUS.

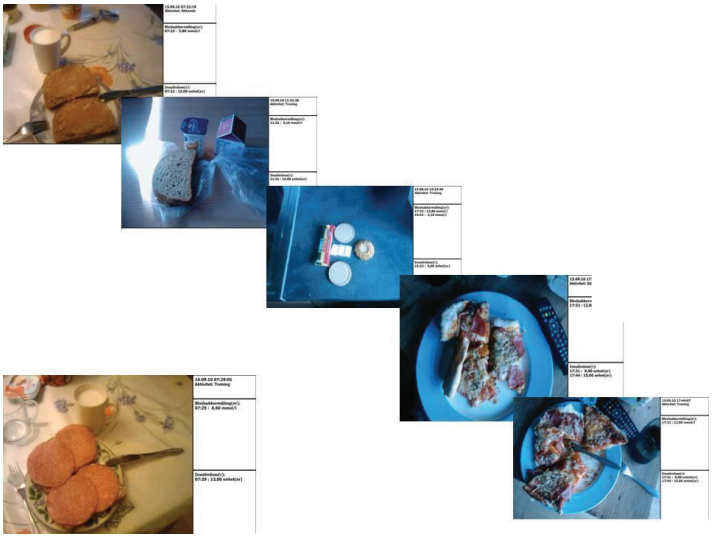

Fig 11 Pictures reporting from a 24hrs registration. Pictures integrate food eaten, insulin dosages taken, pre and post glucose measurements and physical activity. Day 1 diagonal row and breakfast day 2 below.

This study evaluated adolescent patients' experiences with two different mobile phone applications used for diabetes care and examined whether an intervention using information and communication tools could affect level of knowledge and disease management measured by metabolic control, and through qualitative methods. Further, we wanted input to the product development as guidance for additional improvements of the applications.

The most important finding of this study was the report of an educational part of the picture-based diabetes diary. More than facilitating data collection and communication, all the informants reported a new and increased understanding of the cornerstones of diabetes treatment. The informants also reported that access to their doctor through an internet-based encrypted SMS solution gave a feeling of security. They also gave important input to further

development of the applications. The use of triangulation of methods enabled the phenomenon to be viewed from many perspectives and supported the qualitative findings. However, no significant changes in HbA1c were found. (The discussion of these results follows in chapter 5.2.)

5. Discussion

5.1. Methodological considerations, quantitative methods

The **Internal validity** of scientific works is basically the degree to which the conclusions drawn are correct based on the data available. **External validity** of scientific work deals with the inferences that can be drawn from the study setting to the outside world.

In epidemiology, the connotation of this is to what degree the studied sample is representative of the total population. "Fundamentally, **reliability** concerns the extent to which an experiment, test or any measuring procedure yields the same results on repeated trials"(172, p11). In the following section, issues regarding the study design and threats towards internal and external validity, as well as the reliability issues, will be discussed. In relation to this we will particularly emphasize issues related to the use of questionnaires in population-based studies, such as: developmental and conceptual challenges, reliability and validity issues, self-reporting, child and proxy reports, response bias and challenges with multicentre studies.

The major strength of the quantitative parts of this thesis is the use of a population-based cross-sectional design. In paper one, we approached three different hospital cohorts and in study two we intended to approach the whole population of children and adolescents above eight with T1D in Norway. Further, we claim to have good data quality and through cooperation with NCDR we had detailed knowledge on major biomedical background factors for the non-participants as well as the participants. Population-based cross-sectional design has the ability to explore associations, but we did not aim to describe cause-effect relations between various aspects of T1D. Rather we searched for the diabetes population's baseline scores on HRQOL instruments in order to fill in some of the missing parts of the intricate mosaics making up the picture of being young and living with T1D. The results created from

cross-sectional studies like the present ones further allow us to create hypotheses and test them in follow-up studies. It also adds strength to the study that we performed a qualitative study (study 3) as this approach has the ability to further deepen our understanding in regard to diabetes self-care.

5.1.1. Development and conceptual issues

A test instrument is not **valid** if the device does not measure what it intends to measure.

Designing and developing instruments to be used in HRQOL studies is a complex process (98;99).

Conceptually, the DISABKIDS instruments are based on the definition of HRQOL, including mental, social and physical components. Further they focus on the subjective evaluation of these components. The developmental process of the DISABKIDS instrument took into account the main critiques raised in HRQOL literature, the diversity in concepts and operationalizations as well as the multiplicity of test instruments applied in different studies making comparison across cultures and between studies and patient groups difficult (131). The DISABKIDS instruments seem, due to their design process, their underlying constructs, and our and earlier studies, to be valid and reliable enough to be applied on chronic disease groups. Nevertheless, relatively few studies using these instruments have been published so far. The EU-initiated project to develop cross-cultural instruments to measure HRQOL among children makes it possible to compare different patient groups and populations across Europe, making the instrument attractive to stakeholders and decision makers as well. However, as described in chapter 1.10., despite being developed across several European countries it is necessary to apply a thorough translation and validation process to such instruments to ensure their applicability in new populations. Study 1 reports on this procedure in the Norwegian population of T1D patients and their parents.

5.1.2. Reliability and validity of test instruments

Measurement of HRQOL is a process that involves both empirical and theoretical considerations. The empirical focus is on the observable response, a cross in a tick box on an item in a self-report or an answer to a question. The theoretical concern is on the underlying concept meant to be measured. It is imperative to reliability and validity that the relation between the observed response and the underlying construct is strong. The HRQOL concept of the DISABKIDS group has been presented previously. Our validation study found strong internal reliability for most dimensions on the instruments. This confirms that the design process (98) and translation/validation procedure (article 1) have sufficiently addressed these issues, and that the response and the items are closely related to the constructs meant to be described.

Cronbach's alpha or "Inner consistency" is one of the most commonly used indicators of internal reliability and was used to estimate the reliability of the DISABKIDS instruments. The alpha assesses to what degree the items make up a scale or "hang together" (99;132). For group comparison an alpha of .7 or above is recommended. For short scales (less than 10 items), low values are frequently found, and some researchers recommend reporting the inter-item correlations and advise an optimal range for this of between .2 and .4 to avoid redundancy (i.e. that different items measure the same) (128). We therefore applied both these methods as reported (article 1).

In study 1 we conclude that the internal reliability for the DISABKIDS dimensions (subscales) are good except for the physical scale. However, most children with diabetes are not functionally disabled and this might explain why the inner reliability is low in regard to this scale. It is a weakness of our study that we did not apply factor analysis in study 1. In order to apply factor analyses, recommendations on sample size are at least 10 times the number of items in an instrument (99). The total number of participants at the three

contributing centres made such analyses inappropriate. Additionally, the study design did not allow for test-retest procedures, split halves or the alternative-form method to test reliability. However, the DCGM-37 showed high internal consistency reliability, as also reported in other studies (98).

5.1.3. Validity of test instruments

It is necessary to be especially aware of the content validity during the development of a test instrument. The conceptual definition of the constructs and the continuous review of the instrument to make it appear sensible were ensured through the initial developmental process with focus groups and field testing (97 p49). To ensure that the Norwegian edition covered the intended topics clearly and unambiguously, face validity was part of our translation procedure. A pilot study (not reported) was applied in a small group of young diabetes patients and their parents, and interviews were performed to judge the clarity, comprehensiveness and burden of the instrument and to ensure the applicability of the translated version.

To assess construct validity of the DISABKIDS instrument, i.e. the extent to which a measure performs in accordance with theoretical expectation (99), we chose the most common approach: to compare the new instrument with an already valid and reliable HRQOL instrument (convergent validity). In our first study we therefore used the earlier validated and frequently used CHQ-87 and CHQ-PF. Further, we approached this by known group validation (divergent validity) and found that the DISABKIDS instruments are valid in a Norwegian population.

In the second study, the DISABKIDS instruments were applied in a larger population but further validation procedures were not performed.

5.1.4. Self-reports

Paper-based self-report questionnaires on HRQOL among children and adolescents might be seen as a limitation to our study. However, this method has the advantage that information from large samples can be collected in a standardized form. Further, we report parents' data on the same variables in studies 1 and 2 and this adds credibility to the results. Historically it has been argued that children and young people lack the cognitive and linguistic skills to comprehend and respond to questionnaires (133). Further, it is argued that proxy ratings of HRQOL can provide important complementary information. On the other hand, it has been claimed that proxy reports could only be seen as substitutes for the children's own ratings (133). Some researchers have shown that parents are more able to evaluate domains of physical functioning or symptoms and less capable when it comes to emotion and social functioning scales (134). The present consensus is that a self-report, also among children, is advocated (135). Nevertheless, due to discrepancies between children's and parents' reports in our study, we support the approach advocated by several researchers of obtaining information from both children and parents on HRQOL (133;136).

Self-reporting is an easy and feasible way to collect data on large and geographically scattered populations. It gives the participants an opportunity to express subjective experiences, and it is supposed that the anonymity makes it easier to report on sensitive questions (137). However, it may be difficult to find participants and motivate them to fill in the questionnaires, and self-report is challenged by potential biases. Such potential errors that may have influenced our results are discussed later; nevertheless, what people report in studies like this has to be taken at face value (137). On the other hand, observer bias is not a problem in our and similar studies.

5.1.5. Children reports

Due to children's cognitive abilities, their self-reporting on HRQOL has been discussed (88;133). The need for HRQOL instruments that take into consideration different developmental phases for children and adolescents as they mature have been called for. One of the advantages of the DISABKID instruments, in relation to this, is the design process which included children and adolescents with chronic diseases in all phases of the developmental process (98;116). This ensures the adaptation to the developing child, and makes the self-report more valid in itself, especially among the youngest children. The DISABKIDS instruments are designed to be completed down to eight years of age, and the layout, as well as the relatively easy texts in the items, facilitates this approach (Appendix 3,4).

5.1.6. Parent proxy reports

The advantage of proxy reports when measuring HRQOL in children and adolescents has been emphasized (133;138). It is important to bear in mind that in most studies of children with chronic diseases the parents report their child's HRQOL as lower than the child themself. The reason for this might be due to a response shift, i.e. that people, in spite of an illness, express a positive view of their situation due to changes in internal standards, values and conceptualizations of their lives during the course of the disease (139). Studies 1 and 2 confirmed earlier reports of lower scores on HRQOL from parents when than their childrens' and adolescents' scores. However, despite the statistically significant findings (study 2) of differences between children's and parents' scores, the magnitude of these differences was relatively low, indicating that the DISABKIDS instruments might be relatively well tailored to the children and that the parents' scores actually reflect the patients' perspective quite well. This may be an important finding as parents may rate the impact of filling in such questionnaires lower than their children and adolescents.

5.1.7. Internal and external validity

The term "selection bias" mainly refers to the misrepresentation in regard to statistical analysis resulting from the method of collecting samples. If the selection bias is not taken into account, certain conclusions drawn may be wrong. The main concern in regard to internal validity in studies 1 and 2 is selection bias as the participation was voluntary and we report a moderate response rate in both studies 1 and 2. This bias may also be seen as a threat towards external validity (i.e. the ability of the results to be generalized). However this is partly compensated for by the detailed knowledge on other characteristics among both participants and non-participants. Statistically we found significant differences between participants and non-participants in our study; vut when our team discussed these findings, e.g. in relation to metabolic control (HbA1c), the differences were so small that they were not considered clinically significant. In such assessments it is not only important to include mean values and SD, but also to compare the confidence intervals in order to evaluate the mean +- SD and assess this in a clinical context.

Both of the DISABKIDS studies used paper-based questionnaires for data collection. Due to the population-based design and infrastructure-related factors involved in approaching all clinics treating young people with diabetes in Norway, we included a larger instrument panel than the DISABKIDS instruments, in the adolescent group from 11 years and above as well as among the parents' participants. The total amount of items in the instrument package for the parents and for adolescents aged 11 and above was high and this may have affected the response rate in our study. We also decided to leave it to the discretion of the participants whether to fill in the questionnaire at the hospital or at home. This might have influenced negatively the participation rate and may have affected the eventual selection bias. Nevertheless, this procedure was chosen due to the fact that most participants were expected to have long distances to travel, being dependent on public transport and having limited time

in the hospital clinics at each appointment. These were all factors thought to work against a high response rate. We considered allocating tablet computers with computer-based questionnaires at each outpatient clinic, but this was not possible due to time frame and copyright of the included instruments. These technologies are continually being approved and are recommended for future studies in our target population, as this also ensures direct notification of the response. Also, the total number of items in our questionnaires could have been lower. However, nearly half of the total eligible, and 55% of the approached population (see p.42) with T1D, participated. Compared to other population-based studies in Norway, this is as expected, and some have reported even poorer participation rates (140;141). We have considered this participation rate and argue that our knowledge on clinical variables among participants and non-participants rules out a substantial selection bias, minimizing the threat towards internal and external validity.

5.1.8. Response bias

Self-reporting questionnaires raise concerns about response bias or "a systematic tendency to respond to a range of questionnaire items on some basis other than the specific item content" (142). Response bias is a potential threat to the power and validity of the study. *Response set* is a strategy to apply the same response regardless of the question. One way to avoid response set is to mix negatively and positively worded items. Another technique is to keep the numbers of items low. The questionnaires in our study are constructed with a mix of positive and negative items. Further, our study applied a low number of items in the children questionnaire (n=47) (8-10 yrs), but can be criticized for the total number of items in the adolescent and parent questionnaires, as this may have contributed to a tendency towards a level of response set in our material.

When assessing the results from our survey it is important to consider the theory of response shift, i.e. that an individual may change his or her internal standards, values and/or

conceptualizations on variables in his/her own life as a result of external factors such as a treatment or a change in health status (143). Chronically ill children have been found to score equal to or even better than healthy matches on different HRQOL instruments. However, the DISABKIDS instruments were developed in close cooperation with chronically ill children and adolescents, and seem to be well tailored to these young people's values, thoughts and conceptualizations of the construct to be measured (98). In what way response shift may have affected the total results in our studies is uncertain, but our finding of non-significant changes associated with age and duration of disease respectively may be an indication of such shift among patients.

A Likert scale is a psychometric scale commonly used in questionnaires. It consists of one or several Likert items ranging, for instance, from never, to always or completely disagree, to completely agree. In the DISABKIDS instruments the five-point Likert items are described by never, rarely, relatively often, very often and always and given numbers from 1 to 5.

It has been shown that children above eight years old accurately use a five-seven-point Likert item scale (144), and we therefore argue, in line with the developers, that the DISABKIDS instruments can be applied in our population from this age.

Another criticism of these scales is that the Likert scale is based on ordinal data. An ordinal scale organizes the data in a particular order, but does not indicate a specific relationship between each item. This means that we cannot tell the distance between two points on the items; however, the statistical adaptation to such scales implies that they consist of sums across many items and therefore statistically can be treated as interval data (145).

In our studies we have applied parametric statistics; the appropriateness of this could be discussed. We appreciate that some of the continuous variables were not fully normally distributed, and categorical variables were slightly unbalanced, however parametric tests are robust and we argue, in line with others, that they tolerate minor violations of assumptions (146). We are also aware that some other DISABKIDS studies have found their material to be not normally distributed and applied non-parametric tests (119). Distributions of variables in our study were assessed by our group and the option of using non-parametric tests or transforming our variables was discussed. However, these tests also come with assumptions, and for large numbers parametric tests are recommended due to their robustness against non-normality (146-148).

5.1.9. Participation and multicentre studies

Twenty-seven centres treating young people with diabetes were invited to participate in our study, however two centres abstained from participation, and four centres did not complete the study correctly. This highlights the importance of thorough information for those closest to the participants and it also underlines some of the challenges of such large multicentre studies (149). However, we argue that due to the fact that the 21 participating centres were scattered all over the country, the high number of participants and the detailed knowledge on non-participants make it feasible to generalize the results to the whole population (Figure 12).

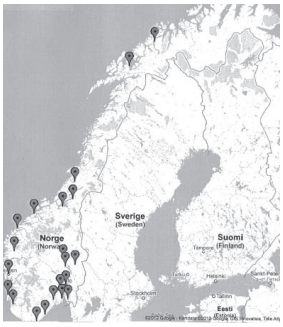

Figure 12: Map of Norway presenting localization of all participating centres.

When calculating the response rate in our study we have used the total number of eligible children and adolescents at each centre. We asked each participating centre to report the exact number of patients not approached, if this for some reason happened. The participating centers reported that the reason that not all patients were approached was because of periods with large workload in the clinics; this, however, happened at random and therefore it did not introduce a bias. Due to the complexity of our study design and the substantial numbers of health-care personnel involved in these reports, only 14 centres reported this number; in addition, the data reported were considered suboptimal. In Figure 8 (p25) we have included the reports from these 14 centres, reducing the total number of eligible patients by 255. We are aware that these acquired data would have increased our participation rate to 55% (Figure 8 p33) and therefore it is debatable whether our reports of 48% are too conservative.

