SHARED DISEASE MANAGEMENT IN PEDIATRIC DIABETES CARE
THE ROLE OF E-HEALTH IN PATIENT–PROFESSIONAL COMMUNICATION AND PATIENT–PATIENT INTERACTION

Emiel A. Boogerd

UITNODIGING
U bent van harte uitgenodigd voor het bijwonen van de openbare verdediging van mijn proefschrift

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THE ROLE OF E-HEALTH IN PATIENT–PROFESSIONAL COMMUNICATION AND PATIENT–PATIENT INTERACTION

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Emiel A. Boogerd
Shared Disease Management in Pediatric Diabetes Care

The role of eHealth in patient-professional communication and patient-patient interaction

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Shared Disease Management in Pediatric Diabetes Care

The role of eHealth in patient-professional communication and patient-patient interaction

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KEEP IN MIND

Andy Warhol
“You need to let the little things that would ordinarily bore you suddenly thrill you.”

Thomas Edison
“I have not failed. I’ve just found 10,000 ways that won’t work.”

Lucius Annaeus Seneca
“One of the most beautiful qualities of true friendship is to understand and to be understood.”

Henry Rollins
“You need a little bit of insanity to do great things.”
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General introduction
Type 1 Diabetes (T1D) is a chronic metabolic disease, characterized by a defect of insulin secretion and/or absorption. Approximately 6000 children (0-18 years) in the Netherlands suffer from T1D, which makes it the second most common chronic disease after asthma in childhood. Since no cure is available yet, the treatment consists of a complex disease management, in which the child or parents measure blood glucose levels and administer insulin several times a day. A team of physicians, nurses, dieticians and psychologists supports them in the disease management. Having to deal with the disease management tasks in everyday life can lay a heavy burden on the child with T1D and her or his parents. This can lead to serious psychosocial problems, which can affect the performance of the disease management. In the last decades, children with T1D and their parents and healthcare professionals have benefited from technological advancement, resulting in increasingly smarter devices with more possibilities to monitor blood glucose levels and administer insulin. Nonetheless, children and adolescents with T1D and their parents are at increased risk for developing psychosocial problems, such as anxiety, depression and psychological distress, which are frequently related to poor disease management. The aim of the studies in this thesis is to support adolescents with T1D and the parents of younger children with T1D in dealing with the disease and the disease management. The foci in this thesis are to (1) identify the needs and preferences of adolescents and parents regarding diabetes care, as well as their expectation about the additional value of eHealth support, and to (2) investigate the feasibility of a web-based patient portal, Sugarsquare. The study focused on parents of children with T1D up to 12 years, and on adolescents with T1D over the age of 12.
Type 1 Diabetes

What is diabetes?
T1D is a chronic autoimmune disease, characterized by an insulin deficiency. Insulin is a hormone produced by the pancreas and regulates the metabolism of carbohydrates and the storage of fats. As such, it is essential for cells in order to use carbohydrates for energy. When insulin production is disturbed or when the body does not react adequately to the produced insulin, diabetes can occur. Diabetes is a group of metabolic diseases, with three main types:

- Type 1 Diabetes, in which insufficient insulin is produced.
- Type 2 Diabetes, in which the body shows an inadequate reaction to insulin.
- Gestational diabetes, which is a state of high blood-sugar levels during pregnancy.

Prevalence and incidence
The quality of registration of diagnoses of T1D differs between countries. In the Netherlands, for instance, a central registration of diagnoses of T1D does not exist, which makes it difficult to report accurate prevalence and incidence numbers. What research does show, is that Europe is the region with the highest registered number of children with T1D. In the Netherlands, researchers estimate that approximately 6,000 children in the age of 0 to 18 and 10,000-12,000 children and adolescents in the age of 0 to 25 have the diagnosis T1D. Each year, about 86,000 new cases of childhood and adolescent T1D (0-14 years old) are presented worldwide. Approximately 21,600 of these cases can be found in Europe, making it the region with also the highest incidence rates. In the Netherlands, incidence rates seem to have doubled during the period from 1980 to 2011.

Generally, worldwide incidence rates have risen over the years. However, the character of these increases in incidence differs between countries. Incidence rates in some countries are characterized by an increase in the age group of 0-5. In other countries, like in the Netherlands, the incidence in the 0-5 group has been steady over the last 20 years, and a rise is found in the 6-14 group.
Diagnosis and start of treatment
A set of acute symptoms is typical for T1D: blurring of vision, weight loss, polyuria (excessive urinating), and polydipsia (excessive thirst). In the Netherlands, children who present these symptoms are examined by the general practitioner, who measures their blood glucose level. If hyperglycemia is present, the child is referred to a pediatrician for diagnostics and treatment. When a pediatrician confirms the diagnosis, the child is referred to a specialized diabetes team the same day. A specialized diabetes team consists of at least one pediatric diabetologist, nurse practitioner, psychologist and dietician, all specialized in pediatric diabetes care. Following initial referral, the diabetes team focuses on stabilizing the child’s health, by starting insulin treatment, and by hospitalization if this is considered vital for recovery. In the weeks following diagnosis, the child and the parents continuously receive intensive daily treatment from the diabetes team, in order to acquire knowledge of diabetes and disease management skills and to identify potential strengths and risks for adequate disease management.

Diabetes management
Since there is currently no cure for T1D available, treatment focuses on external insulin administration performed by the children or their parents, by means of multiple daily injections or continuously by means of an insulin pump. The correct insulin dosage primarily depends on immediate glycemic control (current blood glucose level) and recent or future carbohydrate intake as well as exercise and stress levels. The self-monitoring of blood glucose (SMBG), in which the child or parents determine the amount of glucose in his or her blood, is the best measure for immediate glycemic control. SMBG is generally done by taking a drip of blood from the fingertip, which is then analyzed by a small digital meter. Another option for SMBG is by using a sensor that is placed under the skin, enabling continuous glucose monitoring.
Immediate glycemic control is often used as an indication for adequate disease management, together with Hemoglobin A1c (HbA1c), which reflects the average glucose level over the previous period (approximately 8-12 weeks, depending on the individual). According to
the IDF, the chance for complications is minimized when glucose levels are generally kept between 4.0 and 8.0 mmol/l (4), or between 4.0 and 7.5 mmol/l, according to the American Diabetes Association 17. Exact insulin goals should be individualized, however, based on benefit-risk assessment 4,16,17.

**Acute complications: hypoglycemia, hyperglycemia and diabetic keto-acidosis**
As mentioned, the insulin dosages needed depend on the immediate glycemic control, carbohydrate intake and exercise. Inadequate insulin administration can typically lead to fluctuations in blood glucose levels, varying from very low blood glucose levels (hypoglycemia), when too much insulin is administered, to very high blood glucose levels (hyperglycemia), in case of low insulin administration. Hypoglycemia is characterized by loss of strength, loss of concentration, dizziness and drowsiness and can lead to coma. It is not surprising that hypoglycemia is found to be a significant cause of anxiety and fear in children with T1D and caregivers 18,19. Hyperglycemia is a state in which blood glucose levels rise above an optimal level, which is 7.5 mmol/l (ADA) or 8 mmol/l (ISPAD) in case of children and adolescents 18,19. A lack of energy, tiredness, loss of weight, polyuria and polydipsia, loss of concentration and increased irritability characterize a hyperglycemic state. This can eventually lead to high concentration of ketones (acids) in the blood stream and eventually to a potentially lethal state called Diabetic Keto-Acidosis (DKA). DKA can lead to confusion, a comatose state and eventually death. As such, adequate disease management, consisting of repeated blood glucose monitoring and adequate insulin administration is vital.

**Long term complications: microvascular and macrovascular**
Adequate glucose levels also reduce the chance for development of microvascular complications such as retinopathy, neuropathy and nephropathy or macrovascular complications like coronary artery disease, cerebrovascular disease and peripheral vascular disease, which can lead to severe morbidity and mortality 5,16. Retinopathy can cause reduced sight and blindness, and neuropathy can cause pain, paresthesiae, reduced muscle strength and autonomic dysfunction. Nephropathy can cause hypertension and renal failure 16. Macrovascular complications are related to cardiac disease, stroke and loss of limbs. Adequate glucose levels in childhood and adolescence are crucial for prevention of long-term complications. Other complications related to T1D are cognitive problems, disruptions in growth and pubertal development, degeneration of body-fat, inflammability, limited joint mobility or edema as well as other autoimmune diseases, particularly thyroid and celiac disease 16. Although the first signs of complications can appear during pre-adolescence, the chance for developing complications seems to increase during adolescence 20,21.
How is diabetes care (ideally) organized?

In the Netherlands, usual care is provided by a secondary or tertiary outpatient diabetes team. These diabetes teams are usually affiliated to a hospital, but can also operate as an independent clinic. They ideally operate according to the national and international guidelines for diabetes care, in which is recommended that a child receives treatment from a multidisciplinary diabetes team, consisting of physicians (pediatric diabetologists), nurse practitioners, psychologists and dieticians, all specialized in pediatric diabetes care. Child and parents are invited for a consultation with the physician and nurse practitioner every three months. During these consultations, blood glucose levels are analyzed, HbA1c and growth curves are established and factors that interfere with disease management are discussed. A single consultation with a psychologist and a dietician shortly after diabetes is diagnosed are part of standard care. Children and parents can request consultations with both disciplines during ongoing care. Children are discussed multidisciplinary several times per year.

The diabetes team can be accessed during office hours through regular phone and email. For immediate urgent contact outside office hours, an emergency phone number is available. As such, care is guaranteed on a 24 hours a day basis, seven days a week. Once a year, an extensive blood and urine test is conducted as well as a comprehensive physical examination. During consultations, education concerning diabetes and disease management is repeatedly offered. Education is provided in a group or individually, and in a way that it is applicable to real life situations.

Psychosocial impact of Type 1 Diabetes

For the children in the age of 12 or younger, parents are the primary communicators for the diabetes team. Children in the ages of 13 and older are coached to take on more and more responsibility for their own disease management, in order to become the primary communicator at age 16. Therefore, parents of children (under the age of 13) and adolescents (age 13 and older) were considered as the target populations in this study.
**Psychosocial impact on parents**

Parents described caring for a child with T1D as an overwhelming experience, requiring constant vigilance. Parents must come to terms with having a child with a potentially life-threatening disease and carrying out a labor-intensive and complicated daily disease management. They live with constant worry about hypoglycemia or hyperglycemia, increased feelings of responsibility for their child’s health, and the desire to promote optimal growth and development. Every stage in life is characterized by its own issues. As a result, parents and children need to repeatedly fit the treatment into a new context. Early childhood, for instance, is the stage in which parents have to monitor their child closely, since children themselves are unable or less able to recognize and communicate early signs of hypoglycemia. Although parents remain primarily responsible for the disease management, the child performs the disease management tasks, where possible, and under close or distant supervision of their parents or other caregivers. During pre-adolescence, the responsibility for disease management shifts from parents to child. As such, parents find themselves continuously balancing between letting the child experiment with newly obtained independence and responsibility and intervening in the disease management when necessary. During adolescence the search for this balance continues. This can become problematic when parents attempt to enforce the, in their opinion necessary, performance of disease management.

Studies across different diseases have shown that disease management for T1D is particularly challenging for parents, compared to the disease management of other chronic diseases, such as cystic fibrosis and cancer and can lead to increased levels of parenting stress. Pediatric parenting stress was described as “the interrelationships among three central features: (1) child health, (2) parental roles, responsibility, and burden, and (3) psychological and behavioral response and adaptation to illness” by Streisand and Monaghan. Parenting stress can lead to a decreased quality of life in the parents and in problematic behavior, distress, and decreased quality of life in the child with T1D. This can lead to poor disease management skills by and worsened glycemic control of the child, making parenting stress a relevant factor for diabetes care.

9 years ago, Susan’s parents heard that their seven-year-old daughter was diagnosed with a potentially life-threatening, chronic disease. This initiated a period in which they had to simultaneously process this awful news, and learn how to become experts in managing a complex disease in a couple of days. As Susan grew older, she took over more and more of her disease management. This meant for her parents that they had to let Susan experience (with) her newly earned responsibility, despite the risks of things going wrong.
Psychosocial impact on adolescents

Adolescence is the transitional stage between childhood and emerging adulthood and is often considered as the most difficult stage in life to cope with diabetes. Biological changes during puberty complicate disease management, for instance due to unpredictable changes in secretion of growth hormones that affect insulin sensitivity. From a psychosocial perspective, adolescence is characterized by an increased need for gaining independence and autonomy, illustrated by an increased need for detachment from parents and increased risk-seeking behaviors. During this stage in life, the adolescent experiments with different roles and peer groups for identity-development, which is important for future wellbeing. This need for independence and autonomy can interfere with adequate diabetes management. Especially adolescents with T1D and suboptimal blood glucose levels are, due to the burden of having to cope with diabetes in everyday life, at risk for higher levels of diabetes related distress, such as symptoms of depression and anxiety, behavioral problems and a decreased quality of life. Studies also revealed that adolescents and young adults with T1D are twice as likely to use antidepressant than controls without diabetes, and that referral rates for mental health service were 19% higher in adolescents and young adults with T1D compared to their healthy peers. Silverstein and colleagues found that 13% of T1D patients in the age of 10 to 17 reported symptoms of depression and Herzer and Hood describe a sample of 276 adolescents with T1D, of which 17% reported trait anxiety symptoms and 13% reported state anxiety symptoms.

The importance of adequate assessment and treatment of diabetes related psychosocial problems is stressed by the consequences of these problems for disease management, as they can lead to poorer glycemic control, treatment adherence and more complications during adolescence. As a result, only a small part of the adolescents reaches optimal blood glucose levels. A study in the United States, for instance, revealed that only 21-23% of the 7.303 adolescents enrolled in the study (aged 13 to 19 years) reached an optimal HbA1c. Although some studies do indicate a decrease over time, literature is quite clear about the prevalence of persistent psychosocial problems in a subgroup of children and adolescents with T1D, and also about the importance of adequate screening of those who are at increased risk.

When Susan turned 13, the diabetes seemed to get increasingly unpredictable every day. It became harder for Susan to keep her blood glucose levels within the normal range. This evoked a sense of failure, which made Susan feel down and irritable. She also tended to focus on the differences between her life and those of her classmates and on the impact the diabetes has on her daily life. As Susan’s wellbeing deteriorated, her treatment adherence decreased.
Potential support for parents and adolescents
Given the growing evidence for the relationship between psychosocial problems and disease management, there is a growing attention for psychosocial factors in regular diabetes care and psychosocial care is included in clinical guidelines for diabetes care. Psychosocial interventions for parents of children with T1D predominantly focus on parent-child interaction or intra-psychological mechanisms affecting mental health outcomes or disease management. Results, however, are contradictory and sustainability is unknown. In general, behavioral interventions that include cognitive restructuring, goalsetting and problem solving show the most promising effects. Despite the importance of patient-professional interaction for good disease management, the majority of the available interventions lack attention for the role of healthcare professionals.

EHealth

What is eHealth?
EHealth is increasingly used to facilitate and strengthen the role of health care professionals in supporting daily disease management. EHealth is a broad field of interest that focuses on the impact of technology on health and healthcare, for instance by using devices, the Internet or serious games. EHealth can target anyone, from educating the general public about the consequences of smoking using serious games to supporting diabetes patients through devices that support daily disease management. Using the Internet has great potential for care aimed at the chronically ill, because it is ideal for provision of communication and exchange of information, and for facilitating communication between patients and healthcare professionals outside the boundaries of the hospital, which are both important factors in chronic disease management. Major trends in the domain of implementation of technology in healthcare are the increased focus on convenience in providing general care, the increased focus on chronic conditions and the migration of interventions away from hospitals into the patients’ homes.

EHealth in diabetes care
In a review concerning the state of eHealth in pediatric diabetes care, Harris, Hood, and Mulvaney described three major trends. The first one is the use of devices, such as blood
glucose meters and insulin pumps in combination with online monitoring of outcomes. The second trend concerns telehealth, which includes using cell phones, message services and video-conferencing in order to support disease management. Telehealth was used in the first place for delivering diabetes care to patients in rural or sparsely populated areas. The main benefit of telehealth is that it can intervene in the context in which the targeted behavior occurs. This potentially contributes to the integration of care into patients’ daily disease management. The third trend concerns the provision of online support and exchange of information via the Internet aimed to improve strategies of disease management. EHealth seems to be mainly implemented in diabetes care for adolescents or young adults given their familiarity with the Internet and new technologies. The use of eHealth for supporting parents of children is less widespread. Available studies describe parents’ regular Internet use for seeking information and parents’ expectations of web-based interventions and their positive attitude towards using Internet in care. However, only a few studies actually attempted to systematically develop and evaluate an eHealth intervention for parents of children with T1D. In general, eHealth studies tend to focus on single components of care, such as online cognitive behavioral therapy (cbt), online forums or online education. There is little research into the efficacy and feasibility of Internet interventions that combine multiple aspects of care. Especially interventions that combine multiple components of care with patient-professional interaction are scarce.

Aim of the study

Goal
The goal of the present studies was to develop an eHealth intervention that supports parents and adolescents in their daily disease management and decreasing the parents’ parenting stress and improving the adolescents’ quality of life, by facilitating easy access to the diabetes team, peer contact and the exchange of information.

Research questions
1. What is the psychosocial health of children and adolescents with T1D and what is the level of parenting stress in their parents?
2. What are their needs and preferences regarding care and additional online support?
   a. What are the needs and preferences of adolescents (aged 12-18) with T1D?
   b. What are the needs and preferences of parents of children (aged 0-12) with T1D?
3. What is feasibility of online intervention for parents and adolescents?
   a. Is it feasible to implement an online intervention supporting contact between diabetes team and patients (adolescents and parents of children), and between patients?
b. What is the preliminary effect of an online intervention on adolescents’ quality of life and parents’ parenting stress?

**Description of chapters**

In order to answer these research questions, we assessed psychosocial problems in children and adolescents with T1D and their parents with standardized questionnaires and compared the results with clinical estimations of pediatricians and nurse practitioners (chapter 2). We also gathered the perspectives of adolescents with T1D and parents of children with T1D on current diabetes care and potential points for improvements from their perspective (chapters 3 & 4). The data of the adolescents were used as a basis for the development of a web-based patient portal, Sugarsquare, which we subsequently evaluated for feasibility and preliminary effect (chapter 5). We composed a research protocol, based on the data of the parents, in which we describe the development of a Sugarsquare version for parents of a child with T1D (chapter 6), which we subsequently evaluated for feasibility and preliminary effect (chapter 7).
Reference list


Assessment of psychosocial problems in children with type 1 diabetes and their families: the added value of using standardized questionnaires in addition to clinical estimations of nurses and pediatricians
Abstract

Aims and objectives
To investigate the assessment of psychosocial problems in children with Type 1 Diabetes (T1D) by means of clinical estimations made by nurses and pediatricians and by using standardized questionnaires.

Background
Although children with T1D and their parents show increased risk for psychosocial problems, standardized assessment of these problems lacks in diabetes care.

Design
By comparing these different modes of assessment, using a cross-sectional design, information about the additional value of using standardized questionnaires is provided. Methods. Participants were 110 children with T1D (aged 4–16), their parents, and healthcare professionals. Children filled out the Strengths and Difficulties Questionnaire and the Pediatric Quality of Life Inventory, Diabetes Module. Parents filled out the Strengths and Difficulties Questionnaire parent-report and the Parenting Stress Index. Independently, nurses and pediatricians filled out a short questionnaire, which assessed their clinical estimations of the children’s psychosocial problems and quality of life, and parents’ levels of parenting stress. Reports of children and parents were compared to clinical estimations.

Results
Children in our sample showed more psychosocial problems and lower health-related quality of life than their healthy peers. In approximately half of the children, dichotomous estimations by healthcare professionals and dichotomized reports by patients and parents were in agreement. In 10% of the children, no psychosocial problems were present according to professionals’ estimations, although patients and parents-reported psychosocial problems. In 40%, psychosocial problems were present according to professionals’ estimations, although parents and patients did not report psychosocial problems.

Conclusion
Children with T1D show more psychosocial problems than healthy children. Professionals seem to tend towards overestimating psychosocial problems.