5.1.10. Conclusion, methodological considerations (study 1 and 2)

In their report of one of the landmark studies on risk factors for cardiovascular disease, the research group states: "The phenomena we are reporting are those that have been observed to occur in Evans County. Much as we would like to generalize our findings to other men in the United States, we feel that this is not possible without replication" (150). This excellent testimony of limitations to statistical findings in relation to generalization is rarely reported. We are aware that the assumptions made to generalize our findings to a larger population may be disputed, but as we have argued throughout this text, the number of participants in our studies and the knowledge on several biomedical and socio-demographic variables among the participants and non-participants confirm that the two groups do not differ largely. We therefore argue that we can assume that the findings can be generalized to a larger population of young diabetes patients aged 8-11 in Norway.

5.2. Methodological considerations, qualitative method

In study 3 we applied a multi-method design as this study used triangulation of methods to provide details of the observations that would not be obtainable by using only one method. However, the main focus in this study was to collect patients' experiences through semi-structured interviews, not to develop knowledge through quantitative methods. Nevertheless, all research has a limited validity if it is not successfully communicated (communicative validity) (130;151) the **how** in arguments, the **why** in consensus, and the **who** in regard to communication. Medicine has been closely associated with the positivistic scientific tradition where validity exists, and is thought to be the result and culmination of other empirical conceptions: i.e. universal laws, evidence, objectivity, truth, actuality, deduction, reason, fact and mathematical data (152). In order to communicate qualitative research to our own community we therefore also applied known methods like statistics in describing the participants and methods in our study. This adds strength to the communicative validity as the goal of all science is to create a sensible discussion on new topics.

Qualitative research arising from a post-positivistic tradition is concerned with the meanings and experiences from the participants' own perspectives in a project (130;152). To a large extent, the qualitative researcher embraces the involvement and role into the process, unlike the quantitative researcher who to a large extent attempts to dissociate themselves from the research process. In regard to the credibility of quantitative research, we have discussed, among other things, the construction of a test instrument, while in qualitative research the researcher is also the instrument. This implies that the credibility of qualitative research rests on the craftsmanship of the researcher(s) (153). Thus some state that reliability and validity in qualitative research are terms better described by other words like "credibility", "transferability" and "trustworthiness" (154). However, if we return to communicative

validity, we don't perform well as researchers if we introduce terms not related to the medical context and conceptions when we discuss qualitative methods.

In an effort to reconceptualize reliability, validity and generalizability to be applicable in naturalistic research based on interviews, we therefore refer to Kvale, who says that the reliability and validity aspects need to be part of the craftsmanship of qualitative research in all its steps (p165). The research steps are described in Table 5 and will be used as a skeleton for the methodological discussion.

Thematization
Design
Interviewing
Transcribing
Analysing
Verifying
Reporting

Table 5: Seven steps of qualitative research (Kvale, p165(129)).

5.2.1 Thematization and design of the study

While working with young children with T1D, clinically and as an associated member of NCDR, we have gained knowledge about different aspects of the disease. Despite new innovative treatment options, collaboration between health-care personnel and strategies to support our patients, an improvement in treatment results is difficult to achieve (13). However, the collection of biomedical variables does not obtain data on the subjective experiences of our patients. In this study we have searched for adolescent patients' experiences. Doing this, we have sought to contribute to new hypotheses for further research

on approaches that diabetes teams might apply to facilitate the use of young people's competencies. For that purpose a descriptive qualitative study based on qualitative research and inspired by phenomenology and hermeneutics was designed. As the main author is trained as a medical doctor, the experiences gained through clinical work influenced the planning of the study. This might introduce a bias as the novel mobile phone applications were also designed and planned as a result of subjective appreciation of what young people would prefer. However, as one of the research questions was to describe patients' experiences with two different mobile phone applications used for diabetes care, the design was founded on a patient as expert perspective. We therefore argue that this does not really introduce a validity problem to the study.

The number of participants in a qualitative study needed to create enough data to ensure data saturation is a matter for discussion. In our study, 12 participants were enlisted, seven girls and five boys. Informed consent was obtained from all participants. Due to economic funding in our study and limitations in equipment, the Norwegian Centre for Telemedicine had the ability to deliver a maximum of 12 mobile phone/Bluetooth sets, and this gave the maximum number of participants in our study. However, we argue that the balanced representation of both genders and the variation in age of the participants, as well as their knowledge on mobile phones, represent the background population quite well. However, we are aware that our sample might be biased since it is not random. Those who responded may, for instance, be more technologically savvy, and we are careful not to generalize our findings to other populations. Nevertheless, in light of what Norwegian adolescents achieve in regard to treatment goals and the novel knowledge on brain development in modern neurobiology, the comprehension of our results seem logical and therefore transferable to the discourse on diabetes education and barriers to applied knowledge and action competences among our young patients.

5.2.2. Interviewing and data collection

The reliability of the interviews depends on several steps. A semi-structured interview guide included questions to extract different experiences with the implemented technology. Such interview technique may limit the data collection of the actual experiences in contrast to an more open interview where free association of experiences is sought for. However it also gives an advantage to the analyzes, because the same interview strategy has been used for all participants.

It is imperative to reliability that the interviewer does not directly affect those interviewed and their answers. To avoid this bias we introduced an external researcher to perform 11 out of the 12 interviews. This was provided as the main author is also a clinical practitioner at one of the two outpatient clinics and we appreciated that this could influence the interview and data as participants could feel a pressure to respond in a certain way according to what they thought would be expected. The main author was present as an active observer at the interviews and was allowed to ask questions to deepen the concept if he felt this necessary. However, we are aware that researchers may introduce biases through their active participation and this may have introduced a bias to the responses given by the participants. Nevertheless, this served an important data collection purpose as the main author took field notes on mind maps during the interviews and this also allowed him to observe the non-verbal communication between the participant and the interviewer.

The qualitative interview techniques are complex and we realized there was an ongoing improvement process taking place during our research process and that researchers in this matter can never be fully skilled. However, we aimed to ask open questions, to deepen the understanding of meanings and to recheck whether our comprehension of the phenomenon described was correct. Both researchers felt that the participants responded honestly to the questions and felt free to report both positive and negative experiences in the interviews.

In addition to collecting data from interviews, we also applied a written multiple-choice knowledge test (Appendix 9) and the System Usability Scale (described in article 3) (Appendix 10) as well as pre- and post-interventional HbA1c results. This methodological triangulation gave additional information and increased the reliability and validity of our results.

5.2.3. Transcription

Interviews were recorded and transcribed, including non-verbal communication such as laughter and pauses. All verbatim transcribed interviews were repeatedly listened to and nine out of 12 of the interviews were transcribed by the first author and 3 by external transcriber; this gave an overview of the whole material at the beginning of the analytical process. The interviews were transcribed verbatim in the various dialects spoken in the interviews and this made it difficult to use data programs in the analytical process. The weakness of verbatim transcription is that some statements can appear as incoherent and imprecise. Some therefore advocate using a slightly verbatim mode, but we did not apply in our study (155). Further, when translating into English (with the intention to publish in the *Journal of Medical Internet Research*) we strived to keep the content of the statements as close to the Norwegian meanings as possible. We are aware that this is a challenge to all qualitative researchers publishing in a language other than their native ones. However, the main rule should be to keep as close to the original wording and meaning as possible (151).

5.2.4. Analyses and verification

The analytic approach was based on qualitative description (156) as well as being influenced by phenomenology and hermeneutics (157). Analyses generated themes or codes from the data material. The analysis was conducted by the first author (DHF) and the last author (FS). As recommended, the developing analysis was discussed with the research team, and

continuously monitored by the last author (FS) to add credibility to the study and ensure agreement in main themes. This secured an external check of the research process whereby concepts and interpretations were challenged, discussed and reassessed. These procedures were applied to reduce the bias of one researcher being too involved in the topic, thereby affecting the results through researcher bias. We did not report the exact number of statements in each main theme; however, we are aware that this could have improved the transparency and reliability in the analysis. On the other hand, this could have introduced a positivistic reductionistic limitation to the analytical process.

Our main theme, "visualization", points to another functionality of the mobile application to what was initially intended: instead of being only an electronic diabetes diary designed to discuss insulin dosages and diet in the consultation, the participants reported that the Diamob application increased their understanding of cornerstones in diabetes treatment. The interpretation of this in relation to reliability is that we throughout our analyses were open to the data material and that as researchers we were guided by the responses from participants rather than by our preconceptions.

5.2.5. Conclusion, methodological issues (study 3)

As previously mentioned, communicative validity is important in all science (130). If we try to demystify the term "validation" we can quote Finn Skårderud when he states that "To validate is to convince the critical reader that the research results are direct and probable consequences of the research process itself, and not more or less random statements" (153). In this presentation I have sought to communicate to the critical reader that the reliability and validity of qualitative research have been a continuous imperative throughout the process and that our craftsmanship as researchers has provided trustworthy results.

6. General discussion, clinical and research implications

This study focuses on HRQOL, measured through patients own reports, as an outcome variable thought to be important for the daily self care of people living with diabetes. It also reports on a pilot study indicating that the use of information and communication tools in teaching diabetes self-management to young people might be important. Future research into options optimized to increase patients' applied competences, coping and self-care are important in order to shed light on how to improve health-care strategies and treatment results.

In our first study we report on the psychometric properties of the DISABKIDS instruments. As already mentioned, the use of HRQOL instruments on a routine basis in the follow-up of children and adolescents with diabetes is, to our knowledge, non-existent in Norway. Previous research has documented that the use of such instruments facilitates the process of discussing psychosocial factors, results in more satisfied users, and also makes it easier to uncover those in need of referral to other health-care providers (50;158;159). It is therefore important to find relatively brief, valid and reliable questionnaires in daily practice (160). The fact that the DISABKIDS instruments fulfil these criteria and are available as computer programs and can be completed by the patient and automatically scored prior to consultation make them particularly attractive in clinical practice (161). The Norwegian Childhood Diabetes Registry includes a benchmarking process, where quality variables are standardized and compared between the paediatric clinics, and discussed in annual reports and collaborative meetings (59). In diabetes care it is well documented that the use of annual reports improves the examination of patients and also has the potential to improve outcome (162;163). A slight reduction in the frequency of severe hypoglycaemia has been reported,

but only a minor improvement in HbA1c has been achieved in spite of 11 years of annual benchmarking of biomedical variables in Norway. We therefore suggest that the time has come to implement patient-reported outcomes, such as HRQOL measurements, as one of the benchmarking variables. Further, international recommendations advocate such screening tools to be used in clinical work in order to uncover psychosocial factors that might affect daily self-treatment. The DISABKIDS instruments are relatively brief, culturally and age appropriate for a wide age group, and simple to use. Our findings in study 1 show that the instruments are applicable in the Norwegian diabetes population and this opens up for comparison between different European populations. In reviews of HRQOL studies, the lack of similarity both in instruments and populations is frequently discussed as a challenge in order to compare different studies. Standardized European instruments like DISABKIDS and its sister project KIDSCREEN are therefore important. The DISABKIDS instruments seem to be well adapted to children's and parents' perspectives, but prospective longitudinal studies are needed to prove the applicability of these instruments in clinical work. We do not state that the DISABKIDS HRQOL instruments are superior to other screening tools; in line with others we rather suggest a broad approach as early as possible after diagnosis. However, the cross-cultural development of these instruments and the age appropriateness, earlier reported, make them highly preferable for comparable studies across patient groups and nations (98).

Our second nationwide study is the first larger epidemiological study of the Norwegian child and adolescent population in regard to HRQOL. The significant associations between lower HRQOL score, and poor metabolic control (HbA1c), being a girl and occurrence of one DKA , highlights that HRQOL seems to be one of the components associated with improved self-treatment and metabolic control. Clinicians should also be aware of the strong association between DKA and poor HRQOL. "Psychosocial factors are the most important

influence affecting the care and management of diabetes" (quoted in Delamater, 2009, 52 p175). Despite the awareness of psychosocial issues in T1D, current practice indicates that young people that exhibit clinical levels of maladjustment and distress are not diagnosed or referred for treatment (164) (unpublished reports NCDR). Studies have shown that paediatricians under-identify psychosocial problems (50;158). Paediatricians are found to be highly specific, i.e. identifying correctly those without behavioural or emotional problems but with low sensitivity, i.e. identifying only 17% of those with such problems (50). It is well documented that implementing routine screening of HRQOL improves patient satisfaction with care and psychosocial well-being (52;159;165). The use of HRQOL instruments among children and adolescents in research and clinics has been advocated (52;166). ISPAD and ADA have implemented this in their guidelines for best practice (51). In spite of this, most paediatric centres working with children and adolescents with diabetes in Norway do not have psychologists or social workers in their teams. Further, there are no centres doing routine-based screening of HRQOL parameters, and it is not implemented as an outcome in the annual routine screening of this patient group in relation to benchmarking through the NCDR.

Our results show that although the children on average score similarly to other European populations on the generic instrument, they score substantially differently on the diabetes-specific instrument. The finding of a poor score on the DDM-10 dimension related to treatment itself indicates that this should, to a large extent, be the focus of the consultations among our child and adolescent population. We also conclude that the different modalities of intensive insulin treatment, i.e. insulin pump versus insulin pens, are unrelated to HRQOL score. However, the burden of carrying the equipment and planning the treatment seems to be perceived more negatively in the Norwegian population than in comparable populations.

Psychosocial factors identified at diabetes diagnosis predict later psychological complications, non adherent behaviour and poor metabolic control (40;167). The burden of diabetes among young people with diabetes is well documented. Adolescents with diabetes rated their HRQOL lower than healthy subjects and also lower than adolescents diagnosed with cystic fibrosis, inflammatory bowel disease, epilepsy and post-renal transplantation, when HRQOL was measured among adolescents with eight different chronic conditions (168).

Reports and recommendations highlight the importance of early screening and diagnosis and referral to increased care and support in order to improve outcome (40;51). However, a numbers of barriers (i.e. family factors and aspects of the health-care system) seem to exist before implementing this (30;40;158;167;167). A recent publication on practical advice on the implementation of such strategies includes the combination of semi-structured interviews with one or more screening tool(s) applied by staff trained in behavioural health (167). This underscores the importance of multidisciplinary diabetes teams. Further, De Wit et al. was the first to document improved results among young people with T1D by measuring and discussing HRQOL (159). The same group later documented the importance of follow-up on these variables in order to achieve a lasting effect (53;159). Further studies on background factors to explain why Norwegian children score higher on the DDM-10 Acceptance (Impact) scale and lower on the Treatment scale might shed light on obstacles related to poor metabolic treatment results.

Our finding of a significant association between higher HbA1c and lower HRQOL and relatively low achievement of treatment goals should stimulate further research, to evaluate strategies hypothesized to facilitate the utilization of learned skills and knowledge into applied competences with both biomedical and patient-reported outcome measurers.

In line with international recommendations, we also advocate that diabetes teams find standardized patient-reported outcome measures in order to uncover early those in need of increased support, and also to follow such outcome measures on a longitudinal basis.

Self-management of T1D is highly dependent on research into aspects that relate to diabetes self-management education. The last 20 years of diabetes education has been affected by an increased emphasis on integrated educational strategies, and collaboration with the patient (169;170). The findings from our study (study 3) indicate that visualization of the cornerstones of diabetes self-management, i.e. physical activity, food intake, insulin doses and glucose measurements, seems to improve the applied competences in daily diabetes management. This study suggests that the young people living with T1D, despite having theoretical knowledge, report fragmented understanding of their self-treatment and struggle with the implementation of these fragments into applied competences. It has been shown that visual tools designed by young people in their personal settings seem important for developing patients' comprehension, recall and adherence (71;72). It is possible that the Diamob stimulates reflection in action and facilitates comprehension of patients' own self-treatment. It is likely that this strategy of learning by doing is particularly well suited to young people, as they often oppose correction from others. Our research team hypothesizes that this finding may be related to neurobiology and the continuous development of the brain. Novel longitudinal studies using magnetic resonance imaging (MRI) have provided evidence on the ongoing maturation of the frontal cortex into adulthood (69;70). To perform well in self-care, the patients depend on well-developed executive functions, the abilities to store important information and holding in mind a plan to carry out in the future and inhibit impulses. Work on animals and humans has associated these behaviours with the frontal lobes maturing late in

the adolescent period (70). MRI studies have shown that maturation of the visual cortex and successive pruning of neural contact happen early in childhood compared with the frontal parts of the brain where the centres for cognitive functions like planning and advanced thinking are localized (69;70). The relatively poor treatment results among young people with diabetes challenge us to continuously review our clinical methods and implementation of new strategies to stimulate increased competence and coping among our patients. Further studies on strategies in diabetes treatment utilizing and facilitating eHealth are advocated as we will need to adapt to a new generation of young people who are used to exploiting such tools in daily life and view it as a necessity of their life. New strategies like the ones used in this study (study 3) need to be tested in larger randomized controlled studies to evaluate the effects.