Relevance to clinical practice
Extending the assessment of psychosocial problems with routine screening on patient-reported outcomes, using validated questionnaires, could be of additional value in tailoring care to the needs of the individual child and parents.
Chapter 2

Introduction

Worldwide, the prevalence of Type 1 Diabetes (T1D) among children under the age of 15 is 440,000. It is estimated that 70,000 children develop T1D each year and this incidence is increasing. In the Netherlands, there are currently 6000 children diagnosed with T1D. The nationwide incidence of T1D among 0–14-year olds has risen from 11.1/100,000 per year in 1978–1980 to 18.6/100,000 per year in 1996–1999. This makes T1D, after asthma, the second most common chronic disease in young people in the Netherlands. T1D often requires an invasive treatment regime. Effective diabetes self-management requires child and parents to fit their lifestyle to the disease. This can have a profound impact on the mental health of both the children with T1D and their families. Children with T1D are more likely to experience psychosocial problems and a poor quality of life than their healthy peers. Parents often show increased levels of parenting stress due to diabetes-related events (e.g. diagnosis and hospitalisations), daily hassles (e.g. medical regimens and diets) and worries about unforeseeable implications in their child’s future. In addition, psychosocial functioning of the parent and the child are highly related: parenting stress is one of the strongest determinants of psychosocial problems in children with diabetes. Importantly, the implications of psychosocial problems in children with T1D and their parents are not limited to domains of mental and social functioning. Psychosocial problems have important implications for the success of parenting stress, disease management and medical treatment outcomes. For instance, depressive symptoms, for which children with diabetes have an increased risk, are found to have a negative effect on diabetes self-management and to subsequently lead to worsened glycaemic control, recurrent keto-acidosis and hospitalisation as well as to early onset of complications. High levels of externalising behaviour problems in childhood are associated with poor treatment adherence and subsequent worsened glycaemic control in current and later life. Further, research has shown that elevated levels of parenting stress are associated with poor self-management by the child, low levels of treatment adherence and worsened glycaemic control.
Background

Based on the above findings, diabetes teams are advised to take the psychosocial well being of a child with T1D and their parents into account in their treatment. However, assessing psychosocial wellbeing by healthcare professionals is not yet standardised in paediatric diabetes care. As primary care for children with T1D is provided by healthcare professionals, the need for routine psychosocial screening raises the question to which extent healthcare professionals’ estimations alone suffice to adequately identify psychosocial problems, risk factors and resilience factors in children with T1D and their parents. Recent studies have shown that using standardised questionnaires to assess the child’s psychosocial well being can be of added value for paediatric diabetes care. Unfortunately, these studies neglected to assess parents’ well being and failed to determine the added value of the validated questionnaires on healthcare professionals’ clinical assessments. In order to fill this gap, in this study, the following research questions were investigated:

1. What are the levels of psychosocial problems and diabetes-related quality of life in children with T1D, using self-reported and parent completed standardized questionnaires?
2. What are the levels of parenting stress in their parents, using parent completed standardized questionnaires?
3. What are the levels of psychosocial problems, diabetes related quality of life and parenting stress based on independent clinical estimations by healthcare professionals?
4. What is the agreement between self-reported and parent completed standardized assessments and independent clinical estimations by healthcare professionals?

The study enables us to evaluate the added value of standardized questionnaires in addition to healthcare professionals’ clinical estimations.

Methods

Recruitment and enrolment

Screening, as investigated in this cross-sectional study, was part of the usual diabetes care in our outpatient clinic for diabetes care. The clinic has both a regional and a tertiary function in the treatment and support of children with T1D. In January 2009 to April 2009, eligible parents and children who were scheduled for consultation at the clinic in that period were approached for cooperating in a screening for psychosocial problems by means of an informative letter and were asked if the screening results could be used for this study anonymously. Parents were eligible when they were parents of a child with T1D, aged 4–16. Eligible children were aged 10–16 and diagnosed with T1D.
Procedure
The children and parents completed standardized questionnaires, which assessed psychosocial problems, while in the waiting room prior to their consultation with the pediatrician. A researcher who was not involved in the diabetes care team was available for parents and children and assisted them in case of questions. This procedure ensured privacy and anonymity of parents and children. It also minimized parental involvement in children’s completion, since the researcher could assist children in case of questions. Completed questionnaires were not shared with the diabetes care team. At the end of the day, the healthcare professionals (experienced nurse practitioners and pediatricians) were asked to estimate the psychosocial functioning, health related quality of life, and parenting stress for the children and parents who participated that day. In total, 110 parents and 76 children participated in the study (response rate = 80%). In 12 of these cases, the families did not visit their regular pediatrician at the time of the study because of maternity leave of their regular physician. The substitute pediatrician reported to not know the family well enough to give an adequate estimation. All procedures were carried out with the consent of the Ethics Committee in our institute (Scientific Bureau, Canisius Wilhelmina Hospital) and are in accordance with the Declaration of Helsinki. Written informed consent was obtained from all parents and children.

Data collection

Background information
The parents provided information about educational level, profession and family composition by means of a self-composed questionnaire. Medical information of the children was derived from their medical status.

Psychosocial problems
Children’s psychosocial functioning was measured by means of the Strengths and Difficulties Questionnaire (SDQ) \(^{16}\). The SDQ discriminates well between children with and without psychosocial problems \(^{17}\). The psychometric properties of the Dutch SDQ version are satisfactory \(^{16}\). The SDQ consists of 25 items tapping positive and negative attributes of children. The items load on five subscales: emotional symptoms (five items); conduct problems (five items); hyperactivity/ inattention (five items); peer relationship problems (five items); pro-social behaviour (five items). The first four subscales generate a total difficulties score. The total scores on the SDQ can be categorised into normal psychosocial functioning (score <15), subclinical psychosocial problems (score = 15–16) and clinical psychosocial problems (score >16). The parent proxy version can be used by parents of a
child aged 4–17 and the self-report version is suitable for young people aged around 11–17, depending on their level of understanding and literacy.

**Diabetes-related quality of life**
Diabetes-related quality of life was measured using the Dutch version of the Paediatric Quality of Life Inventory 3.0 Diabetes Module (PedsQL DM). The psychometric properties of the PedsQL DM are satisfactory. The PedsQL DM consists of 28 items, which load on five subscales: diabetes symptoms (11 items), treatment barriers (four items), treatment adherence (seven items), worry (three items) and communication (three items). Since the PedsQL DM does not have population-based norms, the total scores on the PedsQL DM were categorised into three groups based on the dispersion of our data (normal QoL: score >80.30; moderate/subclinical QoL: score = 80.30–60.50; and low/clinical QoL: score <60.50). In this study, the age-appropriate versions of the PedsQL were used (version 8–12y and version 13–18y).

**Parenting stress**
Parenting stress was measured by using the Dutch adaptation of the Parenting Stress Index Short Form (PSI-SF). The reliability and criterion validity of the Dutch PSI-SF are good. The PSI-SF taps aspects of parental distress, parent–child dysfunctional interaction and difficult child characteristics. The scale consists of 25 items. The sum score on the PSI-SF can be categorized for mothers and fathers separately, based on standardized cut-off scores described in the manual (18). This results in three categories: normal (score mothers <74; score fathers <64), subclinical (score mothers 74–89; score fathers 64–78) and clinical (score mothers >89; score fathers >78) levels of parenting stress. The PSI-SF was used for parents of children aged 4–13, according to the manual.

**Estimations of the healthcare professionals**
Healthcare professionals (nurse practitioners and pediatricians) filled out a short form to estimate psychosocial functioning, health-related quality of life and parenting stress. This assessment form for medical caregivers was developed by means of an expert panel, consisting of medical psychologists, nurse practitioners and pediatric endocrinologists and was tested by nurses and pediatricians. We consulted these clinicians, since we aimed to develop a questionnaire that reflected clinical practice and clinical estimations as good as possible. This resulted in a simple form with three straightforward questions. The first question on the form was: How do you estimate the level of psychosocial functioning of your patient in comparison with same-aged peers? Healthcare professionals were asked to answer the questions by using three categories: (1) fewer or similar psychosocial problems, (2) somewhat more psychosocial problems and (3) substantially more psychosocial
problems. The second question was: How do you estimate the level of diabetes-specific quality of life of your patient in comparison with other children? Healthcare professionals could answer with: (1) better or similar, (2) a little lower or (3) substantially lower. The third question was: How do you estimate the level of parenting stress in comparison with other parents? Categories (1) lower or similar, (2) a little higher and (3) substantially higher could be used as an answer.

**Statistical analyses**

Parent and self-report scores on the SDQ and PSI were compared to Dutch norm scores of a nonclinical reference group derived from the manuals of these measures with Students t tests (Welch’s correlation for unequal samples) and Cohen’s d effect sizes. Cohen’s guidelines for the interpretations of d are: 0.20 % small effect, 0.50 % medium effect, 0.80 % large effect. Finally, agreement between estimations of the Healthcare professionals and the category scores on the SDQ, PedsQL and PSI-SF was assessed by means of the Kappa Measure of Agreement. The Kappa’s were interpreted as follows: <0.50 % low agreement, >0.50 % moderate agreement, >0.70 % good agreement, >0.80 % very good agreement (Peat, 2001). All analyses were performed using Statistical Package for the Social Sciences (SPSS version 18 IBM, Armonk, New York, USA).

**Results**

**Sample characteristics**

Demographic statistics of the 110 children and their parents who participated are displayed in Table 1.

**Psychosocial problems, quality of life and parenting stress**

In Table 2, descriptive statistics of the SDQ, PedsQL and PSI-SF are shown. Analyses of skewness and kurtosis indicated acceptable normal distribution of scores on all measures. As can be seen in Table 2, one sample t-test indicates that parents and children reported significantly more psychosocial problems (SDQ) than parents and children in the norm group. The Cohen’s effect sizes d further show that the effect was medium on parent reports and small on child reports. Regarding parenting stress, no significant differences were found between both mothers and fathers of children with T1D compared to mothers and fathers of healthy children, or between mothers (M = 48.46, SD = 23.31) and fathers (M = 51.55, SD = 17.99) within our research population (F = 0.244, p = 0.62).
CHAPTER 2

Table 2.1 Background variables (n=110)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (%)</th>
<th>N (%)</th>
<th>M(SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age child</td>
<td></td>
<td></td>
<td>11.36 (3.28)</td>
<td>4-16</td>
</tr>
<tr>
<td>Gender child</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>female</td>
<td>56 (51)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>54 (49)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educational level parents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>28 (25)</td>
<td>27 (25)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>40 (36)</td>
<td>34 (31)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>28 (25)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>40 (36)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Higher secondary education</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>34 (31)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bachelor or master degree</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>26 (24)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>35 (32)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Not reported</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>16 (13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>14 (13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two-parent families</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>86 (78)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educational level parents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>40 (36)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>34 (31)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bachelor or master degree</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>26 (24)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>35 (32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers</td>
<td>16 (13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers</td>
<td>14 (13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Siblings (including step/half siblings)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 siblings</td>
<td>7 (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2 siblings</td>
<td>91 (82)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;2 siblings</td>
<td>12 (10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c child</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In mmol/mol</td>
<td></td>
<td></td>
<td>8.3 (1.3)</td>
<td></td>
</tr>
<tr>
<td>In %</td>
<td></td>
<td></td>
<td>67 (14.4)</td>
<td></td>
</tr>
</tbody>
</table>

Estimations of healthcare professionals vs. standardized questionnaires

Table 3 shows the extent to which self-reports on the SDQ, PedsQL DM and PSI-SF were in agreement with estimations of healthcare professionals. It is indicated that approximately half of healthcare professionals’ estimations are in line with the results on the questionnaires. In 10% of the children, no psychosocial problems were present according to healthcare professionals’ estimations, although patients and parents-reported psychosocial problems. In 40% of the children, psychosocial problems were present according to healthcare professionals’ estimations, although parents and patients did not report psychosocial problems. The analysis further shows that there is a low but significant agreement between the estimation of the nurse practitioners of the child's quality of life and self-reported scores on the PedsQL DM (K = 0.33, p = 0.001).
Table 2.2 results of study sample on questionnaires and comparisons with nonclinical norm groups

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Fam with T1D M (SD)</th>
<th>Norm group M (SD)</th>
<th>t</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological problems (SDQ parent report) (range 0–40)</td>
<td>110</td>
<td>8.7 (5.1)</td>
<td>5.5 (4.7)</td>
<td>6.54 ***</td>
<td>0.67</td>
</tr>
<tr>
<td>Emotional symptoms (range 0–10)</td>
<td>110</td>
<td>2.6 (2.2)</td>
<td>1.5 (1.8)</td>
<td>5.18 ***</td>
<td>0.59</td>
</tr>
<tr>
<td>Conduct problems (range 0–10)</td>
<td>110</td>
<td>1.3 (1.7)</td>
<td>0.8 (1.2)</td>
<td>3.12 **</td>
<td>0.39</td>
</tr>
<tr>
<td>Hyperactivity/inattention (range 0–10)</td>
<td>110</td>
<td>3.3 (2.6)</td>
<td>2.1 (2.2)</td>
<td>5.04 ***</td>
<td>0.55</td>
</tr>
<tr>
<td>Peer relationship problems (range 0–10)</td>
<td>110</td>
<td>1.4 (1.4)</td>
<td>1.1 (1.6)</td>
<td>2.41 *</td>
<td>0.21</td>
</tr>
<tr>
<td>Prosocial behaviour (range 0–10)</td>
<td>110</td>
<td>8.6 (4.2)</td>
<td>8.5 (1.7)</td>
<td>0.62</td>
<td>0.05</td>
</tr>
<tr>
<td>Psychological problems [Strengths and Difficulties Questionnaire (SDQ) self-report] (range 0–40)</td>
<td>68</td>
<td>8.9 (4.2)</td>
<td>7.5 (5.0)</td>
<td>2.54 **</td>
<td>0.28</td>
</tr>
<tr>
<td>Emotional symptoms (range 0–10)</td>
<td>68</td>
<td>2.3 (2.1)</td>
<td>2.0 (2.1)</td>
<td>1.11</td>
<td>0.14</td>
</tr>
<tr>
<td>Conduct problems (range 0–10)</td>
<td>68</td>
<td>1.4 (1.3)</td>
<td>1.3 (1.6)</td>
<td>0.67</td>
<td>0.06</td>
</tr>
<tr>
<td>Hyperactivity/inattention (range 0–10)</td>
<td>68</td>
<td>8.2 (1.5)</td>
<td>2.9 (2.2)</td>
<td>3.19 **</td>
<td>0.41</td>
</tr>
<tr>
<td>Peer relationship problems (range 0–10)</td>
<td>68</td>
<td>1.4 (1.3)</td>
<td>1.3 (1.6)</td>
<td>0.58</td>
<td>0.06</td>
</tr>
<tr>
<td>Prosocial behaviour (range 0–10)</td>
<td>68</td>
<td>8.2 (1.5)</td>
<td>8.2 (1.6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Diabetes-related QOL (Paediatric Quality of Life) (range 0–100)</td>
<td>64</td>
<td>80.3 (9.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes symptoms (range 0–100)</td>
<td>66</td>
<td>63.1 (14.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment barriers (range 0–100)</td>
<td>67</td>
<td>83.2 (12.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment adherence (range 0–100)</td>
<td>67</td>
<td>85.4 (31.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Worry (range 0–100)</td>
<td>68</td>
<td>85.5 (15.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication (range 0–100)</td>
<td>68</td>
<td>82.7 (15.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parenting stress (Parenting Stress Index Short Form)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers (range 25–131)</td>
<td>65</td>
<td>48.5 (23.3)</td>
<td>54.4 (19.3)</td>
<td>-1.81</td>
<td>-0.29</td>
</tr>
<tr>
<td>Fathers (range 25–131)</td>
<td>16</td>
<td>51.55 (18.0)</td>
<td>48.5 (16.4)</td>
<td>0.64</td>
<td>0.18</td>
</tr>
</tbody>
</table>

1Nonclinical norm group SDQ: n = 562; Parenting stress: n=161 mothers and n=84 fathers.

***p < 0.001, **p < 0.01, *p < 0.05.
Discussion

T1D requires intensive disease management, and is often associated with increased levels of parenting stress and decreased levels of quality of life \cite{21,22}, which, in turn, can interfere with good disease management by parents and child \cite{22,23,24}. It is more and more recognized that healthcare providers play an important role in improving the psychosocial well-being of both child and parents, by addressing the impact of disease and disease management on their everyday lives and, where necessary, referring to psychological support \cite{22,25,26}. A prerequisite for this approach is an adequate assessment of the psychosocial well-being of the child \cite{22,25,26,27,28}. In the present study, the levels of diabetes-related quality of life in children with T1D and the levels of parenting stress in their parents were assessed by means of clinical estimations by nurse practitioners and pediatricians, and patient and parent self-reports using standardized questionnaires. A comparison of these two informants revealed that healthcare professionals’ estimations differed from self-reports in half of the cases, indicating that the questionnaires revealed additional information regarding patients’ psychological functioning and quality of life, and parents’ parenting stress. Comparison of clinical estimations and standardized questionnaires is, in pediatrics, a relatively understudied topic. Kazak, Cant, Jensen, McSherry, Rourke, Hwang, Alderfer, Beele, Simms and Lange found an association between estimations made by nurses and pediatricians and patient reported outcomes regarding disease-specific concepts \cite{29}. In our study, we

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|}
\hline
 & \textbf{Professional: no problems} & \textbf{Professional agrees with self-reports} & \textbf{Professional: problems} & \textbf{K} \\
 & \textbf{Self-reports: problems (%) } & \textbf{Self-reports: (%)} & \textbf{Self-reports: no problems (%)} & \\
\hline
\textbf{Nurse} & & & & \\
Parenting stress & 12 & 54 & 33 & 0.05 \\
Quality of life & 20 & 66 & 14 & 0.33” \\
Psychosocial problems self-report & 7 & 59 & 33 & 0.03 \\
Psychosocial problems parent-report & 10 & 58 & 32 & 0.04 \\
\hline
\textbf{Physician} & & & & \\
Parenting stress & 13 & 29 & 58 & -0.08 \\
Quality of life & 19 & 50 & 31 & 0.08 \\
Psychosocial problems self-report & 3 & 51 & 46 & 0.08 \\
Psychosocial problems parent-report & 11 & 49 & 40 & 0.01 \\
\hline
\end{tabular}
\caption{The estimations of nurses and pediatricians compared to results of the screening tool}
\end{table}

\***p<0.001, **p<0.01, *p<0.05
found the same agreement between estimations by the nurse practitioners and patient-reported outcomes with regard to disease-specific quality of life, although we did not find any association regarding psychosocial problems in the child and parenting stress, which are more general psychosocial concepts. This suggests that estimations made by nurse practitioners and patient-reported outcomes tend to agree to a greater extent on health-related concepts than on general concepts of psychosocial well being. However, we note that clinical estimations and patient-reported outcomes differed in a large number of the cases. As such, patient reports using validated questionnaires contributed significantly to the comprehensive assessment of patients’ and parents’ psychosocial well-being. These results indicate the need for using multiple informants when assessing psychosocial wellbeing of child and parents. It is further worthwhile noting that the assessments using standardized questionnaires resulted in less problems than the assessments made by healthcare professionals, suggesting that healthcare professionals tend to overestimate problems in some children and parents. Therefore, using standardized questionnaires for the assessment of psychosocial well being can lead to increased efficiency in allocation of additional psychosocial support. The relatively moderate levels of parenting stress found in the present study are not in line with comparable studies, which reported higher levels of parenting stress. A possible explanation for these relatively low levels is the intensive patient-centered care provided by the healthcare professionals in our study, in which the impact of diabetes on everyday life was a regular subject of discussion. Another possible explanation is that parents report less parenting stress in later years after diagnosis, as a result of resistance to the burden caused by the intensive disease management. It is also possible that parents inflated their response because they did not want to be perceived as if they were unable to cope. Strengths of this study are the use of validated questionnaires and the high response rate. A possible limitation of the study design may be the lack of standardized assessment of estimations made by nurse practitioners and pediatricians. Although the instrument was not validated, it was developed using an expert panel and tested by clinicians. Also, a global indication of their estimations was what we were looking for in this study, as these are frequently used in daily clinical practice. Our main goal was to report on clinicians’ estimations using a simple form, in which we succeeded. In the present study, questionnaires were completed at the hospital. Since hospital attendance can provoke stress in parents, this might have affected stress scores. Another limitation is the absence of Dutch norm groups for the PedsQL DM and the lack of correction for disease-onset and age or received psychological counseling. Additional research could solve the issue of the norm groups by using general quality of life assessments making comparisons with healthy norm groups possible. Since previous studies have pointed at the high incidence of internalizing problems in youth with diabetes, especially regarding depression, additional research could also focus on assessing these specific internalizing problems.
in more detail than what was done in the present study. In the present study, only general indications of emotional functioning were taken into account, which did not reveal specific information on depression.