7. Implications for future research

The current study examined associations between HRQOL mode of treatment and treatment outcomes in a cross-sectional study. Whether interventions with the goal of improving HRQOL or whether routine assessments of HRQOL improve coping and metabolic control were not answered and need to be addressed in proper intervention studies, preferably randomized control studies. We also advocate including HRQOL results in addition to the traditional biophysical parameters in clinical trials.

Further research into the associations between self reported HRQOL and other outcome variables to investigate their associations and interactions is important and also has the potential to widen our knowledge on such psychosocial factors and their role for patients' coping and treatment results. Studies using instruments that targets more specific psychosocial factors like eating disorders, fear of hypoglycemia, problem areas in diabetes

and family related factors in association to children and adolescent with T1D is recommended.

Longitudinal studies that document HRQOL in the child and adolescent diabetes population as well as implications for HRQOL later in life is suggested. This can be facilitated by including such screening in the ongoing benchmarking in NCDR. Further collaboration across nations and with different patient populations with a standardised instrument make us able to do comparative studies. Such studies across patients and nations will also serve as a response to the criticism on lack of similarity between HRQOL studies.

The pilot study of using mobile phone applications in the management of the disease, points towards interesting new avenues of follow-up. Whether such new technologies represent new meaningful ways of follow-up or how such applications best can be utilized also need to be addressed in randomized control studies where applied knowledge, competences and coping in addition to metabolic control and HRQOL are meaningful outcome variables.
Future studies on brain development and function may also be important to understand further educational strategies towards the child and adolescent patient populations.

The authors highlight the importance of epidemiological, quantitative studies of the total Norwegian population of young people living with diabetes. In order to get wider pictures and uncover the private, often complex reasons behind treatment challenges we also suggest studies using qualitative methods. This thesis therefore suggests that research into new strategies that might have positive implications for diabetes self-management education and self-treatment needs to be tested out in studies using mixed methods. As researchers we will need a variety of methods at our fingertips if we are to understand the complexity of modern

systems (171). We need to be trained in more than one scientific method and be able to utilize the complementarities.

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Artikkel 1

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HEALTH AND QUALITY OF LIFE OUTCOMES

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Reliability and validity of the Norwegian child and parent versions of the DISABKIDS Chronic Generic Module (DCGM-37) and Diabetes-Specific Module (DSM-10)

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Abstract

Background: International guidelines on type 1 diabetes advocate routine screening of health-related quality of life (HRQOL). DISABKIDS questionnaires are the first instruments developed across cultures and nations to provide age-appropriate measures of HRQOL in children with chronic diseases. DISABKIDS includes a Chronic Generic Module 37 (DCGM-37) and disease-specific modules. The purpose of this study was to examine reliability and validity of the Norwegian versions of the DISABKIDS questionnaires in children and adolescents with type 1 diabetes.

Methods: The DCGM-37 and the Diabetes Specific Module-10 (DDM-10) were translated into Norwegian using standard forward-backward translation. Eight to 19 year old children and adolescents with type 1 diabetes scheduled for routine follow-up at three diabetic clinics in Norway and one of their parents were invited to complete the DCGM-37 and the DDM-10. Internal consistency was determined using Cronbach's alpha. Results were compared with those of the Child Health Questionnaire Children Form-87 (CHQ-CF87) and Child Health Questionnaire Parent Form-50 which are established generic questionnaires. DISABKIDS results were related to age, gender, duration of diabetes, mode of insulin delivery and metabolic control. Clinical data were obtained from the Norwegian Childhood Diabetes Registry.

Results: Of 198 eligible child-parent dyads, 103 (52%) completed the questionnaires. Mean age was 13.6 (2.6), range 8-19 yrs, 52% were boys. Cronbach's alpha was > 0.70 for all the DISABKIDS sub-scales except two (physical ability and social inclusion). There were moderate to high correlations (0.65-0.81) between the DISABKIDS scales and mental/emotional sub-scales of CHQ-CF87. Increasing age and higher HbA1c were significantly associated with reduced HRQOL scores. Parents tended to score their child's HRQOL lower than the children/adolescents themselves.

Conclusions: The study shows that the DISABKIDS instruments are applicable to a Norwegian childhood diabetes population. They seem to be a relevant supplement to other clinical indicators in medical practice and research.

Keywords: Health-related quality of life, Type 1 diabetes, Children, Adolescents, Psychometrics, Reliability, Validity, DISABKIDS

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Introduction

Type 1 diabetes is one of the most common chronic diseases of childhood, and the incidence in Norway of 30 new cases per 100 000 person years is one of the highest in the world [1]. Diabetes poses significant every-day challenges since optimal blood glucose control is important in order to avoid severe acute complications (i.e. hypoglycaemia and diabetes ketoacidosis) and long term consequences, such as early onset of cardiovascular disease, visual impairments, renal failure, neuropathy and premature death [2,3]. The burden of diabetes on the children and their families is well known to affect both psychological and total wellbeing [4-6], and young persons with diabetes report impaired self-perceived health-related quality of life (HRQOL) [7,8]. A good quality of life is an important treatment goal in itself [9], but is also important in order to achieve other treatment goals [10-13]. The International Society for Pediatric and Adolescent Diabetes-(ISPAD) guidelines therefore advocate assessment of quality of life as important as screening for other complications related to diabetes [9,14]. HRQOL is a multidimensional construct including at least physical, psychological and social domains. To make international comparisons possible it is advocated that test instruments are developed in cross-cultural and cross-national study groups [15,16]. In line with this goal "The DISABKIDS project", which was funded by the European Commission, was developed in seven European countries with the purpose of developing instruments for assessing HRQOL of children with different chronic health conditions [16,17]. The DISABKIDS instruments consist of questionnaires which include a generic module (DISABKIDS Chronic Generic Module (DCGM-37)) and disease-specific modules (e.g. DISABKIDS Diabetes- Specific Module (DDM-10)) [18]. The DCGM-37 is the only HRQOL instrument developed across cultures for children with chronic diseases [19]. Due to its novelty, relatively few studies using DISABKIDS have been published so far, apart from the psychometric properties reported from the European field study [17]. A literature search disclosed no recent validation studies, but Swedish and Greek groups have published results on DISABKIDS data [19-21].

The aims of the present study were to examine reliability and validity of the Norwegian versions of the DCGM-37 and DDM-10 questionnaires when assessing HRQOL among children and adolescents with type 1 diabetes based on their own report and that of their parents. Internal consistency was assessed by Cronbach's alpha coefficient. Convergent validity was assessed by comparison with established generic instruments, in this case the Child Health Questionnaire Children Form-87 (CHQ-CF87) and Child Health Questionnaire Parent Form-50 (CHQ-PF50). We also evaluated the instruments' ability to discriminate between patients with different characteristics, i.e. age, gender, duration of disease, treatment modalities and metabolic control reflected in HbA1c. Finally, we studied whether the children and their parents assessed the child's HRQOL differently.

Methods

Participants

Except for families who were not able to speak or read Norwegian, all 8-19 year old children or adolescents with type 1 diabetes scheduled for follow-up at three pediatric departments in eastern Norway between October 1st, 2009 through February 28th 2010 and one of their parents were invited by mail to participate in the study before a scheduled consultation.

Whether the cohort in the present study was representative for Norwegian children and adolescents with diabetes was assessed by comparing demographic and clinical characteristics with that of the Norwegian Childhood Diabetes Registry, which is a population based, nationwide registry covering all pediatric departments in Norway. In 2010, 95% of all children and adolescents with diabetes treated by pediatricians were included in the registry [22].

Instruments

DISABKIDS

The DISABKIDS Chronic Generic Module (DCGM-37) is a questionnaire which measures general HRQOL and the level of distress caused by a chronic disease, and can be supplemented with condition-specific modules for asthma, arthritis, cerebral palsy, cystic fibrosis, dermatitis, epilepsy and diabetes [18]. The instruments include one form to be filled in by children between 8 and 18 years of age, and one form for their parents. A four-week recall period is used for all items except item 11 "About symptoms" which has a one year recall in the diabetes specific module.

The DCGM-37 questionnaire contains 37 items which explore six dimensions of HRQOL [16,17] (Figure 1): "Mental independence" assesses whether the child feels confident about the future and is able to live an autonomous life without impairments caused by the condition, "Mental emotion" addresses emotional reactions, such as worries, concerns, anger and problems caused by the child's condition, "Social exclusion" deals with the feeling of being left out and stigmatized, "Social inclusion" focuses on positive social relationships and the understanding of others, "Physical limitation" refers to somatic limitations, due to the condition and "Physical treatment" assesses the impact of taking medication, receiving injections, etc.

Each item is scored on a five-point Likert scale indicating frequency of behaviours or feelings as 1 = never,

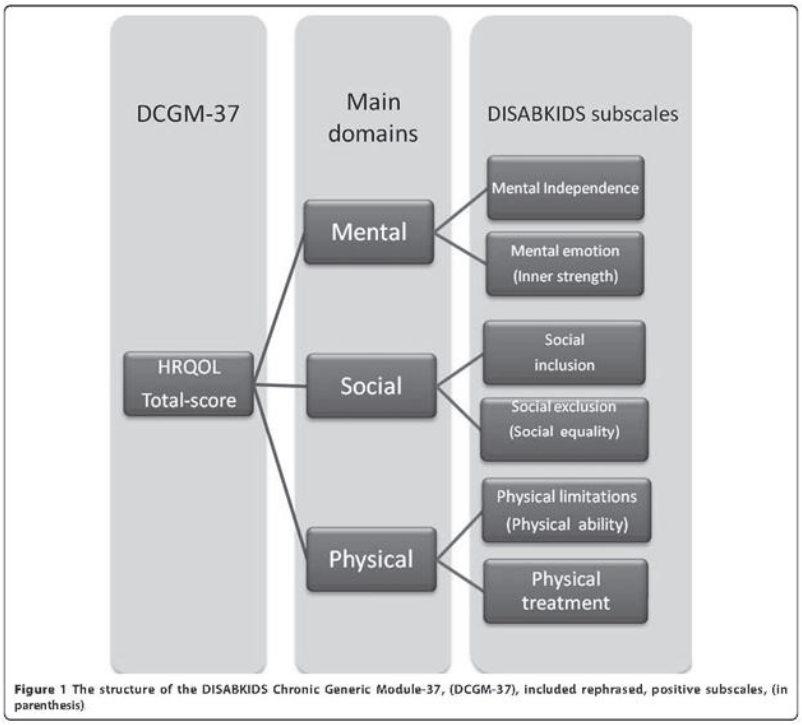

Figure 1 The structure of the DISABKIDS Chronic Generic Module-37, (DCGM-37), included rephrased, positive subscales, (in parenthesis)

2 = seldom, 3 = quite often, 4 = very often, 5 = always. The scale for negatively worded items was reversed according to the manual. In computation of sum scores, missing values were substituted with the mean of non-missing items if only one item of the domain was missing. If more than one item was missing the domain was not scored. The sum score of each domain is the sum of the single item scores. From the raw score a total score may be computed with a range from 0 to 100 with higher scores indicating higher self-perceived HRQOL.

The diabetes specific instrument (DDM-10) consists of an "Impact" and a "Treatment" scale (Figure 2). The "Impact scale" deals with emotional reactions of blood glucose control and adhering to diets in everyday life, and the "Treatment scale" deals with emotional reactions to the planning of treatment and the burden of carrying equipment. DDM -10 items are scored on a five-point Likert scale, and a 0-100 score is calculated for each subscale [23].

The DCGM-37 and DDM-10 forms were forward and backward translated from English to Norwegian according to an international scientific translations procedure [24].

The goal of this process was to keep the original meaning of the questions and simultaneously to find the most appropriate terms in the new language. The final versions were approved by the DISABKIDS research group.

A standard manual detailing the data collection was distributed to each of the three participating centres.

In the past, presentations of HRQOL results have been criticised for being incomprehensible in relation to

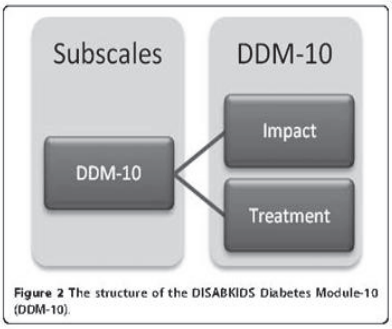

Figure 2 The structure of the DISABKIDS Diabetes Module-10 (DDM-10).

clinical relevance [25]. To address this critique, Osobo et al have suggested that HRQOL results will be more meaningful if negative domains were reconceptualised to positive statements [20,26]. Therefore, in the following, similar to the presentation of results from Chaplin and colleges [20]"Mental emotion" is rephrased as "Inner strength", "Social exclusion" as "Social equality", and "Physical limitations" as "Physical ability".

Child Health Questionnaire

In additions to the DISABKIDS questionnaires, the children and adolescents were asked to complete the Child Health Questionnaire Form-87 (CHQ-CF87), and their parent the Child Health Questionnaire Parent form-50 (CHQ-PF50). The CHQ-CF87 is a generic HRQOL questionnaire designed to measure physical, emotional, behavioural and social well being [27]. From 10 years of age children were asked to complete the CHQ-CF87 independently, while the questions could be read to younger children [28,29].

Health is assessed over several domains i.e. general health perceptions, physical functioning, role/social- physical functioning, bodily pain, role/social- emotional and behavioural functioning, parent impact-time and parent impact-emotional, self-esteem, mental health, behaviour, family activities and family cohesion. The responses are indicated on 4 to 6 point Likert scales specifying level of agreement to a certain categorical statement such as "very often" to "not at all". The responses within each subscale are summed, and the raw scores are transformed to a score between 0 and 100, with higher scores indicating better functional health and well-being. Extensive studies on the psychometric properties of the CHQ-CF87 and CHQ-PF50 suggest strong internal consistency, content validity and construct validity. Translation to Norwegian has been carried out previously, and the instruments have been used in several Norwegian patient cohorts [30-32]. A four- week recall period is used for all scales except for the "Change in Health" and "Family Cohesion" items which refer to last year, and the "General health" scale which has no recall period.

The questionnaires were completed at the clinic when the participants met for their follow up. As recommended for CHQ-87, health care personnel were available to clarify questions for the age group 8-9 years, if necessary. The child/adolescent and their parent completed the questionnaire independently of each other.

The completed questionnaires were scanned using Tele Form (Cardiff software, Vista, CA) and checked for scanning errors.

Clinical characteristics

HbA1c was analyzed at the same visit as the questionnaires were filled in using Bayer DCA 2000 (Tarrytown, NY - normal reference range 3.4-6.1%). The incidence of reported ketoacidosis and hypoglycaemia was too low to allow analyses of HRQOL scores in relation to these clinical markers.

Ethical considerations

The children and adolescents and their parents gave written consent according to Norwegian requirements. The study was approved by the Regional committee on medical research ethics.

Statistical analyses

Results are presented as means with one standard deviation (SD) or as rates (percentages). Floor and ceiling effects are reported in numbers of patients with HRQL scores of 0 (floor) and 100 (ceiling). A percentage above 25 was characterized as high.

Internal consistency refers to the degree to which the different items in a scale measure the same construct. For the DISABKIDS questionnaires reliability was assessed by tests of internal consistency of each of the subscales and the overall sum score. Cronbach's alpha coefficients above 0.70 are generally viewed as acceptable when instruments are used for group level analyses [33,34]. With short scales as in DCGM-37 and DDM-10 it is often more appropriate to report mean inter item correlations. Upper and lower limits of mean inter item correlations are a matter of discussion. Some authors claim that values between 0.2 and 0.4 are optimal [35], while others argue that a mean inter item correlation consistently above 0.70, may indicate redundancy [36]. In the present article, we consider mean inter item correlations between 0.2 and 0.7 as satisfactory.

Convergent and divergent validity of the DISABKIDS questionnaires DCGM-37 and DDM-10 were assessed with reference to the generic questionnaires CHQ- CF87 and CHQ-PF50, respectively, using Pearson correlation adjusted for age and gender. A correlation coefficient (r)

above 0.5 between measures of construct related to each other was considered as high and a coefficient between 0.3 and 0.5 as moderate convergence, while measures were not considered to be related if correlation coefficients were below 0.3 [34].

DISABKIDS' discriminant validity in relation to age, gender, duration of diabetes, mode of insulin delivery and metabolic control (i.e. levels of HbA1c) was assessed using multiple regression analysis.

Paired sample t-tests were used to assess associations between scores obtained by the children and their parents.

Significance was defined as $p < 0.05$. SPSS version 18.0 (SPSS IBM, NY, USA) was used for analyses.

Results

Of 198 eligible child-parent dyads 103 (52%) completed the questionnaires. Mean age was 13.6 (2.6), range 8-19 years, and 53 (52%) were boys. Compared with the national diabetes cohort, the participants had similar gender distribution, mean age, mean duration of diabetes and mean body mass index (BMI), but somewhat lower mean HbA1c, lower average numbers of consultations and higher rate of insulin pump use (Table 1).

Mean scores on the children's and adolescents' self report forms varied between 62 and 83. Very few had floor or ceiling values (Table 2).