**Conclusion and practical implications**

In sum, the results of our study indicate that the additional use of patient-reported outcomes by means of standardized questionnaires is valuable when screening for psychosocial problems and quality of life in children with T1D and their parents. It will not only help healthcare professionals in their psychosocial anamnesis, but will also provide healthcare professionals with additional information concerning issues on which they can focus in consultations\(^6,34\). Additionally, it can assist them in the process of allocating additional care to those who need it most\(^30,31\). Future studies can add to our findings by investigating the effect of regular screening on referral patterns of pediatricians. In addition, the long-term effects of using standardized questionnaires on psychosocial health and disease-specific outcome measures should be addressed. The medical team in this study consisted of nurses and pediatricians specialized in diabetes care with extensive clinical experience with these patients. In half of the investigated cases, standardized questionnaires provided additional information. To adequately assess the psychosocial wellbeing of child and parents, routine screening should be conducted using validated questionnaires\(^6,30,31\).
References


Adolescents’ Perspectives on Having Type I Diabetes, on Current Outpatient Diabetes Care, and on Improvement of Care by Using the Internet

Emiel A Boogerden
Jan AM Kremer
Judith B Prins
Kees Noordam
Chris M Verhaak

Journal of Participatory medicine (2016), aug.
Abstract

Objective
Adolescence is considered the most difficult stage in life for coping with diabetes. As a result, pediatric diabetes care is continually in need of better management tools, such as many that can be found on the Internet. Research shows that care is most effective when tailored to an individual patient’s needs and wishes. The present study gives insight on the latter by describing the disease and current outpatient pediatric diabetes care as experienced by adolescents with Type 1 Diabetes (T1D) and their recommendations for improvement of care by using the internet.

Research design and methods
Data were gathered by interviewing adolescents who were diagnosed with T1D (N=16), aged 13 to 19 and treated in a tertiary care diabetes center. Interviews focused on 1) problems adolescents encounter in their diabetes self-care, 2) whether current diabetes care addresses these problems and 3) improvement of care by implementing an online treatment environment (yet to be developed). Audio recordings were analyzed qualitatively.

Results and conclusions
Adolescents experienced diabetes as an unpredictable disease, especially in stressful events. Having the disease made them feel different from their healthy peers. They were content with their own involvement in their treatment and the approach of the diabetes team, although less satisfied about accessibility of physicians in case of non-urgent matters. Adolescents expected that an online treatment environment would contribute to improvement of organization of diabetes care, low level contact with their diabetes team and peer support.
Introduction

Type 1 diabetes mellitus (T1D) is a disorder of carbohydrate metabolism caused by an insulin deficiency. Effective disease management requires patients to closely monitor their blood glucose levels several times a day and additionally administer insulin. Food intake, stress and physical exercise also have a profound influence on blood glucose levels, which therefore have to be taken into account as well. Adolescence is often considered as the most difficult phase in life for dealing with diabetes. Adolescents tend to focus on short-term rather than on long-term outcomes. So, although good disease management results in fewer complications in the long run, in the short-term, it can be associated with lower quality of life. Diabetes can also conflict with the growing need for autonomy and independence, a characteristic of adolescence and a necessity for successful diabetes self-care. Some parents have trouble decreasing control over their adolescent child, which can hinder growth in self-confidence and development of self-identity. In addition, adolescents are afraid to be excluded or rejected by their peers. When they frequently encounter lack of understanding or ignorance from healthy peers, they tend to ignore their condition, leading to decrease in diabetes control. Diabetes management requires adapting one's lifestyle to the necessary demands and the adolescents' willingness to do so.

Patients' perspectives

The complicated character of disease self-management during adolescence encourages practitioners and scientists to continuously work to find ways to improve diabetes care. For instance, there is a growing recognition of the importance of patients' perspectives on healthcare practice. In this study, the authors aimed to contribute to the knowledge on adolescents' perspectives by reporting on the results of interviews with adolescents' preferences for diabetes care. Information and communication technology (ICT) has become increasingly important in pediatric diabetes care. Although most research on ICT usage was conducted in adult diabetes care, promising results have also been shown in pediatric age groups. Harris and colleagues (2012) describe the use of devices, delivery of care by telehealth and providing support and information through the Internet as three major eHealth components. Use of the Internet has been found to facilitate interaction and support among adolescents with diabetes and their health care providers. It can also provide adolescents, families, health care providers, the health care industry, policy makers, and the general public with platforms to interact and to learn from each other. Although the number of studies that investigate the use of Internet in care is growing, there is still much to learn about optimal utilization for specific patient populations. Support of day-to-day diabetes self-care, access to information and support of patients by health care providers are three key examples. A first step is to identify users' attitudes towards Internet use for these purposes.
Aim
In the present study, the authors assessed the views of adolescents with T1D about their diabetes, their outpatient diabetes care provided by the Children’s Diabetes Center Nijmegen (KDCN) and the potential value of using the Internet in diabetes care. Qualitative research methods were used to explore three research questions:
1. What problems do adolescents encounter in their diabetes self-care?
2. How do adolescents evaluate their current diabetes care in relation to these problems?
3. In what ways do adolescents think an online treatment environment might improve current diabetes care?

This study will add to knowledge about adolescents’ perspectives on having T1D and their received care. Further, the authors believe this is the first study assessing adolescents’ expectations of the potential value of the Internet in their diabetes care. The input of participants was translated into recommendations for usual care and used as a basis for development of an Internet intervention. This study was approved by the medical-ethical board.

Research design and methods

Sample and Procedure
Participants were 16 adolescent patients between the ages of 13 to 19 years, who were diagnosed with T1D and received regular outpatient hospital-delivered diabetes care. Adolescents who were unable to read questionnaires because of language or cognitive problems were excluded. Thirty-five patients who visited the KDCN in March of 2008 received an invitation by mail to participate in a 60-minute, semi-structured group interview in April of 2008. Three of the 35 (8.6%) invited patients decided to participate. Subsequently, in May and June of 2008, another 35 adolescents were requested by their physician during their regular consultation, to participate in a semi-structured, individual interview subsequent to their consultation. Thirteen adolescents (37%) agreed to participate in the individual interviews. Altogether, nine boys and seven girls with a mean age of 15.5 years (sd=1.79) were included in the final analyses. The interviews were conducted by the authors (EB, CV) who were not involved in the delivered diabetes care. Interviews all took place outside of the diabetes clinic, without the presence of parents or healthcare professionals. Main questions used in the interviews were developed by the research team (EB, CV and CN) and screened by a team of pediatric endocrinologists and nurse practitioners prior to the study. A list of questions is displayed in Table 1.
Current Diabetes Care

The current diabetes care conforms to standards published by the American Diabetes Association (ADA) and the International Diabetes Federation (IDF), the leading authorities in international clinical guidelines. As such, diabetes care is delivered by a multidisciplinary team, consisting of a pediatric diabetologist, a nurse practitioner, a psychologist and a dietician. Adolescents visit the center once every 3 months. When problems arise, interim visits are planned. During these outpatient visits approximately 30 minutes are spent consulting the diabetes nurse and approximately 15 minutes consulting the pediatrician. Further, adolescents meet the dietician yearly and a consultation with the psychologist can be planned on adolescents’ or physicians’ demand.

Data Analysis

Data on patient characteristics were analyzed by means of descriptive statistics in SPSS. Relevant themes on having diabetes, on pediatric diabetes care and on the potential of the Internet in diabetes care were derived from interview-transcripts, using thematic content analysis. All interviews were recorded on audio and prepared for analysis by means of verbatim transcription. Information that might reveal the participants’ identities was removed for anonymity. Results were explored following steps for qualitative content analysis.
Considering the group size, the authors regarded the three participants as three different sources of information. Therefore, the transcript of the group interview was broken down into three transcripts, each containing one participants’ opinion. This led to 16 transcripts (three derived from the group interview and the transcripts from the 13 individual interviews). Step 1 in the final analyses (initial coding) was to divide these transcripts into text segments, by means of incidence-to-incidence coding. In step 2 (axial and selective coding), all codes and segments were compared to assess whether text segments with comparable codes covered the same topics. The text segments that covered the same topic were then clustered and one theme was identified for every cluster of text segments. In step 3 (theoretical coding), meaning was given to the themes, by consulting the content of the segments. The results were discussed several times during the process within the research team to clarify the themes.

Results

Analyses resulted in 10 themes, each allocated to one of the three research questions.

1. What problems do adolescents encounter in their diabetes self-care?
   
   **Unpredictability**
   
   The adolescents in our study perceived their diabetes as unpredictable, which made it difficult to take on a proactive attitude. Undertaking physical exercise was often mentioned as difficult because of difficulty in predicting glucose levels. Adolescents reported that their stamina decreased after they were diagnosed with diabetes. The adolescents who felt strongly about this were all male.

   **Feeling different**
   
   The interviewed adolescents mentioned that having diabetes made them feel different compared to peers without diabetes. They brought up everyday situations like eating in a snack bar or drinking alcohol when going out at night, noting that and they couldn’t eat or drink in as carefree a fashion as a ‘regular teenager’. Further, they declared that they felt uncomfortable measuring blood glucose levels and injecting insulin in public spaces, such as at school or when going for a swim since the insulin pump stands out:
   
   “... I have sort of a pump and a patch on my belly and I think that’s, well, I don’t like everybody seeing that, you know, in the pool, and well, I think that’s very bothersome... ”

   **Peer contact**
   
   Adolescents declared that they had little or no contact with peers with diabetes. A few
adolescents in the interviews stated they had visited a diabetes camp in the past and had made friends there with whom they were still in touch, although mostly at a minimal level. When asked, the interviewees responded that they believed contact with peers with diabetes enhanced self-care capabilities or capabilities of other, less experienced teens with diabetes. Adolescents explicitly stated that they preferred online contact over real-life contact. The adolescents who regularly talked to peers with diabetes did so using instant-messenger programs on the Internet or email.

2. How do adolescents evaluate the current diabetes care in relation to these problems?

Attitude of the diabetes team
The adolescents believed that their diabetes nurse and, to a lesser extent, their physician, were on a personal level with them. This facilitated an open atmosphere in which they felt free to discuss personal issues as was expressed by one of the interviewed adolescents:

“... they know who you are and that's, in my opinion, a big plus. I mean, you should know who your patient is. And they also remember what... Look, if I had said something about my book reports the diabetes-nurse would remember that the next time I get here...”

Adolescents stated that their physician and diabetes nurse explicitly asked for their perspective and ideas about interventions and lifestyle changes, as this interviewee clearly stated:

“...yes, they listen to me, yes. They always ask me what I want to change or ehm... what I should do about it (...) well, they let me think about it for myself properly, because it is up to me, right?”

They also reported that the diabetes team provided them with advice that was relevant to their own personal situation, which was, most of the times, aimed at enhancing self-care capabilities. Additionally, adolescents attributed different roles to the nurse and physician. The first was perceived as someone to share your diabetes-related problems with and the latter as the person who could intervene. One adolescent stated that her medical physician should “loosen up a little.”

Coordination of care
Although the nurse and physician generally achieved a good fit of care content to adolescents’ personal needs and wishes, they failed to do so regarding the coordination of care. Firstly, the preset time schedule of consultations could be improved. Although some adolescents stated that consultations were okay the way they were, another part of our sample preferred a better fit to their medical conditions or a longer consultation with the physician. One of the adolescents described the consultation with her nurse as a waste of time:
“It’s not that I find it very annoying, but it feels like I’m just sitting there (at the consultation with the nurse) for thirty minutes.”

Adolescents of 15 and over urged for the above-mentioned improvement. Participants further stated that they would prefer to decide upon the frequency of their consultations to the diabetes center, instead of a standard frequency of once every 3 months. Also, adolescents complained that they had to “tell their story twice.” In the reported situation, the nurse provided the physician with a summary of her 30-minute conversation, but adolescents still had to repeat “the important stuff” in the additional consultation with the physician.

Patient-professional communication in between visits.
Adolescents stated that physicians are hard to reach regarding non-urgent matters. Concerning the accessibility by telephone, one adolescent stated:
“...there is this telephone number. I can use that to make a reservation for a telephone-consultation with the physician. Both numbers are accessible only when I’m at school. And the other thing: When I call in on Tuesday, they have a free spot no earlier than on Thursday...”

Communicating with the diabetes nurse through email was perceived as efficient and fast: answers were received within a satisfying period of time. Some adolescents stated that they communicated with their nurse at least once in the period in between the quarterly visits, although most adolescents declared that they communicated with their nurse rarely or not at all in between consultations. Although communication with the diabetes nurse was considered functional, adolescents declared they almost never exchanged information, for example on recent blood glucose levels.

Alignment of diabetes team
Alignment of the multidisciplinary diabetes team was considered important for continuity of delivered care. For good alignment, effective communication among caregivers was essential, according to adolescents. In the present study, only one of the interviewed adolescents recollected miscommunication within the diabetes team that had interfered with the treatment during the previous year.

Best physician
Adolescents concluded by stating that dealing with diabetes was a different process for every individual. The diabetes team could offer support, but everyone had to find out for themselves what worked best, as this eighteen-year-old spoke out:
“I think that you have to help yourself a little, because you know your body better than any physician does. So I think you are the best physician for yourself...”
3. What do adolescents think about an online treatment environment improving current diabetes care?

The Internet and diabetes care.
All adolescents reacted very positively to the idea of an internet-delivered online treatment environment to current diabetes care. That the internet was considered a suitable medium for this group of patients was colorfully declared by one adolescent:

“I am on the internet all the time already, so opening another browser window is not such a big effort...”

They mentioned that easy communication with the diabetes team should be facilitated in an online treatment environment as well as contact with peers with diabetes. Two interviewees assumed that uploading blood glucose values online would be helpful, because it kept the physician up-to-date on this data and they could stop keeping a diary of glucose values.

Expected usage
Adolescents stated that they would actively use an online treatment environment to some extent, if it were a part of their diabetes care. Only one adolescent declared that, although she supported the project, she would not use it herself.

Discussion
Adolescents explained that daily situations not related to diabetes obstruct good disease management. To support them through outpatient diabetes care, medical providers should involve adolescents in their treatment and decision-making and take note of diabetes-related issues such as physical exercise, snacking and peer contact. The Internet could contribute to improvement of pediatric diabetes care and could enhance contact among adolescents with diabetes.

Adolescents on Having Diabetes
Adolescents mentioned that physical activity was hard to combine with diabetes self-care. This is consistent with studies, which have noted a variety of explanations for avoidance of physical activity. But we were pleased to see that our participants did not let complaints hinder them from engaging in physical activities. Our participants stated that they sometimes felt different compared to their healthy counterparts. This is generally found in studies among adolescents with T1D. Adolescents in the study by Carroll and Marrero expressed similar concerns about how to react when confronted with distrust or over involvement by friends.
However, friends can also be of great support when managing this disease. Contact with peers with the same disease is helpful, but opportunities are often limited. According to our participants, this type of interaction should be facilitated online rather than face-to-face.

**Adolescents’ Perspectives Concerning Their Diabetes Care**

As in other studies, our adolescents appreciate being able to communicate on a personal level with their diabetes nurse and their physician. They are also content with the extent to which they can participate in their personal diabetes care and medical decision-making. Newbould, Smith and Francis emphasized the importance of a sense of equality in the relationship between patient and health care professional in adolescent diabetes care. Our study also supports this notion. Adolescents’ remarks about the limited time spend with the physician in quarterly visits found by Carroll and Marrero was also evident in our sample. In particular, the older (15+) participants would rather have more time with their physician, even if that is at the expense of time with the diabetes nurse. Further, our adolescents’ request for easier access to physicians for non-urgent matters was similar to results in earlier studies.

Conversely, adolescents realize that their treatment team should have better access to their blood glucose levels. The lack of reporting and tracking of blood glucose data by adolescents in our sample is a well-known problem in adolescent diabetes management.

**Adolescents’ Perspectives Concerning Usage of the Internet to Improve Pediatric Diabetes Care**

Studies on the use of ICT in adult and adolescent diabetes care were mostly aimed at users’ experiences following several months of intervention. In the present study, however, participants were asked to report their preferences and expectations prior to using an internet-delivered intervention rather than their experiences of using one. Our results show similarities to the results of former studies. For instance, in one study of an internet-based communication device d’Annunzio and colleagues found that adolescents with diabetes were most positive about the quick and easy private contact with the diabetes team, which is in line with our adolescents’ expectations about usage of the Internet. Adolescents are optimistic about what the Internet has to offer them, and consider it useful for pediatric diabetes care as a supplement to face-to-face outpatient visits.

**Implications for Clinical Diabetes Care**

The most important message of our adolescents is that the diabetes team should approach them on an individual personal level, whether it is face-to-face or through the Internet. They appreciate the level of involvement in their treatment and the attention given to personal diabetes-related problems. Further, adolescents state that they need better coordination of their diabetes care with their individual needs and wishes. The results of our study also
underscore the importance of the direct impact of everyday situations, like physical exercise, snacking and peer contact on glycemic control. Adolescents should therefore be offered guidance in developing coping strategies that prepare them for stressful situations that are not directly related to diabetes. Further, most adolescents stated that they would appreciate more contact with peers who also have diabetes, preferably in an online environment. A good next step would be to develop and study an Internet based patient portal, which facilitates online patient-professional interaction, and interaction between peers with diabetes.

Implications for Further Research
Research should focus on the effects of online peer support for coping with the disease. Although adolescents who had attended diabetes camps were found to show better treatment behavior and sometimes improved glycemic control, adolescents in our sample prefer peer contact to be online. Also, future studies should try to identify the view and expectations of adolescents and the treatment team on ICT devices prior to implementation. This will enhance insight in how to fit ICT use in pediatric diabetic patients with their needs and wishes.

Limitations
Although data were gathered and carefully studied by trained professionals and analyzed through tested steps of qualitative research, this study also has some limitations. First is the use of a convenience sample, which can limit the generalizability of the findings. Therefore, interviews were conducted until saturation occurred. A second limitation is that analysis was conducted under supervision of a team of researchers, rather than by a team of researchers directly. To minimize bias, the participants themselves checked the results from the group interview. In addition, several peer debriefings were conducted in which interpretations were discussed by a small group of scientists to enhance the quality of general interpretations. The data were gathered in 2008 and, since then, there have been significant changes within the field of eHealth. However, the problems faced by adolescents in our study have been found in previous studies as well as in more recent studies. This emphasizes the ongoing need for studies, which report needs and wishes of patients and focus on the importance of the patients’ view on care in order to improve it. This reflects the importance of our results, when aiming to develop innovative interventions to improve current diabetes care.

Conclusion
Patient centeredness has become an important part of health care delivery and quality management. This study shows that adolescents can point out remarkably well what they need, what they appreciate and what fits them. Explicitly asking adolescents for their opinion
has helped us find a better match between their wishes and needs as a part of pediatric diabetes care. We discovered that more knowledge is needed regarding coping with diabetes in stressful situations. Further, equality in the relationship between patient and healthcare professional and coordination of care that is a good fit with individual needs are essential for good diabetes care. The Internet is considered as a suitable medium to achieve better pediatric diabetes care.
References


Parents’ experiences, needs, and preferences in pediatric diabetes care: Suggestions for improvement of care and the possible role of the Internet. A qualitative study

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Kees Noordam
Hans J Marks
Chris M Verhaak

Abstract

Purpose
To investigate the needs and preferences of parents of children with Type 1 Diabetes (T1D) concerning pediatric diabetes care and use of Internet in care.

Design and methods
Parents of 34 children, aged 2–12, with T1D participated in seven focus group interviews.

Results
Analysis revealed provision of tailored care, disease information, peer support, and accessibility of healthcare professionals as major needs in parents. Internet could be used to satisfy these needs.

Practical implications
According to parents, diabetes teams should focus on the impact of the disease, parents’ experience, and the child’s development, and provide online professional and peer support.
Introduction

Type 1 Diabetes (T1D) is a chronic disease that requires a complex daily treatment regime, consisting of a variety of health-related disease management behaviors, such as blood glucose monitoring, insulin therapy, dietary restrictions, and exercise. Good disease management decreases the chance of hypoglycemia and hyperglycemia in the short term and the development of complications in the long term. Parents are primarily responsible for performance of disease management in children younger than 13 years. The complex task of taking care of a child with diabetes in everyday life can have a profound impact on parents. For example, parents who raised a child with diabetes were found to experience higher levels of parenting stress than parents of healthy children. Other researchers reported that raising a child with diabetes was related to increased levels of parental anxiety and diminished feelings of self-efficacy in parents. The poor psychosocial well-being of parents might affect how well they provide disease management, potentially leading to poor glycemic control in the child.