Reliability

For the children's questionnaires the internal consistency of the DCGM-37, calculated as Cronbach's alpha, varied between 0.55 and 0.92 (Table 2.). Cronbach's alpha was above 0.70 for all subscales except for "Physical ability" and "Social inclusion". Mean inter item correlations were above 0.20 and below 0.50 for all subscales except for the "Physical ability" subscale which was 0.19. For the DDM-10 Cronbach's alpha was 0.79 for both scales, and mean inter-item correlations were 0.41-0.49.

For the parent's questionnaires, Cronbach's alpha varied between 0.74 and 0.89 for the DCGM-37 and was 0.83 for both scales on the DDM-10. Mean inter item correlations varied from 0.32 ("Physical ability") to 0.55 ("Inner strengths").

Convergent validity

Correlation coefficients between the DCGM-37 and DDM-10 scales and the "Mental health" subscale in CHQ-CF87 were in the range 0.54-0.81 (Table 3). Correlation coefficients were in the range 0.65-0.81 between the DCGM-37 total score and six of the twelve subscales in the CHQ-CF87, and in the range 0.49-0.67 between "Role emotional" in CHQ-87 and the DCGM-37 "Treatment" scale and the DDM-10 ("Impact" and "Treatment" scales).

Correlation coefficients between the DCGM-37 scales and the CHQ-CF87 scales "Physical function" "Role behavioral", "Global behavior" and family related dimensions were low.

Discriminant validity

The generic as well as the diabetes-specific module of DISABKIDS discriminated between age groups and levels of HbA1c (Table 4). Higher age and increasing HbA1c were associated with lower HRQOL scale scores.

Boys tended to score higher than girls, and children using insulin pump higher than those on multi-injections on total sum-scores and scores on most subscales. With respect to treatment modality, the differences in mean score between insulin pump and multi-injection users were between 3.5-4.0 on "Social equality "and "Physical treatment" subscales on DCGM-37 as well as for both subscales in the DDM-10 (results not shown).

Table 1 Demographic and clinical characteristics of the children and adolescents included in the Norwegian Childhood Diabetes Registry and the study population.

	Norwegian Childhood Diabetes Registry (n = 2109)			Study cohort (n = 103)			p
	Number examined			Number examined			
HbA1c (%) - mean (SD)	2048	8.65	(1.4)	101	8.04	(1.1)	< 0.001
Boys - n (%)	2109	1114	(53)	102	53	(52.0)	0.92
Age(yrs)-mean (SD)	2109	12. 9	(3.8)	102	13.6	(2.6)	0.07
BMI kg/m^2- mean (SD)	2081	20.4	(3.9)	100	20.8	(3.6)	0.29
Consultations last year - mean (SD)	2068	3.7	(1.7)	102	3.3	(1.3)	0.02
Diabetes duration (yrs) -mean (SD)	2109	5.2	(3.6)	102	4.6	(3.5)	0.06
Insulin pump - n (%)	2109	1073	(51)	102	74	(73)	< 0.001

Table 2 Subscale and total sum scores on the Norwegian self report version of DISABKIDS.

	Scale	n	Mean score (1-100)	Standard Deviation	Floor/ceiling n/n	"Chronbach alpha"	Mean inter-item correlation
Mental	Mental independence	103	78	13.7	0/7	0.75	0.33
	Mental Emotion (Inner strength)	103	77	15.6	0/8	0.85	0.47
Social	Social Inclusion	102	80	11.5	0/3	0.60	0.22
	Social exclusion (Social equality)	103	83	13	0/8	0.70	0.30
Physical	Physical limitations (Physical ability)	103	77	11.4	0/5	0.55	0.19
	Medication/Treatment	101	75	17.2	0/9	0.80	0.40
Total score	HRQOL	100	78	16.9	0/0	0.92	0.25
Diabetes module	Impact	102	70	16.9	0/6	0.79	0.41
	Treatment	100	62	20.7	1/5	0.79	0.49

All subscales are scored from 0 to 100 with higher scores indicating higher self-perceived HRQOL.

There were no differences in scores with regard to duration of diabetes. Twelve (12%) of the participants had diabetes duration of less than one year. This group scored slightly higher on all subscales as well as on the HRQOL total score, but these differences were not statistically significant.

Comparison of children's and parents' scores

Generally, children and adolescents tended to give higher scores than their parents. This was true for all subscales in DCGM-37 and for the "Impact" scale in DDM-10. Significant mean (SD) differences were found for the DCGM-37 total score (78 ± 11.0 vs. 76 ± 11.1, p = 0.03), the subscales

Table 3 Correlations[a] between the DISABKIDS and the CFQ-CF87 scales in a cohort of 103 children and adolescents with type 1 diabetes

CHQ-CF87	DISABKIDS								
	DCGM-37							DDM-10	
	Mental Independence (Inner strength)	Mental Emotion	Social Excl	Social Incl (Equality)	Physical limitations (abilities)	Treatment	DCGM-37 sumscore	DDM impact	DDM treatment
Physical function	0.21	0.15	0.21	0.21*	0.06	0.20	0.22 *	0.19	0.19
Role emotional	0.30**	0.39***	0.28**	0.27*	0.36**	0.59***	0.81***	0.67***	0.49***
Role behavioral	0.20	0.23*	0.15*	0.11	0.32**	0.23*	0.27*	0.22*	0.19
Role physical	0.26*	0.18	0.21*	0.17	0.34***	0.22*	0.29**	0.30**	0.15
Bodily pain	0.47***	0.51***	0.56***	0.49***	0.54***	0.49***	0.65***	0.38***	0.22*
Behavior	0.56***	0.59***	0.45***	0.45***	0.64***	0.60***	0.70***	0.54***	0.58***
Global behavior	0.26*	0.32**	0.23*	0.315**	0.32**	0.19	0.34***	0.26*	0.05
Mental health	0.69***	0.71***	0.58***	0.59***	0.71***	0.57***	0.81***	0.54***	0.55***
Self-esteem	0.60***	0.58***	0.52***	0.58***	0.64***	0.50***	0.72***	0.51***	0.44***
General health	0.54***	0.59***	0.54***	0.55***	0.60***	0.50***	0.70***	0.51***	0.44***
Change in Health	0.21*	0.25*	0.13	0.16	0.23*	0.07*	0.22*	0.11	0.11
Family activity	0.32*	0.33***	0.24*	0.14	0.22*	0.34***	0.35***	0.34***	0.38***
Family cohesion	0.33***	0.26*	0.35***	0.36***	0.45***	0.31**	0.43***	0.26*	0.28**

[a] Pearsons's correlation coefficient adjusted for age and gender

*p < 0.005. **p < 0.01. ***p < 0.001

Table 4 Effects of age and HbA1c on total and self reported scores in DISABKIDS.

		Age				HbA1c			
	Subscale	Unadjusted effect	p	Adjusted effect[a]*	P	Unadjusted effect	p	Adjusted effect[a]**	p
Total sum- score	HRQOL	*-0.94*	*0.08*	*-0.94*	*0.04*	*-2.49*	*0.01*	*-2.40*	*0.01*
Mental	Mental independence	*-0.78*	*0.15*	*-0.87*	*0.13*	*-0.58*	*0.64*	*0.62*	*0.62*
	Mental Emotion (Inner strength)	*-1.58*	*0.01*	*-1.684*	*0.01*	*-2.77*	*0.05*	*-2.73*	*0.05*
Social	Social inclusion	*-0.75*	*0.11*	*-0.61*	*0.21*	*-2.49*	*0.02*	*-2.26*	*0.03*
	Social exclusion (Social equality)	*-0.57*	*0.29*	*-0.48*	*0.37*	*-2.16*	*0.06*	*-2.02*	*0.09*
Physical	Physical limitations (Physical Ability)	*-0.78*	*0.09*	*-0.91*	*0.05*	*-3.19*	*0.001*	*-3.39*	*0.001*
	Medication/Treatment	*-1.27*	*0.07*	*-0.97*	*0.19*	*-3.77*	*0.01*	*-3.37*	*0.03*
Diabetes module	Impact	*-1.47*	*0.03*	*-1.38*	*0.04*	*-4.43*	*0.002*	*-4.38*	*0.002*
	Treatment	*-3.01*	*0.001**	*-2.84*	*0.001*	*-3.44*	*0.06*	*-2.54*	*0.16*

[a]Adjusted for gender, duration of diabetes and use of insulin pump vs. multi-injections using multiple linear regression analyses
*Effect per year of age, **Effect per % increment of HbA1c.
All subscales are scored from 0 to 100 with higher scores indicating higher self-perceived HRQOL.

"Inner strength" (77 ± 15.8 vs. 72 ± 13.1, $p < 0.01$) and "Social inclusion" (80 ± 11.7 vs. 74 ± 15,0 $p < 0.001$). In the DDM-10 "Treatment" scale parents tended to score higher than their children (66 ± 17.1 vs. 63 ± 20.4 $p = 0.14$).

Discussion

Applied to this Norwegian child and adolescent population with diabetes and their parents the internal consistency reliability of the DISABKIDS instruments was satisfactory for all except two scales judged by Cronbach's alpha. Furthermore, the scores on the DCGM-37 subscales showed moderate to high correlations with the "Mental health" subscale, but low correlations with the "Physical function" and family related subscales on the previously validated CHQ-CF87 and CHQ-PF50 questionnaires. The DISABKIDS instruments discriminated between groups based on metabolic control (HbA1c) and age in that increasing HbA1c and age were associated with lower HRQOL, while no significant differences were found with respect to gender, duration of diabetes or insulin pump vs. multi-injections treatment, although there was a tendency that pump-users rated the impact of disease less and social equality higher than those on multi-injections. Parents generally scored their children's HRQOL lower than the children and adolescents themselves.

Strengths and limitations

The major strength of the study was that the DISABKIDS questionnaires were applied to a wide age-range of children and adolescents (8-19 years old). Also, a broad perspective was taken by the collection of both self-reported and parent data. Furthermore, the results of the DISABKIDS were compared with those obtained with a HRQOL instrument (CHQ) which is well validated in Norwegian populations. Major weaknesses were the limited sample size and low participation rate. The reasons why 48% of the total population did not participate were multifactorial. The main reason reported by the nurses at the participative centers was that not all families were approached during periods with large work load in the clinic. However, this happened at random and we are confident that it did not introduce a bias.

Compared to the children registered in the national diabetes registry the study cohort had a somewhat lower mean HbA1c and higher proportion of insulin pumps users, but we still suggest that the results are representative of the national cohort for the following reasons: The difference in mean HbA1c was probably too small to be of major significance, and the difference in proportion of pump users was likely due to differences in treatment traditions. In Norway, pumps are, in practice, available without extra charge for all children, and the proportion choosing pumps is mainly a result of how familiar and confident the medical staff is with this modality. The clinics participating in the study have an active approach to encourage the use of pump, and the proportion of pump users in the study group was similar to the proportion among all the patients followed in the clinics.

Due to the relatively small sample size we did not perform factor analyses to assess the factor structure of the DCGM-37 or DDM-10 instruments, which is advocated when the instrument is applied to a larger population. With regard to reliability the study may be criticised for not applying test- retest reliability scores. However, this

was not included because of concern for the patients and logistic challenges.

It is suggested that the CHQ-CF87 can be read to children less than ten years of age. The medical staff, after piloting, reported that some children between 8-9 years had insufficient reading skills to respond reliably on the DISABKIDS. Use of the instruments might therefore have a limitation in the youngest population if the questions are not read to them.

Internal consistency

Most of the sub-scales showed Cronbach's alpha coefficients above 0.7, which are in agreement with the European field study [17]. The "Physical ability" scale had a low Cronbach's alpha compared to what was reported in the European field study where the patient populations consisted of seven different chronic conditions [17]. The "Physical ability" items in the DCGM-37 range from questions about difficulties with moving and running to questions on how life is ruled by the condition. Young persons with diabetes rarely experience physical complications due to the disease and, therefore, usually have no physical limitations. However, they experience significant practical and often emotional challenges due to repeated blood glucose measurements and administration of insulin, fear of hypoglycaemia, ketoacidosis and long term complications on a daily basis. Therefore, a low Cronbach's alpha was not unexpected. The Cronbach's alpha was also low for the "Social inclusion" subscale. In line with earlier reports, we suggest that the demands of adhering to treatment may create a feeling of separation from peers [20]. Also, differences in the experiences between users of pump and multi-injection treatments may create an incoherent scoring, explaining the lower alpha on this scale.

In general, few items in a scale, such as six items in the DISABKIDS subscales, may make Cronbach's alpha calculations vulnerable to variations between items, and mean inter-item (MII) correlation has been suggested as an alternative analysis of consistency [35]. This method modifies the findings in our study, as only the "Physical ability" subscale had a MII correlation below the lower acceptable limit of 0.2 underscoring that this subscale may not be informative for young people with diabetes. Furthermore, no scales in the two questionnaires had a MII above 0.50, strongly suggesting that the items in the scales were not redundant.

On the parents' reports Cronbach's alpha was above 0.7 on all subscales, and consistently higher than those of their children. Still, the pattern was the same as for their children in that the same subscales "Physical ability" and "Social inclusion" had the lowest Cronbach's alpha. These findings are in accordance with the European study [24].

The heading in both the child's and parent's form "About your typical day" may not be explicit enough for young people to connect it to "Physical ability". Parents, however, may have interpretive abilities that cause them to answer more consistently.

Convergent validity

Considering the content of the DISABKIDS questionnaires, some scales were expected to correlate better than others with the CHQ-CF87 scales. The pattern of associations between the subscales of the two instruments largely supported the validity of the DISABKIDS instruments. The European validation procedure used only a few of the questions from CHQ-CF87 (personal communication, John Chaplin, 2009). As far as we know a comparison with complete CHQ questionnaires has not been done earlier when examining the validity of DISABKIDS.

Six of the subscales from CHQ-CF87 showed high correlation with DCGM -37 total score. This is as expected since these six subscales, "Role emotional", "Bodily pain", "Behavior", "Mental health", "Self esteem" and "General health" all have items that are similar to those in the DCGM-37 Questionnaire. On the other hand, the DCGM-37 does not have any sub-scales mirroring the "Change in health", "Family activity" or "Family cohesion". It is therefore appropriate that these scales in CHQ-CF87 showed low correlation with the subscale scores in DCGM-37. This feature may have clinical and scientific implication for children with diabetes. Other instruments than DISABKIDS may therefore be more applicable if the primary goal is to measure family related factors [37,38]. Furthermore, clinicians and researchers need to be aware that the DISABKIDS instruments seem to have their strength in measuring the mental and emotional aspects rather than detecting physical health and family related aspects of HRQOL.

The different subscales of the two instruments demonstrated correlations that may seem surprisingly high or low with reference to how they are named. However, when considering the content of the respective items in the DCGM-37 and CHQ-CF87, associations were mainly as expected. For example, the names of the subscales "Physical ability" in the DCGM-37 and "Physical function" in the CHQ-CF87 give the impression that they measure similar functions. However, the "Physical function" subscale in CHQ-CF87 measures limitation in nine specific physical activities due to health problems, while DCGM -37's "Physical ability" scale is constructed differently, e.g.- items like "Is your life ruled by you condition" and "Does it bother you that you have to explain to others what you can and can't do?" measure emotional reactions to living with impairments, while the CHQ-CF87 to a larger extent addresses physical limitations. The "Physical ability" subscale in DCGM-37 correlated best with "Mental health" in CHQ-CF87, suggesting that the six questions measure a wider construct than physical abilities alone.

"Inner strength" (DCGM-37) correlated well with "Mental health" (CHQ-CF87) as would be expected due to the construction of single items in the two scales. The same was true for "Mental independence" in DISABKIDS vs. "Mental health" and "Self esteem" subscales in CHQ-CF87. The three constructs "Mental health", "Self esteem" and "General health" in CHQ-CF87 have 40 items covering most of the 37 item DISABKIDS questionnaire. The DCGM-37 therefore seems to be well suited for measuring the mental and emotional burden of a disease like diabetes.

The two DDM-10 subscales "Impact" and "Treatment" and correlated well with the "Role emotional" subscale on the CHQ-CF87. The two DDM-10 subscales actually measure the emotional consequences of having a chronic illness, quite similar to what "Role emotional" measures. The "Treatment scale" in DCGM-37 and the "Role emotional" scale were similarly correlated. These findings suggest that the DISABKIDS instruments are suitable for an early detection of mental and emotional worries with possible negative influence on self-management. The fact that these instruments are available as computer programs and can be completed by the patient and automatically scored prior to consultation, make them particularly attractive in clinical practice [39].

Discriminant features

The DISABKIDS generic instrument discriminated between patients based on age and metabolic control. It is likely that the scores on both of these variables have clinical significance as well [34]. Older children scored lower than the younger, a finding that is consistent with other studies on HRQOL using different instruments [31,40]. The effect of age may indicate a higher level of stress during puberty and late adolescence because of greater responsibility for own disease management and better cognitive ability to understand possible consequences of the disease, while parents, by taking more responsibility, tend to relieve the younger children from psychosocial burden [40].