In the Netherlands, parents of children with T1D have access to diabetes care provided according to international guidelines for diabetes care by healthcare professionals specialized in pediatric diabetes care. The extent to which care is tailored to the needs and preferences of parents determines the extent to which the care supports them in the disease management in everyday life. As such, knowledge on parents’ needs and preferences is of utmost importance. There is a lot known about how to support the parents of a child with T1D in coping with diabetes. However, little of that knowledge was gathered from the perspective of the parents themselves. Studies that investigated parents’ perspectives suggest that parents prefer their physician to provide tailored care, support their empowerment, get to know their child and share knowledge. Since most research is focused on the first few weeks after diagnosis, more needs to be learned about the long-term requirements of parents in order to tailor care to their needs and preferences. The Internet is frequently suggested as a promising means for tailoring care to patients’ needs. In the past decade, the Internet has become a part of everyday life and also has offered parents huge resources for information and support concerning their child’s health. It is suggested that pediatric patients with a chronic condition, such as diabetes, and their parents can benefit from the added value of the Internet in care as well. However, research on how the Internet could support tailoring pediatric care to parents’ needs and preferences in general, and specifically regarding parents of children with T1D, is still scarce. Although knowledge of users’ preferences is essential for the development of an Internet application, only one study was found assessing the needs and wishes of parents of a child with T1D concerning online support. They recognized online peer support and online disease information as major needs in parents. Information from parents’ perspectives on their needs and wishes...
concerning pediatric diabetes care, as well as their preferences for using the Internet in care, is only scarcely available. In order to add to the existing body of knowledge, this study assessed parents’ needs and preferences concerning pediatric diabetes care, as well as their needs and preferences concerning the use of the Internet in diabetes care. Qualitative research methods were used to answer the following questions:
1. What are the experiences, needs, and preferences of parents of a child with T1D concerning pediatric diabetes care?
2. What is, according to parents of a child with T1D, the added value of using the Internet in pediatric diabetes care?

The research reported in this article is the first stage of a larger study in which an Internet application for parents of a child with T1D is developed and tested for feasibility and efficacy. Information on the needs and preferences concerning pediatric diabetes care and on the possible added value of using the Internet was intended to serve as a starting point for the development of this application.

Research design and methods

Subjects and setting
Seven focus group interviews were carried out, each in one of seven clinics for pediatric diabetes care in the Netherlands. All eligible participants were parents of children younger than 13 years diagnosed with T1D. The parents were recruited by a local diabetes nurse practitioner. In each clinic, the parents of 35 children were randomly selected and asked to participate. Recruitment was stopped when six or more parents were willing to participate. If fewer than six parents were willing to participate, a second recruitment round was performed, by means of purposive recruitment. In this second round, nurse practitioners were asked to recruit parents who were known to have ideas about improving diabetes care or who had criticized existing care. This method (purposive recruitment) for recruitment of “information-rich” cases is common in qualitative research. Initially, in the two calls, the parents of 260 patients were invited to participate. The parents of 44 patients consented to participate. The parents of 44 patients consented to participate in the focus groups. Participants received a brochure that explained that the aim of the study was to investigate their experiences, needs, and wishes concerning their child's pediatric diabetes care and their thoughts about using the Internet in pediatric diabetes care. The study would involve their participation in focus group interviews held in the absence of their healthcare professionals. Due to dropout, the parents of 34 children attended the focus group interviews. This qualitative study was part of a larger study, which was approved by the medical ethics board of the authors’ institution.
Usual care
All children of the participating parents received care as usual consistent with international standards for pediatric diabetes care provided by a multidisciplinary team of healthcare professionals, consisting of pediatric diabetes-endocrinologists, diabetes nurse practitioners, dieticians, and psychologists, all experienced in diabetes care. Parents and children attend the outpatient diabetes clinic for consultations with a pediatrician and nurse practitioner four times a year. Dieticians and psychologists can be consulted if requested by parents, children, or physicians. The diabetes team uses telephone and e-mail as primary methods for communication during office hours. In six clinics, an additional emergency telephone number is manned by a diabetes-endocrinologist outside office hours to guarantee continuous access to care. In the remaining clinic, the emergency telephone is operated by a regular pediatrician.

Focus group interviews and protocol
The focus group interviews took place on location, in a conference room made available by the respective clinic, in the evening. The interviews lasted approximately 90–105 min and were recorded on audio using two different recorders. Five of the focus group interviews were co-conducted by two of the authors (EB & CV, EB & CN, or CV & CN), and two were conducted by one author (EB or CV). Interviewers were not members of the diabetes care teams. A questioning route, which is a set of questions asked in a specific order (Table 1), was developed by the research team (EB, CV, and CN), according to the guidelines of Krueger and Casey (2009).

Table 4.1 Questioning Route

<table>
<thead>
<tr>
<th>Categories</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening questions</td>
<td>Explanation of purpose of the focus group. Introduction of researchers.</td>
</tr>
<tr>
<td></td>
<td>What is your name?</td>
</tr>
<tr>
<td></td>
<td>How old is your child with diabetes?</td>
</tr>
<tr>
<td></td>
<td>When was he/she diagnosed?</td>
</tr>
<tr>
<td>Introductory</td>
<td>When was your most recent contact with the team?</td>
</tr>
<tr>
<td>questions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>With whom do you have the most contact?</td>
</tr>
<tr>
<td></td>
<td>How do you contact the team?</td>
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<tr>
<td></td>
<td>Why did you contact the team?</td>
</tr>
<tr>
<td></td>
<td>How was that contact?</td>
</tr>
<tr>
<td>Transition</td>
<td>When was your most recent contact with the team?</td>
</tr>
<tr>
<td>questions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>With whom do you have the most contact?</td>
</tr>
<tr>
<td></td>
<td>How do you contact the team?</td>
</tr>
<tr>
<td></td>
<td>Why did you contact the team?</td>
</tr>
<tr>
<td></td>
<td>How was that contact?</td>
</tr>
<tr>
<td>Key questions</td>
<td>How did you receive feedback?</td>
</tr>
<tr>
<td></td>
<td>What was positive about the support provided by the treatment team?</td>
</tr>
<tr>
<td></td>
<td>What was negative about the support provided by the treatment team?</td>
</tr>
<tr>
<td></td>
<td>Could use of the Internet improve current diabetes care and, if so, in what way?</td>
</tr>
<tr>
<td>Ending questions</td>
<td>Summary of the content of the focus group: Is this summary complete?</td>
</tr>
</tbody>
</table>
This approach allowed parents to become familiar with the setting and the subjects, and allowed researchers to gradually reach more depth in discussions. It also contributed to homogeneity between the focus groups because in each clinic the same questioning route was used. The interviews started with a welcome, an introduction of the interviewers, purpose of the interview, and the opportunity for interviewees to pose questions. Thereafter, the questioning route started with opening questions (for participants to introduce themselves), followed by introductory questions in which the subject was introduced; e.g., “When did you last contact the diabetes care team,” transition questions to gain more detailed information; e.g., “Why did you last contact the diabetes care team,” key questions in which the key subject is discussed; e.g., “What was positive about the support provided by the treatment team,” and end questions to summarize the contents of the interviews. Demographical data of the participants were collected from patients’ medical files.

**Analyses**

The recorded focus group interviews were transcribed verbatim. Transcripts were then imported into Atlas.ti, which is software that is widely used in qualitative analyses. In the analyses, the steps for thematic content analysis were followed, by means of multiple coding, in order to extract themes, formulate concepts, and derive theory from the raw data (see also Figure 1).

Incident-by-incident open coding was used as initial coding, since the segments provided context to participants’ input, which was needed for interpretation later on in the analysis. Some segments were linked to one code, and other segments were linked to multiple codes. Axial coding was used for distilling important concepts based on the codes and for providing meaning to those concepts. To do so, related codes or codes that overlapped were clustered. The raw data (text segments) were used to determine whether clusters were related and/or should be regarded as subcategories of a more general category. Selective coding was used for interrelating codes and categories. In this phase, meaning was given to the categories and subcategories by consulting the content of the segments. In some cases, a core category was related to a single category. In other cases, a core category was related to several categories and subcategories. Theoretical coding was included as a last step to interpret the core categories. In this phase, the wider meaning and implication of core categories was established by comparing their content to the literature and daily practice.

**Quality control**

The design, in which we used a questioning route, provided for internal and external validity and reliability. The questioning route also contributed to homogeneity in the focus groups and thus to process validity. To establish process validity and internal validity from
the participants’ perspective, a member check took place. All participants received a written summary of the focus groups they attended within 2 weeks of the interview, with the request that they critically read the summaries and send any comments, by e-mail, to the research team. Also, for internal validity, the content of each focus group interview was studied before conducting the next one, during the process of gathering data. This enabled the researchers to check during each interview for themes that were mentioned in previous interviews. Initial coding was done by a single researcher. For internal validity as well as for reliability, proceedings and results were checked and discussed collaboratively and extensively in each step of the analysis. In the analyses, the research team was complemented by a clinician experienced in diabetes care (NM) and an expert in qualitative analyses (HM) to obtain insight from different perspectives. Finally, for external validity, results were compared with current literature.
CHAPTER 4

Results

The descriptive statistics of the research population are displayed in Table 2. The mean age of the children with T1D was approximately 8 years, and the average duration of diabetes was almost 4 years. Qualitative analysis of the data resulted in 1,420 segments, which were linked to 241 codes. These codes were subdivided into 23 clusters, which were subsequently rearranged to give 12 categories and 17 subcategories. Selective coding led to seven core categories or themes, which are described in the following section.