The finding of higher HRQOL score with better metabolic control is also in accordance with earlier studies [41]. The fact that the DISABKIDS instruments are able to identify these differences is important, and of interest for both clinical work and further studies.

The reason why we did not find significant differences in scores related to gender, type of treatment or duration of diabetes may be due to lack of statistical power because of limited sample size. The trends were, however, similar to what has been found as statistical significant differences in larger studies [41].

When evaluating differences in HRQOL studies, it is equally important to evaluate the statistical findings and numeric differences in scores in relation to clinical importance. We believe that the statistically significant findings in our study are clinically significant as well. Generally, it has been suggested that on a scale of 0-100 a change of 5-10 points is clinically significant for an individual [34]. The numeric differences between those using insulin pump and multi-injections on the subscales "Impact" and "Treatment" on DDM-10 and on "Social equality" on the DCGM-37 may be clinically important, although they were not statistically significant in this limited study. The "Social equality" subscale consists of questions regarding external stigma. It has been reported that pump users have the ability to "hide" their disease better than those in need of other equipment for insulin delivery [42]. The feelings of less impact of disease and smaller problems related to treatment might therefore contribute to the pump users scoring higher on this subscale.

In agreement with earlier HRQOL studies we did not exclude diabetes patients with onset of disease less than one year prior to the study [40]. Patients with diabetes less than one year had non-significantly better HRQOL scores than those with longer duration. The lack of substantial difference may partly be due to the fact that most of those with duration less than one year had duration more than 6 months.

The DISABKIDS generic and diabetes specific modules showed differences between the children's and parent's score. The same findings, with parents tending to perceive their children's HRQOL lower than the children themselves, have been reported previously, for DISABKIDS as well as for other HRQOL instruments, and for other chronic diseases [20,43,44]. These findings may be due to changes in conceptualization of health related quality of life over the course of the disease trajectory towards better acceptance with duration of the disease [31,45]. It is also notable that the reverse was found on the DDM-10 "Impact scale", i.e. that disease was felt to have less impact by the parents than by their children or adolescents. The reason for this finding is not obvious, but may at least partly be due to the high proportion of pump users and parents believing that treatment with pumps implies less impact of the disease.

Conclusions

The Norwegian version of the child and parent DISABKIDS instruments DCGM-37 and DDM-10 had acceptable reliability and validity in a population of children and adolescents with type 1 diabetes. DISABKIDS also discriminated between clinical characteristics that are important for disease management. We therefore suggest that HRQOL assessment with DISABKIDS may be of importance as a supplement to other clinical indicators in medical practice and research.

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Authors' contributions
DHF designed the study, collected and analyzed the data and drafted the manuscript. TM, TW-L, MG contributed to conceptualisation and design, data analysis, interpretation of results, drafting and revising the manuscript. KD-J and TS invited DHF to research collaboration with the Norwegian Childhood Diabetes Registry, contributed to conceptualisation and design of the study, collection of data and revising the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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Artikkel 2

Artikkel 3

Appendices

Appendix 1: Information to Health care personell

Kodelisten

- Pasientens barkodelapp klistres på venstre side av kodelisten.
- Pasientnummer i Barnediabetessregisteret (Benchmarkingen) føres inn i den midterste rubrikken.
- Livskvalitetsstudiens Pasientnummer er en tallkode i høyre rubrikk på kodelisten
- **Pasientnummeret føres inn på forsiden av spørreskjemaene(hhv barn/ungdom og forelder.)**
- Det skal være **samme** nummer på både barnet /ungdommen sitt skjema og forelderen sitt skjema.
- "Kodelisten" skal oppbevares i låsbare skap på låste kontor frem til denne leveres til studieleder ved avslutning av avdelingens deltagelse i studien.

Utfylling

Vi ber dere informere både barnet /ungdommen og foreldrene at de helst ikke skal snakke sammen mens de fyller ut og at de selv skal legge skjemaene i konvolutt og levere tilbake til dere

Spesielt for barna mellom 8 og 10 som skal fylle ut bare skjemaet DISABKIDS vil det være fint hvis noen på poliklinikken eller den av foreldrene som ikke fyller ut leser spørsmålene for barna.

Spørsmål verørende studien kan stilles til
Dag Helge Frøisland, tlf: 90650835
dag.froisland@hil.no

"Barn og unge med diabetes – hvordan har de det?"

Informasjon til helsepersonell

Studien gjennomføres av Nasjonalt medisinsk kvalitetsregister for barne og ungdomsdiabetes
(Barnediabetesregistret)

Kontaktperson
Overlege og stipendiat
Dag Helge Frøisland
Tlf: 90650835
Email:dag.froisland@hil.no

Barnediabetesregisteret er et nasjonalt medisinsk kvalitetsregister for barne og ungdomsdiabetes.

Barn og unge med diabetes - hvordan har de det?

- Barnediabetesregistret vil i løpet av 2010 gjennomføre en landsdekkende studie basert på anerkjente testinstrumenter for å avdekke livskvalitet og comorbiditet hos barn og ungdom med diabetes.
- Vi trenger litt hjelp fra dere i som arbeider på helseinstitusjonene for gjennomføre datainnsamlingen.
- Det er viktig at vi får gjennomført denne studien av livskvalitetsfaktorer hos barn og unge med diabetes. Vi håper dere deler vår entusiasme selv om det blir noe ekstra arbeid for dere.

Instrumentpakken

Instrumentpakkene består av forskjellige skjema avhengig av alder:

- Barn 8-10
- Ungdom 11-18
- Foreldre 8-18

Hvem skal delta i studien?

Barn 8-10 = årskullene født 2000, 2001, 2002.
Barn 11-18= årskullene1991 til og med 1999 med Type I diabetes
Foreldre 8-10= en forelder til hver deltager fra årskullene 2000, 2001, 2002
Foreldre 11-18= en forelder til deltager fra årskullene 1991-1999

Eksklusjonskriterier:

Barn eller foreldre uten tilstrekkelige norsk kunnskaper.

Gjennomføring

Pasientbrosjyre og følgeskriv

- Pasientbrosjyre, (vedlegg 1)
- Følgebrev (vedlegg 2)

Foreslås lagt ved innkallingen til en av konsultasjonene i 2010.

Samtykkeerklæring og Underskrift

På selve konsultasjonen ber vi om at foreldre og barn presenteres for pasientbrosjyren og samtykkeerklæringene
Samtykkeerklæringene må signeres av:

- **Barn under 12 år: minst en av de foresatte**
- **Ungdom mellom 12 og 16 år undertegne sammen med minst en av de foresatte.**
- **Ungdom eldre enn 16 år undertegner selv**

- **Helsepersonell som har gitt informasjon skal også undertegne samtykkeskrivet**

Det er fint hvis dere viser at dere støtter studien og evt svarer på spørsmål. Studien er basert på avidentifiserte personopplysninger.

3: SKJEMAENE

- Skjemaene skal deles ut til hhv. en foreldre og barnet/ungdommen, deretter skal skjemaene fylles ut uten at foreldre og barn snakker sammen om spørsmålene.
- Barn mellom 8 og 10 kan trenge litt hjelp med å lese spørsmålene. (sekretær)
- Skjemaene legges i konvolutt av den som har fylt ut, som også lukker konvolutten og leverer den til helsepersonell på poliklinikken.
- Det vil ikke bli gitt tilbakemelding til poliklinikkene på enkeltpasienter.

4: Kodeliste og Pasientnummer

- For gjennomføringen vil det være best om en av personalet, gjerne diabetessykepleier ved poliklinikken, har som oppgave å registrere de som samtykker og dele ut skjema.
- Hvis barnet og foreldrene samtykker til å delta, skal de føres inn i en kodeliste (vedlegg 4).

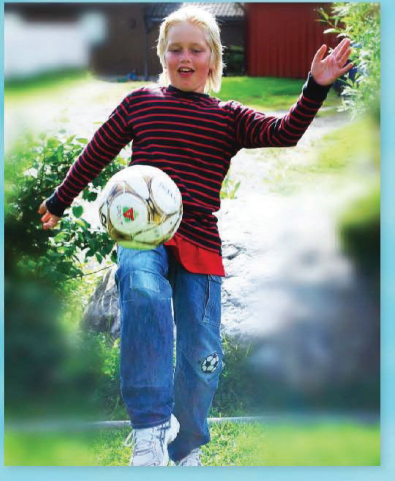
(se siste side)

BARN OG UNGE MED DIABETES - HVORDAN HAR DE DET?

VI SPØR DEG OM HJELP

-til å finne ut hvordan norske barn og unge med diabetes har det

HEI!
Vi er en gruppe som arbeider sammen for å støtte barn og unge med diabetes på best mulig måte. For å kunne gjøre det, er det viktig å vite noe om hvordan gruppen barn og unge med diabetes faktisk har det i Norge i dag.

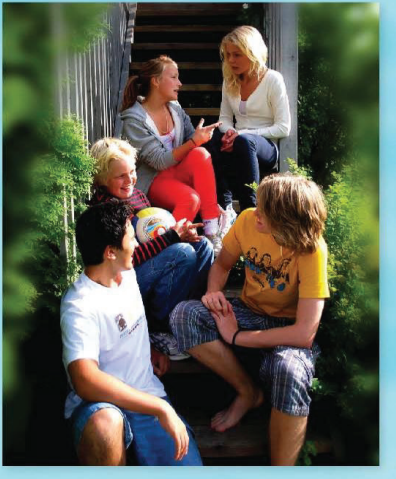


En måte å finne ut det på er ved å bruke spørreskjema som den som har diabetes og foreldrene kan fylle ut hver for seg.

En slik studie av livskvalitet hos barn og unge med diabetes har ikke blitt utført tidligere her i norge.

For å kunne få til dette trenger vi hjelp fra de som har diabetes og foreldrene deres.

Sammen med denne brosjyren ligger det et informasjonsskriv vedrørende denne studien.



Når du kommer til konsultasjon vil du bli spurt om du vil være med og du vil få spørreskjemaet utdelt slik at du kan fylle det ut mens du er på sykehuset.

I løpet av 2010 vil vi spørre alle barn og unge over 8 år og foreldrene deres om de kan tenke seg å delta i denne studien.

Hvis du ikke får en slik forespørsel kan du fortsatt delta ved å kontakte sykepleier på poliklinikken eller overlege Dag Helge Frøisland.

Det er helt frivillig om man vil delta eller ikke.

Trenger du mer informasjon om hva dette er, kan du kontakte sykepleier på barnepoliklinikken eller prosjektleder Dag Helge

KONTAKTINFO

Overlege

Dag Helge Frøisland
Tlf: 90 65 08 35
Mail: dag.froisland@hil.no

Dato: ID-nummer:
(Dag Måned År)

disabkids

Spørreskjema for barn og unge med kroniske sykdommer

Hei,

Vi vil gjerne at du svarer på noen spørsmål om hvordan du har hatt det i løpet av de siste fire ukene. Vi ber deg om å svare på alle spørsmålene hvis det er mulig for deg. Hvis det er et spørsmål du ikke forstår eller ikke ønsker å svare på, så hopp over det og gå til det neste

- Tenk tilbake på de fire siste ukene når du svarer på spørsmålene.
- Velg det svaret som du synes passer best og kryss av i ruten som hører til.

Hvis du er sammen med vennene dine «svært ofte» krysser du av i ruten som vist i dette eksempelet.

For eksempel:	Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
Hvor ofte er du sammen med venner?	☐	☐	☐	☒	☐

Det er ingen riktige eller gale svar. Det som er viktig er hva du mener.

Noen spørsmål om deg

A	Er du gutt eller jente?	☐ jente	☐ gutt		
B	Hvor gammel er du?	☐ år			
C	Hvilken kronisk sykdom har du? Kryss bare av for en sykdom.				
	☐ astma	☐ leddgikt	☐ eksem		
	☐ cerebral parese	☐ diabetes	☐ cystisk fibrose		
	☐ epilepsi	☐ andre → hvilke	☐		

I noen spørsmål bruker vi betegnelsen "sykdommen din". Når du ser betegnelsen "sykdommen din" ber vi deg tenke på hva du krysset av for ovenfor.

Om livet ditt

		Tenk på de fire siste ukene				
		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
1	Er du trygg på at du vil ha det bra i fremtiden?	☐	☐	☐	☐	☐
2.	Trives du med livet ditt?	☐	☐	☐	☐	☐
3.	Er du i stand til å gjøre alt du har lyst til, til tross for sykdommen din?	☐	☐	☐	☐	☐
4.	Føler du deg som alle andre til tross for sykdommen din?	☐	☐	☐	☐	☐
5.	Kan du leve det livet du ønsker til tross for sykdommen din?	☐	☐	☐	☐	☐
6.	Er du i stand til å gjøre ting uten foreldrene dine?	☐	☐	☐	☐	☐

Om en typisk dag for deg

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
7.	Er du i stand til å løpe og bevege deg som du vil?	☐	☐	☐	☐	☐
8.	Føler du deg sliten på grunn av sykdommen din?	☐	☐	☐	☐	☐
9.	Styrer sykdommen din livet ditt?	☐	☐	☐	☐	☐
10.	Plager det deg at du må forklare andre hva du kan og ikke kan gjøre?	☐	☐	☐	☐	☐
11.	Er det vanskelig å sove på grunn av sykdommen din?	☐	☐	☐	☐	☐
12.	Plager sykdommen deg når du leker eller gjør andre ting?	☐	☐	☐	☐	☐

Om dine følelser

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
13.	Gjør sykdommen din at du ikke trives med deg selv?	☐	☐	☐	☐	☐
14.	Er du lei deg på grunn av sykdommen din?	☐	☐	☐	☐	☐
15.	Bekymrer du deg på grunn av sykdommen din?	☐	☐	☐	☐	☐
16.	Gjør sykdommen deg sint?	☐	☐	☐	☐	☐
17.	Er du redd for framtiden på grunn av sykdommen din?	☐	☐	☐	☐	☐
18.	Gjør sykdommen din deg nedfor?	☐	☐	☐	☐	☐
19.	Plager det deg at livet ditt må planlegges?	☐	☐	☐	☐	☐

Om deg og andre mennesker

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
20.	Føler du deg ensom på grunn av sykdommen din?	☐	☐	☐	☐	☐
21.	Behandler lærerne deg annerledes enn de behandler andre elever?	☐	☐	☐	☐	☐
22.	Har du problemer med å konsentrere deg på skolen på grunn av sykdommen din?	☐	☐	☐	☐	☐
23.	Føler du at andre har noe i mot deg?	☐	☐	☐	☐	☐
24.	Opplever du at andre stirrer på deg?	☐	☐	☐	☐	☐
25.	Føler du deg annerledes enn andre barn/ ungdommer?	☐	☐	☐	☐	☐

Om deg og vennene dine

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
26.	Forstår andre barn/ungdommer sykdommen din?	☐	☐	☐	☐	☐
27.	Er du sammen med vennene dine?	☐	☐	☐	☐	☐
28.	Er du i stand til å leke eller gjøre ting med andre barn/ungdommmer (som idrett)?	☐	☐	☐	☐	☐
29.	Tror du at du kan gjøre de fleste ting like godt som andre barn/ungdommer?	☐	☐	☐	☐	☐
30.	Liker vennene dine å være sammen med deg?	☐	☐	☐	☐	☐
31.	Synes du det er lett å snakke med andre om sykdommen din?	☐	☐	☐	☐	☐

Om den medisinske behandlingen din

Tar du noen former for medisin for sykdommen din? (med medisin mener vi tabletter, krem, spray, insulin eller andre former for medisin)	Ja ☐	Nei ☐

Hvis ja, vennligst svar på spørsmålene under,
Hvis nei, hopp over dette avsnittet.

Tenk på de fire siste ukene!

	Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
32. Plager det deg å trenge hjelp med medisiner fra andre?	☐	☐	☐	☐	☐
33. Er det irriterende for deg å måtte huske på medisinen din?	☐	☐	☐	☐	☐
34. Er det noe ved medisinen du tar som gjør deg bekymret?	☐	☐	☐	☐	☐
35. Plager det deg å ta medisin?	☐	☐	☐	☐	☐
36. Hater du å ta medisinen din?	☐	☐	☐	☐	☐
37. Blir hverdagslivet ditt forstyrret av at du tar medisiner?	☐	☐	☐	☐	☐

Takk for hjelpen!

De tre siste spørsmålene tar for seg hvor mye problemer du har hatt med din diabetes **det siste året**

Om symptomer

		Tenk på det siste året				
		Aldri	En gang	Noen få ganger	Ofte	Hele tiden
a.	Hvor ofte har du hatt problemer med din diabetes det siste året?	☐	☐	☐	☐	☐
		Ikke i det hele tatt	Litt	Moderate	Ganske alvorlige	Ekstremt alvorlige
b.	Hvor alvorlig har problemene med din diabetes vært det siste året?	☐	☐	☐	☐	☐
		Aldri	I det siste året	Siste seks måneder	Siste måneden	Siste uka
c.	Når var siste gangen du hadde alvorlig føling(lavt blodsukker)?	☐	☐	☐	☐	☐

Takk for hjelpen

Dato: (Dag Måned År) ID-nummer:

Spørreskjema for barn og unge med diabetes

Hei,

Vi vil gjerne at du svarer på noen spørsmål om hvordan du har hatt det i løpet av de siste fire ukene.

Vi ber deg om å svare på alle spørsmålene hvis det er mulig for deg. Hvis det er et spørsmål du ikke forstår eller ikke ønsker å svare på, så hopp over det og gå til det neste

- Tenk tilbake på de fire siste ukene når du svarer på spørsmålene.
- Velg det svaret som du synes passer best og kryss av i ruten som hører til.

Hvis du er sammen med vennene dine «svært ofte» krysser du av i ruten som vist i dette eksempelet.

	Tenk på de fire siste ukene				
For eksempel	Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
Hvor ofte er du med vennene dine?	☐	☐	☐	☐	☐

Det er ingen riktige eller gale svar. Det som er viktig er hva **du** mener.

Om din diabetes

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
1.	Hindrer din diabetes deg fra å gjøre ting du har lyst til?	☐	☐	☐	☐	☐
2.	Styrer din diabetes dagen din?	☐	☐	☐	☐	☐
3.	Plager det deg at du må tenke på hva du spiser?	☐	☐	☐	☐	☐
4.	Er det vanskelig for deg å holde deg til matreglene dine?	☐	☐	☐	☐	☐
5.	Bekymrer du deg for blodsukkeret ditt?	☐	☐	☐	☐	☐
6.	Plager det deg at andre alltid kan spise og drikke så mye de vil?	☐	☐	☐	☐	☐

Om din diabetes

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
7.	Gjør det deg noe å ta insulin?	☐	☐	☐	☐	☐
8.	Blir du lei av å måle blodsukkeret ditt	☐	☐	☐	☐	☐
9.	Er du irritert over å måtte ha med deg måleutstyret ditt?	☐	☐	☐	☐	☐
10.	Plager det deg at du må planlegge alt?	☐	☐	☐	☐	☐

De tre siste spørsmålene tar for seg hvor mye problemer du har hatt med din diabetes det siste året

Om symptomer

		Tenk på det siste året				
		Aldri	En gang	Noen få ganger	Ofte	Hele tiden
a.	Hvor ofte har du hatt problemer med din diabetes det siste året?	☐	☐	☐	☐	☐
		Ikke i det hele tatt	Litt	Moderate	Ganske alvorlige	Ekstremt alvorlige
b.	Hvor alvorlig har problemene med din diabetes vært det siste året?	☐	☐	☐	☐	☐
		Aldri	I det siste året	Siste seks måneder	Siste måneden	Siste uka
c.	Når var siste gangen du hadde alvorlig føling(lavt blodsukker)?	☐	☐	☐	☐	☐

Takk for hjelpen

Date: (Dag Måned År) ID-nummer:

disabkids

Spørreskjema for foreldre til barn og unge med kroniske sykdommer

Kjære foresatt

Takk for at du tar deg tid til å fylle ut dette spørreskjemaet om ditt barns velvære og helserelaterte livskvalitet.

Vi vil gjerne at du svarer på dette spørreskjemaet på vegne av barnet ditt, men vennligst besvar spørsmålene uten å be barnet ditt om hjelp. Alle svarene du gir vil bli behandlet strengt konfidensielt.

Med mindre du blir bedt om noe annet ber vi deg tenke over hvordan barnet ditt har hatt det i løpet av de siste fire ukene når du svarer på spørsmålene.

Velg det svaret som du synes passer best og kryss av i ruten som hører til.

Hvis barnet ditt er sammen med vennene sine «svært ofte» krysser du av i ruten som vist i dette eksempelet.

	Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
Hvor ofte er barnet ditt sammen med venner?	☐	☐	☐	x	☐

Noen spørsmål om barnet ditt

A	Er barnet ditt gutt eller jente?	☐ jente	☐ gutt
B	Hvor gammel er barnet ditt?	☐ år	

C Hvilken kronisk sykdom har barnet ditt? Kryss bare av for en sykdom.

☐ astma	☐ leddgikt	☐ eksem
☐ cerebral parese	☐ diabetes	☐ cystisk fibrose
☐ epilepsi	☐ andre → hvilke	☐

Hvem fyller ut spørreskjemaet?

☐ mor ☐ far

☐ stemor/fars partner

☐ stefar/mors partner

☐ Andre → Hvem ?

I noen spørsmål bruker vi betegnelsen "sykdom". Når du ser betegnelsen "sykdom" ber vi deg tenke på hva du krysset av for ovenfor.

Om livet til barnet ditt

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
1	Er ditt barn trygg på at han/hun vil ha det bra i fremtiden?	☐	☐	☐	☐	☐
2.	Trives barnet ditt med livet sitt?	☐	☐	☐	☐	☐
3.	Er barnet ditt i stand til å gjøre det han/hun har lyst til, tross for sykdommen sin?	☐	☐	☐	☐	☐
4.	Føler barnet ditt seg som alle andre til tross for sykdommen sin?	☐	☐	☐	☐	☐
5.	Opplever barnet ditt å kunne leve livet slik han/hun ønsker til tross for sykdommen sin?	☐	☐	☐	☐	☐
6.	Opplever barnet ditt seg i stand til å gjøre ting uten deg/dere?	☐	☐	☐	☐	☐

Om en typisk dag for barnet ditt

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
7.	Opplever barnet ditt at hun/han er i stand til å løpe og bevege seg som det vil?	☐	☐	☐	☐	☐
8.	Føler barnet ditt seg sliten på grunn av sykdommen sin?	☐	☐	☐	☐	☐
9.	Føler barnet ditt at livet hans/hennes blir styrt av sykdommen?	☐	☐	☐	☐	☐
10.	Plager det barnet ditt å måtte forklare andre hva hun/han ikke kan gjøre?	☐	☐	☐	☐	☐
11.	Er det vanskelig for barnet ditt å sove på grunn av sykdommen?	☐	☐	☐	☐	☐
12.	Plager sykdommen barnet ditt når hun/han leker eller utfører andre aktiviteter?	☐	☐	☐	☐	☐

Om hvordan barnet ditt føler seg

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
13.	Gjør sykdommen at barnet ditt ikke trives med seg selv?	☐	☐	☐	☐	☐
14.	Er barnet ditt lei seg på grunn av sykdommen sin?	☐	☐	☐	☐	☐
15.	Er barnet ditt bekymret på grunn av sykdommen sin?	☐	☐	☐	☐	☐
16.	Blir barnet ditt sint på grunn av sykdommen?	☐	☐	☐	☐	☐
17.	Er barnet ditt redd for framtiden på grunn av sykdommen sin?	☐	☐	☐	☐	☐
18.	Blir barnet ditt nedfor på grunn av sykdommen sin?	☐	☐	☐	☐	☐
19.	Plager det barnet ditt at livet hans/hennes må planlegges?	☐	☐	☐	☐	☐

Om barnet ditt og andre mennesker

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
20.	Føler barnet ditt seg ensom på grunn av sykdommen sin?	☐	☐	☐	☐	☐
21.	Opplever barnet ditt at lærerne behandler henne/ham annerledes enn de andre elevene?	☐	☐	☐	☐	☐
22.	Opplever baret ditt at han/hun har problemer med å konsentrere seg på skolen på grunn av sykdommen sin?	☐	☐	☐	☐	☐
23.	Føler barnet ditt at andre har noe i mot ham/henne?	☐	☐	☐	☐	☐
24.	Opplever barnet ditt at andre stirrer på ham/henne?	☐	☐	☐	☐	☐
25.	Føler barnet ditt seg annerledes enn andre barn/ ungdommer?	☐	☐	☐	☐	☐

Om barnet ditt og vennskap

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
26.	Opplever barnet at andre barn/ungdommer forstår sykdommen hennes/hans?	☐	☐	☐	☐	☐
27.	Er barnet ditt sammen med vennene sine?	☐	☐	☐	☐	☐
28.	Opplever barnet ditt seg i stand til å leke eller gjøre ting sammen med andre barn/ungdommer?(for eksempel idrett)	☐	☐	☐	☐	☐
29.	Tror barnet ditt at han/hun kan gjøre de fleste ting like godt som andre barn/ungdommer?	☐	☐	☐	☐	☐
30.	Opplever barnet ditt at vennene liker å være sammen med ham/henne?	☐	☐	☐	☐	☐
31.	Synes barnet ditt at det er lett å snakke med andre om sykdommen sin?	☐	☐	☐	☐	☐

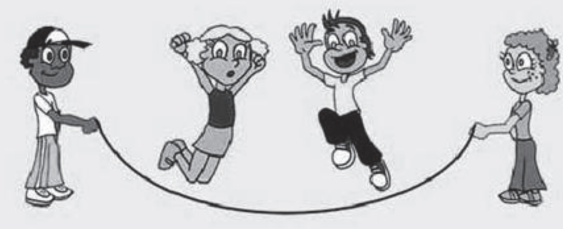
Om den medisinske behandlingen til barnet ditt

Tar barnet ditt noen former for medisin for sykdommen sin? (med medisin mener vi tabletter, krem, spray, insulin eller andre former for medisin)	Ja	☐	Nei	☐

Hvis ja, vennligst svar på spørsmålene under,
Hvis nei, hopp over dette avsnittet.

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
32.	Plager det barnet ditt å trenge hjelp med medisiner fra andre?	☐	☐	☐	☐	☐
33.	Er det irriterende for barnet ditt å måtte huske på medisinen sin?	☐	☐	☐	☐	☐
34.	Er det noe ved medisineringen som gjør barnet ditt bekymret?	☐	☐	☐	☐	☐
35.	Plager det barnet ditt å skulle ta medisin?	☐	☐	☐	☐	☐
36.	Hater barnet ditt å ta medisinen sin?	☐	☐	☐	☐	☐
37.	Opplever barnet at å ta medisin forstyrrer hverdagslivet hans/hennes?	☐	☐	☐	☐	☐



Takk for hjelpen!

Dato: (Dag Måned År) ID-nummer:

disabkids

Spørreskjema for foresatte til barn og unge med diabetes

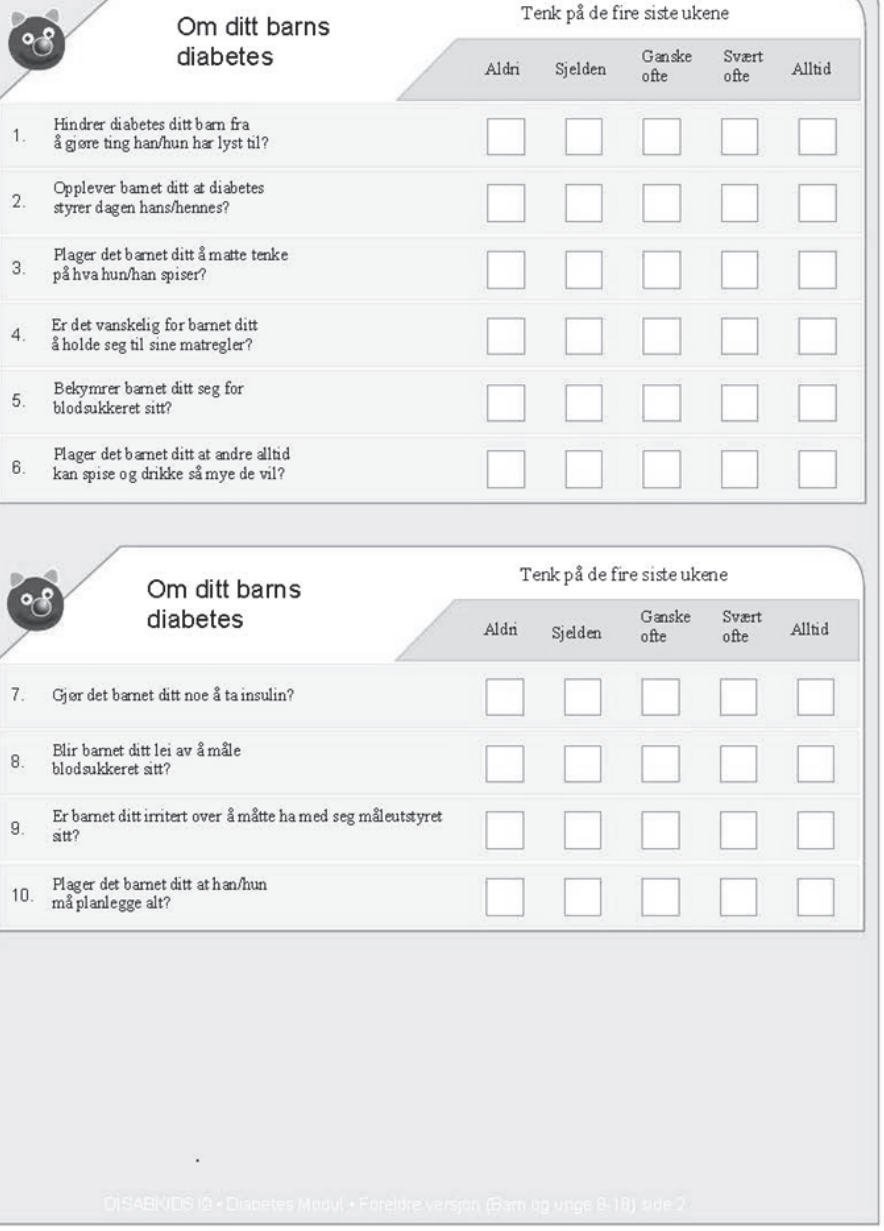
Kjære foresatte

Takk for at du tar deg tid til å fylle ut dette spørreskjemaet om ditt barns velvære og helserelaterte livskvalitet.

Vi vil gjerne at du svarer på dette spørreskjemaet på vegne av barnet ditt, men vennligst besvar spørsmålene uten å be barnet ditt om hjelp. Alle svarene du gir vil bli behandlet strengt konfidensielt.

Med mindre du blir bedt om noe annet ber vi deg tenke over hvordan barnet ditt har hatt det i løpet av de siste fire ukene når du svarer på spørsmålene

For eksempel:	Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
Hvor ofte er barnet ditt sammen med vennene sine?	☐	☐	☐	X	☐



Om ditt barns diabetes

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
1.	Hindrer diabetes ditt barn fra å gjøre ting han/hun har lyst til?	☐	☐	☐	☐	☐
2.	Opplever barnet ditt at diabetes styrer dagen hans/hennes?	☐	☐	☐	☐	☐
3.	Plager det barnet ditt å matte tenke på hva hun/han spiser?	☐	☐	☐	☐	☐
4.	Er det vanskelig for barnet ditt å holde seg til sine matregler?	☐	☐	☐	☐	☐
5.	Bekymrer barnet ditt seg for blodsukkeret sitt?	☐	☐	☐	☐	☐
6.	Plager det barnet ditt at andre alltid kan spise og drikke så mye de vil?	☐	☐	☐	☐	☐

Om ditt barns diabetes

Tenk på de fire siste ukene

		Aldri	Sjelden	Ganske ofte	Svært ofte	Alltid
7.	Gjør det barnet ditt noe å ta insulin?	☐	☐	☐	☐	☐
8.	Blir barnet ditt lei av å måle blodsukkeret sitt?	☐	☐	☐	☐	☐
9.	Er barnet ditt irritert over å måtte ha med seg måleutstyret sitt?	☐	☐	☐	☐	☐
10.	Plager det barnet ditt at han/hun må planlegge alt?	☐	☐	☐	☐	☐

De siste tre spørsmålene handler om hvor mye problemer barnet ditt har hatt med sin diabetes **i løpet av det siste året**.

Om symptomene til barnet ditt

Tenk på det siste året

		Aldri	En gang	Noen få ganger	Ofte	Hele tiden
a.	Hvor ofte har barnet ditt hatt problemer med sin diabetes det siste året?	☐	☐	☐	☐	☐
		Ikke i det hele tatt	Litt	Moderate	Ganske alvorlige	Ekstremt alvorlige
b.	Hvor alvorlige har barnets problemer med diabetes vært det siste året?	☐	☐	☐	☐	☐
		Aldri	I det siste året	Siste seks måneder	Siste måneden	Siste uka
c.	Når var siste gangen barnet hadde alvorlig føling (lavt blodsukker)?	☐	☐	☐	☐	☐

Takk for hjelpen!

Appendix 7: CHQ-87 questionnaire

Spørreskjema om barns helse - CHQ - CF 87

Til barn og ungdom

1. Vi vil gjerne spørre om hvordan du har det, hvordan du føler deg og aktiviteter du gjør hver dag. Dine svar vil ikke bli vist til andre.
2. Deltagelsen er frivillig.
3. Du svarer ved sette kryss i en av rutene (☐ ☐ ☐ ☐ ☐).
4. Selv om enkelte spørsmål kan se like ut, er det viktig at du svarer på alle spørsmålene.
5. Det finnes ingen riktige eller gale svar.

Del#1:Generell helse

1.1. Stort sett, vil du si at din helse er:

Utmerket	Meget god	God	Ganske god	Dårlig
☐	☐	☐	☐	☐

Del#2: Fysisk aktivitet

2.1. I løpet av de siste 4 ukene , har det vært vanskelig for deg å gjøre noen av de følgende aktiviteter på grunn av helseproblemer?

		Ja, svært vanskelig	Ja, ganske vanskelig	Ja, litt vanskelig	Nei, ikke vanskelig
a.	gjøre ting som krever **mye** anstrengelse som å spille fotball , løpe eller gå på tur?	☐	☐	☐	☐
b.	gjøre ting som krever **ganske mye** anstrengelse, som å sykle eller gå på skøyter?	☐	☐	☐	☐
c.	gå langt eller gå opp flere trapper?	☐	☐	☐	☐
d	gå rundt i nabolaget, til lekeområde eller til skolen?	☐	☐	☐	☐
e.	gå ett kort stykke eller gå opp en trapp?	☐	☐	☐	☐
f.	hjelpe til hjemme?	☐	☐	☐	☐
g.	sitte på huk, løfte noe eller bøye deg?	☐	☐	☐	☐
h.	spise, kle på deg, bade eller gå på toalettet alene?	☐	☐	☐	☐
i.	komme deg opp i og ut av sengen?	☐	☐	☐	☐

Del#3: Daglige aktiviteter

3.1. Har det, i løpet av de siste 4 ukene, vært vanskelig for deg å gjøre skolearbeid eller delta i vanlige aktiviteter med venner fordi du har følt deg TRIST eller ENGSTELIG?

	Har det vært vanskelig å:	Ja, svært vanskelig	Ja, ganske vanskelig	Ja, litt vanskelig	Nei, ikke vanskelig
a.	gjøre visse TYPER skolearbeid eller aktiviteter med venner	☐	☐	☐	☐
b.	bruke like MYE tid som du pleier på skolearbeid eller aktiviteter med venner	☐	☐	☐	☐
c.	GJØRE skolearbeid eller delta i aktiviteter med venner i det hele tatt	☐	☐	☐	☐

3.2. Har det, i løpet av de siste 4 ukene, vært vanskelig for deg å utføre skolearbeid eller vanlige aktiviteter med venner på grunn av problemer med din OPPFØRSEL?

	Har det vært vanskelig å:	Ja, svært vanskelig	Ja, ganske vanskelig	Ja, litt vanskelig	Nei, ikke vanskelig
a.	gjøre visse TYPER skolearbeid eller aktiviteter med venner	☐	☐	☐	☐
b.	bruke like MYE tid som du pleier på skolearbeid eller aktiviteter med venner	☐	☐	☐	☐
c.	GJØRE skolearbeid eller delta i aktiviteter med venner i det hele tatt	☐	☐	☐	☐

3.3. Har det, i løpet av de siste 4 ukene, vært vanskelig for deg å utføre skolearbeid eller vanlige aktiviteter med venner på grunn av problemer med din FYSISKE helse?

	Har det vært vanskelig å:	Ja, svært vanskelig	Ja, ganske vanskelig	Ja, litt vanskelig	Nei, ikke vanskelig
a.	gjøre visse TYPER skolearbeid eller aktiviteter med venner?	☐	☐	☐	☐
b.	bruke like MYE tid som du pleier på skolearbeid eller aktiviteter med venner?	☐	☐	☐	☐
c.	GJØRE skolearbeid eller delta i aktiviteter med venner i det hele tatt?	☐	☐	☐	☐

Del#4: Om å ha vondt

4.1. I løpet av de siste 4 ukene, hvor mye vondt eller hvor sterke smerter har du hatt?

☐	☐	☐	☐	☐	☐
Ingen	Meget svake	Svake	Moderate	Sterke	Svært sterke

4.2. I løpet av de siste 4 ukene, hvor ofte har du hatt smerter eller vondt?

☐	☐	☐	☐	☐	☐
Aldri	En eller to ganger	Noen få ganger	Ganske ofte	Meget ofte	Hver dag eller nesten hver dag

Del#5: Om deg selv

5.1. I løpet av de siste 4 ukene, hvor ofte kunne hver av de følgende uttalelser beskrive deg?

		Svært ofte	Ganske ofte	Noen ganger	Nesten aldri	Aldri
a.	oppført deg barnslig?	☐	☐	☐	☐	☐
b.	kranglet?	☐	☐	☐	☐	☐
c.	hatt vanskelig for å konsentrere deg?	☐	☐	☐	☐	☐
d.	latt være å gjøre som læreren eller foreldrene dine har bedt deg om?	☐	☐	☐	☐	☐
e.	villet være alene?	☐	☐	☐	☐	☐
f.	løyet eller jukset?	☐	☐	☐	☐	☐
g.	hatt problemer med å bli likt?	☐	☐	☐	☐	☐
h.	følt deg kløne te?	☐	☐	☐	☐	☐
i.	rømt hjemmefra?	☐	☐	☐	☐	☐
j.	hatt talevansker (f.eks. stamming)?	☐	☐	☐	☐	☐
k.	stjålet noe hjemme?	☐	☐	☐	☐	☐
l.	stjålet noe borte?	☐	☐	☐	☐	☐
m.	blitt sur hvis du ikke har fått det som du ville?	☐	☐	☐	☐	☐
n.	blitt skikkelig sint hvis du ikke har fått det som du ville?	☐	☐	☐	☐	☐
o.	syntes det har vært vanskelig å være sammen med andre?	☐	☐	☐	☐	☐
p.	syntes det har vært vanskelig å være venner?	☐	☐	☐	☐	☐

5.2. Sammenliknet med andre barn på din alder, vil du si at din oppførsel er:

Utmerket	Meget god	God	Ganske god	Dårlig
☐	☐	☐	☐	☐

Del#6: Følelser og humør

6.1. I løpet av de siste fire ukene, hvor stor del av tiden har du:

		Hele tiden	Nesten hele tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a.	følt deg trist?	☐	☐	☐	☐	☐
b.	hatt lyst til å gråte?	☐	☐	☐	☐	☐
c.	følt deg redd eller skremt?	☐	☐	☐	☐	☐
d.	bekymret deg for ting?	☐	☐	☐	☐	☐
e.	følt deg ensom?	☐	☐	☐	☐	☐
f.	vært ulykkelig?	☐	☐	☐	☐	☐
g.	vært nervøs?	☐	☐	☐	☐	☐
h.	følt deg irritert eller sint?	☐	☐	☐	☐	☐
i.	vært glad?	☐	☐	☐	☐	☐
j.	vært i godt humør?	☐	☐	☐	☐	☐
k.	trivdes med det du gjør?	☐	☐	☐	☐	☐
l.	hatt det morsomt?	☐	☐	☐	☐	☐
m.	følt deg rastløs?	☐	☐	☐	☐	☐
n.	hatt problemer med å sove?	☐	☐	☐	☐	☐
o.	hatt hodepine?	☐	☐	☐	☐	☐
p.	likt deg selv?	☐	☐	☐	☐	☐

Del#7: Selvtillit

7.1. I løpet av de siste 4 ukene, hvor fornøyd har du vært med:

		Svært fornøyd	Ganske fornøyd	Hverken fornøyd eller misfornøyd	Nokså mis-fornøyd	Svært mis-fornøyd
a.	deg selv?	☐	☐	☐	☐	☐
b.	skolearbeidet ditt?	☐	☐	☐	☐	☐
c.	hvor flink du er i idrett?	☐	☐	☐	☐	☐
d.	vennene dine?	☐	☐	☐	☐	☐
e.	de tingene du KAN?	☐	☐	☐	☐	☐
f.	hvordan du kommer overens med andre?	☐	☐	☐	☐	☐
g.	kroppen og utseendet ditt?	☐	☐	☐	☐	☐
h.	hvordan du stort sett føler deg?	☐	☐	☐	☐	☐
i.	hvordan du kommer overens med familien?	☐	☐	☐	☐	☐
j.	livet ditt?	☐	☐	☐	☐	☐
k.	deg selv som venn?	☐	☐	☐	☐	☐
l.	hva andre synes om deg?	☐	☐	☐	☐	☐
m.	hvor flink du er til å snakke med andre?	☐	☐	☐	☐	☐
n.	helsen din?	☐	☐	☐	☐	☐

Seksjon#8: Helse

8.1. Hvor riktig eller gal er hver av de følgende påstander for deg?

		Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a.	Min helse er utmerket.	☐	☐	☐	☐	☐
b.	En gang var jeg så syk at jeg trodde jeg skulle dø.	☐	☐	☐	☐	☐
c.	Jeg pleier ikke ut å bli så veldig syk.	☐	☐	☐	☐	☐
d.	Jeg tror ikke jeg er like frisk som andre barn jeg kjenner.	☐	☐	☐	☐	☐
e.	Jeg har aldri vært veldig syk	☐	☐	☐	☐	☐
f.	Jeg blir alltid syk.	☐	☐	☐	☐	☐
g.	Jeg tror jeg kommer til å få dårligere helse når jeg blir eldre.	☐	☐	☐	☐	☐
h.	Jeg tror jeg kommer til å ha veldig god helse når jeg blir eldre.	☐	☐	☐	☐	☐
i.	Jeg bekymrer meg aldri om helsen min.	☐	☐	☐	☐	☐
j.	Jeg føler meg frisk nå.	☐	☐	☐	☐	☐
k.	Jeg tror jeg bekymrer meg mer for min helse enn andre på min alder.	☐	☐	☐	☐	☐

8.2. Sammenliknet med for ett år siden, hvordan vil du vurdere helsen din nå:

☐	☐	☐	☐	☐
Mye bedre nå enn for 1 år siden	Litt bedre nå enn for 1 år siden	Omtrent den samme nå som for 1 år siden	Litt dårligere nå enn for 1 år siden	Mye dårligere nå enn for 1 år siden

Del#9: Familien

9.1. I løpet av de siste 4 ukene, hvor ofte har din helse eller atferd:

		Svært ofte	Ganske ofte	Noen ganger	Nesten aldri	Aldri
a.	begrenset de aktivitetene familien kunne gjøre sommen?	☐	☐	☐	☐	☐
b.	avbrutt forskjellige daglige familie aktiviteter (måltider, se på TV)?	☐	☐	☐	☐	☐
c.	begrenset familiens muligheter til å gjøre noe på kort varsel?	☐	☐	☐	☐	☐
d.	ført til spenning eller konflikter i hjemmet?	☐	☐	☐	☐	☐
e.	vært en årsak til uenighet eller krangling i familien?	☐	☐	☐	☐	☐
f.	gjort at familien har måttet forandre eller avlyse planer i siste liten?	☐	☐	☐	☐	☐

9.2. Iblant har familier problemer med å fungere sammen. De er ikke alltid enige og de kan bli sinte på hverandre. Stort sett, hvordan vil du vurdere din families evne til å fungere sammen?

Utmerket	Meget god	God	Nokså god	Dårlig
☐	☐	☐	☐	☐

Del#10: Om deg selv

10.1. er du

☐ Gutt

☐ Jente

10.4. Har du noen gang søkt hjelp hos noen på skolen, helsestasjon eller legekontor for?
(Kryss av for Ja eller Nei ved hvert spørsmål)

	Ja	Nei
a. Skader som følge av ulykker?	•	•
b. Sengevæting?	•	•
c. Brystsmerter?	•	•
d. Diare eller forstoppelse?	•	•
e. Langvarig slapphet?	•	•
f. Hodepine?	•	•
g. Dårlig matlyst over tid?	•	•
h. Mareritt eller søvnproblemer?	•	•
i. Magesmerter?	•	•

TAKK FOR AT DU SVARTE PÅ SPØRSMÅLENE!

Appendix 8: CHQ-Parent form 50

CHILD HEALTH QUESTIONNAIRE (CHQ-PF50)

SPØRRESKJEMA OM BARNS HELSE

PARENT FORM – 50 NORWEGIAN (NORWAY)

REG. NUMMER

DATO

DAG / MÅNED / ÅR

FORKLARINGER: Dette skjemaet handler om ditt barns helse og hvordan han/hun føler seg. Svarene vil bli behandlet konfidensielt. Det finnes ingen riktige eller gale svar. Hvis du er usikker på hva du skal svare på et spørsmål, gi det beste svaret du kan. Det er viktig at du fyller ut for hvert spørsmål. Vennligst bruk blå eller svart penn.

Korrekt avkryssing: ■ ☒ ☑ ⇨

DEL 1: BARNETS GENERELLE HELSE

		Utmerket	Meget god	God	Ganske god	Dårlig
1.1.	Stort sett, vil du si at ditt barns helse er:	☐	☐	☐	☐	☐

DEL 2: BARNETS FYSISKE AKTIVITET

De følgende spørsmålene handler om fysiske aktiviteter som barnet kanskje utfører i hverdagen.

		Ja, svært begrenset	Ja, ganske begrenset	Ja, litt begrenset	Nei, ikke noe begrenset
2.1.	I løpet av de siste 4 ukene, har barnet ditt vært begrenset i utførelsen av noen av de følgende aktiviteter på grunn av helseproblemer?				
	a. Gjøre ting som krever mye anstrengelse, som å spille fotball eller løpe?	☐	☐	☐	☐
	b. Gjøre ting som krever nokså mye anstrengelse, som å sykle eller gå på skøyter?	☐	☐	☐	☐
	c. Evne (fysisk) til å bevege seg rundt i nabolaget, på lekeplassen eller på skolen?	☐	☐	☐	☐
	d. Gå hundre meter eller gå opp en trapp?	☐	☐	☐	☐
	e. Sitte på huk, løfte ting eller bøye seg?	☐	☐	☐	☐
	f. Ta vare på seg selv, med hensyn til å spise, kle på seg, bade eller gå på toalettet?	☐	☐	☐	☐

DEL 3: BARNETS DAGLIGE AKTIVITETER

3.1. I løpet av de siste 4 ukene, har ditt barns skolearbeid eller aktiviteter med venner vært begrenset på en av følgende måter på grunn av FØLELSESMESSIGE problemer eller problemer med hans/hennes ATFERD?	Ja, svært begrenset	Ja, ganske begrenset	Ja, litt begrenset	Nei, ikke noe begrenset
a. begrenset i TYPE skolearbeid eller aktiviteter med venner han/hun kunne gjøre	☐	☐	☐	☐
b. begrenset i HVOR MYE tid han/hun kunne bruke på skolearbeid eller aktiviteter med venner	☐	☐	☐	☐
c. begrenset i å UTFØRE skolearbeid eller aktiviteter med venner (det krevde ekstra anstrengelse)	☐	☐	☐	☐

3.2. I løpet av de siste 4 ukene, har ditt barns skolearbeid eller aktiviteter med venner vært begrenset på en av følgende måter på grunn av problemer med hans/hennes FYSISKE helse?	Ja, svært begrenset	Ja, ganske begrenset	Ja, litt begrenset	Nei, ikke noe begrenset
a. begrenset i TYPE skolearbeid eller aktiviteter med venner han/hun kunne gjøre	☐	☐	☐	☐
b. begrenset i HVOR MYE tid han/hun kunne bruke på skolearbeid eller aktiviteter med venner	☐	☐	☐	☐

DEL 4: SMERTE

4.1 I løpet av de siste 4 ukene, hvor sterke kroppslige smerter eller ubehag har barnet ditt hatt?

Ingen	Meget svake	Svake	Moderate	Sterke	Meget sterke
☐	☐	☐	☐	☐	☐

4.2 I løpet av de siste 4 ukene, hvor ofte har barnet ditt hatt kroppslige smerter eller ubehag?

Aldri	En eller to ganger	Noen få ganger	Ganske ofte	Meget ofte	Hver/nesten hver dag
☐	☐	☐	☐	☐	☐

DEL 5: BARNETS ATFERD
Nedenfor finner du en liste med punkter som beskriver barns atferd eller problemer de av og til har.

5.1. Hvor ofte i løpet av de siste 4 ukene kunne en av de følgende uttalelser beskrive barnet ditt?	Meget ofte	Ganske ofte	Noen ganger	Nesten aldri	Aldri
a. Kranglet mye?	☐	☐	☐	☐	☐
b. Hatt problemer med å konsentrere seg eller å følge med?	☐	☐	☐	☐	☐
c. Løyet eller jukset?	☐	☐	☐	☐	☐
d. Stjålet ting hjemme eller borte?	☐	☐	☐	☐	☐
e. Hatt raserianfall eller heftig humør?	☐	☐	☐	☐	☐

5.2 Sammenliknet med andre barn på samme alder, vil du si at hans/hennes oppførsel er:

Utmerket	Meget god	God	Ganske god	Dårlig
☐	☐	☐	☐	☐

DEL 6: BARNETS FØLELSER OG HUMØR
De følgende utsagnene handler om barns humør.

6.1. I løpet av de siste 4 ukene, hvor mye av tiden tror du barnet ditt har:	Hele tiden	Nesten hele tiden	En del av tiden	Litt av tiden	Ikke noe av tiden
a. Vært på gråten?	☐	☐	☐	☐	☐
b. Følt seg ensom?	☐	☐	☐	☐	☐
c. Virket nervøs?	☐	☐	☐	☐	☐
d. Virket irritert eller sint?	☐	☐	☐	☐	☐
e. Virket glad?	☐	☐	☐	☐	☐

DEL 7: SELVTILLIT

De følgende spørsmålene handler om hvor fornøyd barnet er med seg selv, skolen og andre mennesker. Det kan være greit å tenke på hvordan andre barn på samme alder kanskje føler om de samme tingene.

7.1. I løpet av de siste 4 ukene, hvor fornøyd tror du barnet ditt har vært med:	Svært fornøyd	Ganske fornøyd	Hverken fornøyd eller misfornøyd	Ganske misfornøyd	Svært misfornøyd
a. Hvor flink han/hun er på skolen?	☐	☐	☐	☐	☐
b. Hvor flink han/hun er i idrett?	☐	☐	☐	☐	☐
c. Sine venner?	☐	☐	☐	☐	☐
d. Sitt utseende?	☐	☐	☐	☐	☐
e. Sine familieforhold?	☐	☐	☐	☐	☐
f. Sitt liv generelt?	☐	☐	☐	☐	☐

DEL 8: HELSE

De følgende utsagnene handler om helse generelt.

8.1. Hvor riktig eller gal er hver av de følgende påstander for ditt barn?	Helt riktig	Stort sett riktig	Vet ikke	Stort sett gal	Helt gal
a. Mitt barn ser ikke ut til å være like friskt som andre barn jeg kjenner.	☐	☐	☐	☐	☐
b. Mitt barn har aldri vært alvorlig sykt.	☐	☐	☐	☐	☐
c. Når det er "noe som går", får som regel mitt barn det.	☐	☐	☐	☐	☐
d. Jeg tror at barnet mitt vil få et friskt liv.	☐	☐	☐	☐	☐
e. Jeg bekymrer meg mer for mitt barns helse enn hva andre gjør for sine barn.	☐	☐	☐	☐	☐

8.2 Sammenliknet med for ett år siden, hvordan vil du vurdere ditt barns helse nå:

Mye bedre nå enn for 1 år siden	Litt bedre nå enn for 1 år siden	Omtrent den samme nå som for 1 år siden	Litt dårligere nå enn for 1 år siden	Mye dårligere nå enn for 1 år siden
☐	☐	☐	☐	☐

DEL 9: DU OG DIN FAMILIE

9.1. I løpet av de siste 4 ukene, hvor MYE uro eller bekymring medførte hvert av det følgende for DEG?

	Ingen	Litt	En del	Ganske mye	Svært mye
a. Ditt barns fysiske helse?	☐	☐	☐	☐	☐
b. Ditt barns følelsesmessige velvære eller atferd?	☐	☐	☐	☐	☐
c. Ditt barns konsentrasjonsevne eller evne til å lære?	☐	☐	☐	☐	☐

9.2. I løpet av de siste 4 ukene, var tiden DU hadde til å dekke egne behov BEGRENSET på grunn av:

	Ja, svært begrenset	Ja, ganske begrenset	Ja, litt begrenset	Nei, ikke begrenset
a. Ditt barns fysiske helse?	☐	☐	☐	☐
b. Ditt barns følelsesmessige velvære eller atferd?	☐	☐	☐	☐
c. Ditt barns konsentrasjonsevne eller evne til å lære?	☐	☐	☐	☐

9.3. I løpet av de siste 4 ukene, hvor ofte har ditt barns helse eller atferd:

	Meget ofte	Ganske ofte	Noen ganger	Nesten aldri	Aldri
a. Begrenset de aktiviteter dere kunne gjøre sammen som familie?	☐	☐	☐	☐	☐
b. Avbrutt forskjellige daglige familieaktiviteter (måltider, se på TV)?	☐	☐	☐	☐	☐
c. Begrenset familiens muligheter til å gjøre noe på kort varsel?	☐	☐	☐	☐	☐
d. Ført til spenning eller konflikter i hjemmet?	☐	☐	☐	☐	☐
e. Vært en årsak til uenighet eller krangling i familien?	☐	☐	☐	☐	☐
f. Gjort at du har måttet avlyse eller forandre planer (privat eller arbeid) i siste liten?	☐	☐	☐	☐	☐

9.4. Iblant har familier problemer med å fungere sammen. De er ikke alltid enige, og de kan bli sinte. Stort sett, hvordan vil du vurdere din families evne til å fungere sammen?

Utmerket	Meget god	God	Ganske god	Dårlig
☐	☐	☐	☐	☐

SPØRREQUIZ

Diabetesbehandlingen stiller store krav til den som lever meddiabetes. Noen ganger er det lurt å repetere litt om hva diabetes er. Fyll ut spørreskjemaet og svar det du mener er riktig

1:Det finnes to typer diabetes. Type 1 er den som flest ungdom har. Type 1 diabetes skyldes...

- At man har spist for mye sukker da man var mindre
- At man er overvektig og insulin virker dårligere i kroppen.
- At cellene i bukspyttkjertelen ikke lenger produserer nok insulin

2: Blodsukker er mengden glukose i blod. Normalt blodsukker varierer mellom...

- 0-3
- 4-8
- 6-10

3: Når du går til kontroll på poliklinikken måles HbA1c. Hva er HbA1c?

- Den sier noe om hvor høyt blodsukkeret har vært siste 3-4 uker
- Den sier noe om hvor høyt blodsukkeret har vært i gjennomsnitt de siste 2-3 månedene
- Den forteller hvor mange doser insulin jeg har satt siden jeg var hos legen sist.

4: Lavt blodsukker kalles hypoglykemi. Symptomer på dette kalles føling. De fleste tar druesukkertabletter hvis de får føling(det er lurt å måle blodsukkeret først) Hvilket utsagn under synes du stemmer best?

- Man bør alltid ta druesukker hvis blodsukkeret er under 6
- Man bør ikke ta druesukker før blosukkeret er under 2
- På dagtid er det greit å vente på neste vanlige måltid hvis blodsukkeret er rundt 4

5: Føling kan være ubehagelig. Mange tror føling er svært farlig. Hva mener du er riktig av utsagnene under?

- Det er bedre for kroppen å unngå føling og at man forsøker å ha et blodsukker mellom 9 og 15
- Det er best for kroppen at man ligger lavt i blodsukker og ofte måler blodsukker mellom 2 og 4
- Det er best for kroppen at man verken har mange høye eller mange lave blodsukkerverdier.

6: Høyt blodsukker over tid..

- kan man lett merke på kroppen at man har
- er lurt å ha fordi man unngår alvorlige følinger
- kan gi akutte plager, men også komplikasjoner senere i livet

7: Druesukkertabletter inneholder karbohydrat. Hvilken vekt har du og hvor mange tabletter eller hvor mange gram karbohydrat tar du hvis du har føling?

Jeg er _____KG . Jeg tar _____tabletter av typen_____ når jeg har føling.

Jeg tar _____gram karbohydrat for å heve blodsukkeret med ca 2 enheter når jeg har føling

8: Hva er glukagon?

- Et motreguleringshormon som kroppen selv produserer hvis man får veldig lavt blodsukker.
- Et stoff som diabetikere bør spise ofte.
- Glukagon er akkurat som Insulin og virker slik at blodsukkeret synker.

9: Når du har blodsukker over 15 kan det være lurt å måle ketoner. Hvilket utsagn er mest riktig.

- Det gjør ingen ting om jeg har ketoner over 4
- Ketoner i blodet betyr at jeg har fått for lite insulin over tid og at kroppen bryter ned fett som energi til cellene.
- Ketoner i blodet betyr at jeg har spist for mye sukker

10: For lite insulin til maten jeg spiser fører til..

- At maten ikke blir fordøyd ordentlig
- Lavt blodsukker og føling
- At jeg får høyt blodsukker

11: Novo Rapid er et hurtigvirkende insulin som mange bruker i pumpe eller penn.

- Novo Rapid har sin maksimale virkning etter ca 1 time og det passer med blodsukkerstigningen etter et måltid.
- Novo Rapid skal settes ca 2 timer etter måltid, hver gang.
- Det er bedre å bruke langtidsvirkende insulin (Insulatard)når man skal spise.

12: I puberteten skjer det masse med kroppen. For de som har diabetes endrer også mye seg. Hvilket utsagn under er mest korrekt?

- Man trenger mindre insulin enn man gjorde før man gikk inn i puberteten
- Man får ofte større insulinbehov når man er i pubertet, spesielt om natten
- Puberteten fører til mer hormoner. Slik at kroppen også produserer mer av hormonet Insulin enn før puberteten.

13: Hvilken av disse uttalelsene om karbohydrater er <u>feil</u>?

- Karbohydrater finnes bare i sukker.
- Karbohydrater gir kroppen energi.
- Karbohydrater bør utgjøre omtrent halvparten av vårt daglige energiinntak.
- Karbohydrater øker blodsukkeret.

14: Det anbefales at vi spiser nesten halvparten av energien vår som karbohydrater. Hvilken av matvarene under er det lurt å spise mer av? Kryss av for det riktigste svaret.

- Korn, poteter, ris, pasta
- Karbohydrater fra brød og fiber
- Sukkerholdige matvarer

15: Hvilken av disse faktaopplysningen om juice er riktig?

- Juice inneholder masse fett
- Juice inneholder veldig lite sukker
- Juice er en god proteinkilde
- Det er nesten dobbelt så mye sukker i 1 glass juice som i 1 glass melk

16: Alternativene under er råd for et godt kosthold, men ett råd er dårlig,hvilket?

- Spis relativt lite fett
- Unngå mettet/animalsk fett
- Drikk mer vann
- Drikk helmelk
- Spis mer fiberrik mat

17: Hvis du har diabetes, hvilket nivå bør blodsukkeret ligge på ved måling 2 timer etter middag?

- 2-4 mmol/L
- 4-10 mmol/L
- 10-14 mmol/L
- Høyere enn 14 mmol/L

18: Hva er forskjellen på type 1 og type 2-diabetes?

- Type 1-diabetes er forstadiet til type 2-diabetes
- Type 1-diabetes debuterer ofte hos barn Type 2-diabetes debuterer som regel hos godt voksne
- Insulin er standardbehandlingen ved type 2, men ikke ved type 1-diabetes
- Type 1-diabetes skyldes insulinmangel, mens type 2-diabetes skyldes insulinoverskudd

19: Hva er hovedoppgavene til hormonet insulin?

- Å senke blodsukkeret
- Å heve blodsukkeret
- Å øke frigivingen av sukker fra leveren
- Å øke utskillelsen av sukker fra musklene

20: Hvordan oppdages diabetes vanligvis?

- Det måles et for lavt blodsukker
- Det foreligger "føling" + at blodsukkeret måles for lavt
- Det foreligger symptomer på høyt blodsukker tørste, økt mengde tissing, slapphet.
- Det måles for høyt blodsukker

21: Hvilke av følgende komplikasjoner er ikke typisk for diabetes?

- Åreforkalkning (arteriosklerose)
- Lavt blodsukker (hypoglykemi)
- Høyt blodsukker (hyperglykemi)
- Hard avføring

22: Hva er <u>ikke</u> en vanlig årsak til lavt blodsukker?

- For mye insulin
- Dårlig regulert diabetes med store reperasjonsdoser
- Fysisk aktivitet
- Glemt dose med insulin

23: Hva er det vanligste problemet ved diabetes?

- At blodsukkeret er for høyt
- At blodsukkeret er for lavt

24: Hva er et bra (ikke-fastende) blodsukker?

- 4-10 mmol/L
- 10-14 mmol/L
- 14-18 mmol/L
- Over 18 mmol/L

25: Hvilken matsort nevnt nedenfor er gunstigst for blosukkerreguleringen din?

- Poteter
- Pasta
- Småkaker
- Kornblanding

26: Er regelmessig mosjon bra for behandlingen av diabetes?

- Ja
- Nei, man bør ta det med ro
- Nei, blodsukkeret stiger ved mosjon
- Nei, det øker risikoen for "føling"

27: Hvis du regelmessig kontrollerer ditt blodsukker, når skal du da teste deg?

- 2 timer før måltid
- 30 minutter etter måltid
- 1,5 timer etter måltid

System Usability Scale (SUS)

Norwegian version (translated by Eirik Årsand)

	Helt uenig				Helt enig
1. Jeg kunne tenke meg å bruke dette systemet ofte	1	2	3	4	5
2. Jeg synes systemet er unødvendig komplisert	1	2	3	4	5
3. Jeg synes systemet er enkelt å bruke	1	2	3	4	5
4. Jeg skulle gjerne hatt teknisk hjelp for å være i stand til å bruke systemet	1	2	3	4	5
5. Jeg synes de ulike delene i systemet henger fint i sammen	1	2	3	4	5
6. Jeg synes det var for mye uoverensstemmelse mellom de ulike delene i systemet	1	2	3	4	5
7. Jeg vil tro at de fleste vil kunne lære seg dette systemet veldig raskt	1	2	3	4	5
8. Jeg synes dette systemet er veldig tungvint å bruke	1	2	3	4	5
9. Jeg føler at jeg mestrer dette systemet veldig bra	1	2	3	4	5
10. Jeg trenger å lære meg mange flere ting før jeg kan komme i gang med å bruke systemet	1	2	3	4	5

Intervjuguide

START:

Hvorfor vil jeg snakke med deg?

Hvor lang tid vil det ta?

Anonymt.

SELVE INTERVJUET:

Tredelt - studie:

1. SMS inn
2. SMS ut
3. Diadagboka

FØR PROSJEKTET

1. **Diabetessykdommen - livet med?Empowerment, Kompetanse, mestring og egenomsorg**
   - Fortell litt om livet ditt som diabetiker. Sammenheng mellom sykdommen du har og livet du lever?
   - Fortell hva du opplever som mest utfordrende i ditt liv med daibetes?
   - Hvorfor opplever du dette som mest utfordrende?
   - Fortell hvordan du opplevelr **mestring** – herunder tilgang til kunnskaper, sosiale ressurser eller utstyr, og evne til å utnytte disse.
   - **Kompetanse:** Hva forbinder du med ordet kompetanse og kompetanse i relasjon til diabetes?
   - Hvordan vil du beskrive din kompetanse for å leve med diabetes?
   - **Kontekst:**Varierer du mye bruken av diabetesoppførsel ettersom hvilken sammenheng du er i?
   - Hvilke faktorer i behandlingsapparatet påvirker din behandling mest?

- Fortell litt om din innflytelse over eget liv/sykdommen? – mestring
- Hvordan kan helsepersonell styrke deg som diabetiker til større grad av mestring for egen sykdom? MAKT VS. MEDVIRKNING
- Fortell om du kan litt om dine ønsker om å bedre din egen livssituasjon?

UNDERVEIS I PROSJEKTET

2. **Kompetanse, mestring og egenomsorg**

- Fortell litt om hvordan du oppfatter prosjektet? –Si litt om opplevelsen av om de ble tilrettelagt for deg?
- Fortell litt om din egeninnsats til prosjektet – Hvordan har du mestret prosjektet? Konsekvenser, endringer. Og evt om prosjektet har hatt noen betydning for deg?
- Fortell om dine rutiner i din hverdag er noe blitt forandret? Mat, søvn, trening? - Hvordan har prosjektet hatt innvirkning på ditt daglige arbeid med egenbehandling av sykdommen din?
- Kan du si noe om din forståelse av sykdommen diabetes?
- Si litt om mobiltelefonprosjektet i relasjon til den praktiske hverdagen som diabetiker.
- Opplevelse av **mestring** – herunder tilgang til kunnskaper, sosiale ressurser eller utstyr, og evne til å utnytte disse.
- Følelsen av anerkjennelse i forbindelse med egenmedisinering
- Hvordan kan helsepersonell styrke deg som diabetiker til større grad av mestring for egen sykdom? MAKT VS. MEDVIRKNING
- Hva tror du er viktige faktorer for at ungdommen skal la seg påvirke til bedre kontroll i sin hverdag (irettesettelse,trusler,ros,kommunikasjon?)
- Hvilke faktorer i prosjektet opplevde du påvirket deg mest? SMS, Opplæringsbeskjeder, Dagboka.

ETTER PROSJEKTET

- Si litt om evt ønsker for å endre/ bedre din egen livssituasjon?
- Hvordan er din motivasjon til å forsette å jobbe med diabetessykdommen?
- Hvis du hadde fått muligheten, ville du ha fortsatt med mobilen?

Teknikk/forbedringspotensialet

a. Fortell om hvordan det har vært å bruke mobilen?
b. Hva har fungert med mobilen?
c. Hva har ikke fungert på mobilen?

Hva kunne vært annerledes på mobilen?

Noe du har lyst til tilføre?

AVSLUTNING:

Parafrasering av det viktigste.
Takk for intervjuet.
Spør om det er mulig å ta kontakt igjen hvis det er noe som er uklart.