Table 4.2 Demographics of Participants and Their Children

<table>
<thead>
<tr>
<th>Groups</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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<td>N (parents)</td>
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<td>3</td>
<td>5</td>
<td>5</td>
<td>8</td>
<td>34</td>
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<td>M</td>
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<td>7.50</td>
<td>7.33</td>
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<td>8.26</td>
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<tr>
<td>(SD)</td>
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<tr>
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<td>2 (60)</td>
<td>3 (75)</td>
<td>2 (67)</td>
<td>4 (80)</td>
<td>1 (20)</td>
<td>2 (25)</td>
<td>17 (50)</td>
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<td>3 (40)</td>
<td>1 (25)</td>
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<td>4 (80)</td>
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<tr>
<td>Mother, n</td>
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<td>3</td>
<td>3</td>
<td>5</td>
<td>3</td>
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</tr>
<tr>
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<td>0</td>
<td>2</td>
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<td>10</td>
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<tr>
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<td></td>
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<td></td>
</tr>
<tr>
<td>M</td>
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<td>5.20</td>
<td>7.33</td>
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<td>4.00</td>
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<td>(SD)</td>
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<td>8 (100)</td>
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Impact of diabetes on daily life

Parents described the confrontation with their child’s diagnosis and getting introduced to the complex skills involved in the management of diabetes as overwhelming. They indicated that feelings of uncertainty and anxiety were evoked by the switch from intensive coaching by healthcare professionals in the first week, to independently performing self-management
tasks at home. Illustrative for this issue is the quote of a parent who brought her child home after a 5-day hospitalization:

“It is almost incomprehensible what happened and then suddenly you find yourself back home thinking how to do all this at home . . .”

Parents said that diabetes and its treatment had a profound impact on their daily lives. Taking care of a child with a chronic disease restricted social activities and work:

“If I am honest, you see I work during the evenings and when I see him getting along during the day I think by myself that I would like to work during the day as well, but I feel I can’t because he is sometimes ill in the morning . . .”

The parents also said that diabetes and its treatment affected their children’s lives and activities, which made them (the parents) feel powerless. Concerns about the short and long-term consequences of diabetes for the children made parents stressed and sad. Parents mentioned that they searched for information on the Internet, as a way to cope with the situation. They indicated that the information they found about complications and other diabetes related problems increased stress and anxiety.

**Social and professional support**

Parents did not feel adequately supported by their regular social network as friends and family often had difficulties adjusting to the disease and treatment. The support provided by school and teachers varied considerably, with some parents experiencing great support from teachers and others facing complete lack of support:

“. . . with track and field-day at school the other day they had a 15-minute break and the teacher puts a full glass of syrup in front of the teacher with info she didn’t read it at all her (. . .). And I had provided and everything . . . I just think . . .”

Parents thought it would be helpful if the diabetes team could make basic information about the disease and its treatment available through the Internet, so that their friends and family could read it. Some parents suggested having standard letters and information for teachers. They also thought it would be very helpful to have access to an online tool, so that they could exchange these documents and their experiences and tips on how to deal with ignorance in the regular social environment.

The lack of support from their regular social environment meant that parents perceived their diabetes care team as their major source of support, as this parent clearly stated:

“Because you feel . . . yes . . . they [the diabetes team] are the only ones who you can talk to about diabetes. Because in the family no one is familiar with it, so it’s just them you know . . . clinging so to say, because that’s what I did, I got real clingy . . . because you’re so insecure . . .”
Parents considered it essential to be given the support of a specialized diabetes care team. As parents found the diagnosis to be a life-changing event, specialized support is important from the moment of diagnosis. Parents stated that, in retrospect, they needed more support from the dietician and the psychologist in the first weeks after diagnosis. Parents appreciated the attention healthcare professionals gave to the impact of diabetes on daily life, even though parents had to raise the topic themselves. The parents thought that healthcare professionals should actively address this more frequently.

**Local peer support**

According to parents, peer support is a useful supplement to usual pediatric diabetes care, as it provides reassurance:

“It’s a relief to just hear someone tell you that they have been through that as well and that it will pass . . . ,”

and tips and tricks on how to deal with diabetes in everyday life:

“ . . . that’s when you get to know people and you don’t have to reinvent the wheel. Like a birthday party, how do you deal with that . . . .”

The parents said that although peer support is very much needed in the first few weeks following diagnosis, it is also relevant throughout the entire childhood because every developmental level comes with new challenges that need new solutions. Parents considered current facilities for peer support to be unsatisfactory. Most peer support networks are organized on a nationwide basis, and do not take differences in diagnosis, age, residence, diabetes care clinic, or treatment into consideration, which makes it difficult for parents to interpret the tips and advice given. The parents considered that peer support should be organized online by local diabetes care teams. They would prefer peer support facilities (e.g., meetings, bulletin boards) to be limited to parents of an individual diabetes clinic and to take differences in age or treatment into account. An advantage of this local approach would be that as the children are treated at the same clinic, children and parents can meet each other in person as well as online. To ensure quality of input on the applications, parents would like a nurse practitioner to have a moderating role. Although the parents preferred to share worries with peers face to face, they thought that experiences, tips, and tricks are suitable for online exchange. The following quote illustrates parents’ attitudes to online peer support:

“You can ask other parents: how did you experience this? Do you have any tips on how to manage that? And the beauty of this [online] is that all information is gathered and if someone asks the same question in like 10 years, he or she can easily look it up . . . .”

**Involvement and alignment of the healthcare team**

The high level of personal involvement of healthcare professionals in the diabetes center and the care for their children was very much appreciated by the parents:
Parents stated that, although they would prefer to be treated by the same healthcare professionals at each consultation, they considered alignment within the team to be more important than seeing a fixed physician or nurse practitioner, since conflicting advice from healthcare professionals evoked insecurity in parents. Parents also appreciated healthcare professionals being decisive, when necessary.

**Development-oriented and demand-driven care**

Parents reported noticing that, as their child grew up, their skills and capability regarding diabetes disease management increased, which changed the level and nature of the involvement of child and parents in the diabetes management. Moreover, with time, parents became more experienced and novel situations occurred less often. As such, they experienced less stress and anxiety:

“...when you are somewhat further down the road and pump settings improve and it’s all better adjusted, ...you tend to get confused a lot less. I mean, last week we were busy all night with [child], with glucose values of 30, 26 and back again, but I’m not calling [the physician] any more for that, because I’ve been there before...”

According to parents, experienced parents primarily need support in case of incidental situations, such as when going on vacation or in case of sickness or when changing treatments (injection vs. infusion), and for them availability of dietician and psychologist upon request suffices. Parents suggested that consultations with dieticians and psychologists could be done online, for instance by using a webcam, which would lower the threshold for contact. Also, parents would very much appreciate receiving more general information from dieticians and psychologists; this information could also be provided and archived online. Treatment advice should fit the needs and wishes of individual children and parents, according to the parents. They expected that this could improve their treatment adherence. Although most healthcare professionals achieved this, some were considered to be too restrictive in their treatment advice. Parents said that, when the treatment was not fully tailored to their or their child’s needs, wishes, or capabilities, they tended to alter treatment goals and agreements, making it more suitable for their circumstances in everyday life, with a view to achieving a balance between normal glucose levels, normal HbA1c, and a good quality of life.

**Applicable information on disease and treatment**

Parents reported that they find it difficult to find and assess the reliability of online disease information and to know how scientific results should be translated into everyday diabetes management:
“. . . How far are we? How long do we have to wait, you know, until there is a cure? Is there going to be a cure?”

Healthcare professionals should periodically provide parents with reliable up-to-date information on the disease and its treatment, translating study results into everyday diabetes management and providing parents with the opportunity to discuss this new information. The information should preferably be provided and archived online, so that it can develop into a library of reliable and easily accessible information for parents to use or give to others (family, teachers, coaches).

**Accessibility of the healthcare team**

The 24/7 accessibility of the diabetes team for urgent issues reassured parents that they were not alone in the care for their child and made them feel more secure:

“They [the diabetes team] are accessible 24 hours a day. That gives me, although I have never actually used it, it gives me a very safe feeling.”

According to the parents, one clinic did not provide 24/7 access to the diabetes care team, a situation that should be corrected as soon as possible. Some parents found it difficult to decide whether an issue was urgent or not. They experienced a certain barrier for using the team’s emergency access. Reliable communication regarding non-urgent issues was also important to parents as it enabled them to discuss their child’s treatment with experts. Some parents indicated that they did not know how soon they could expect an answer to their questions, which caused stress and insecurity. They mentioned that it is less important to them how much time it takes before the response reaches them, to a certain amount, as long as healthcare professionals are clear about it and live up to expectations:

“last week [diabetes nurse practitioner] called us up for this evening, whether we wanted to participate . . . I said I would call or e-mail her. And then I wrote ‘it [the focus group] was in the clinic, right?’ with a question mark so I expected a response. But you just don’t get one. Just a little feedback like, even if it only says ‘yes,’ that’s enough . . .”

Parents preferred to use telephone in the case of urgency because they could then discuss the matter at hand. They thought that the Internet would be a suitable medium for non-urgent communication with healthcare professionals. Questions posed could be archived and retrieved online. A decision aid to help parents decide how urgent an issue is and who to contact could also be provided online.
Discussion

This study describes the qualitative assessment of parents’ experiences, needs, and preferences concerning pediatric diabetes care, and their needs and wishes regarding the use of the Internet in pediatric diabetes care. It adds to the literature by also reporting on actual suggestions made by parents for improving pediatric diabetes care and by reporting on the use of the Internet in pediatric diabetes care. Five strategies could be derived from the parents’ input, potentially enabling them to tailor care to their needs and preferences:

1. Nurses and physicians could explicitly address psychosocial well being of parents and child, starting on the day of diagnosis.
2. Nurses and physicians could adjust their approach to the level of experience of the parents and to the developmental level of the child.
3. Nurses and physicians could provide patients with recent findings and overviews of ongoing studies in pediatric diabetes care and translate these new findings to everyday diabetes management.
4. Nurses and physicians could facilitate local peer support.
5. Nurses and physicians could be clear and reliable about accessibility.

The Internet could, according to parents, be used to support these different needs and preferences as an addition to usual care, but not as a substitute. What this study clearly points out is the lack of diabetes-specific support parents perceive from their regular social network, since specific disease knowledge in friends and family is considered to be insufficient. Where regular social network support seems to suffice in regular conditions, parenting a child with T1D seems to be exceptional. Healthcare professionals need to be aware that parents consider them as the first line of support and information. It is also from this perspective that parents expressed their need for healthcare professionals pay attention to their child’s as well as their own psychosocial well being. In addition, they indicated the importance of clear and consistent information as contradictory advice from different members of the diabetes care team evoked uncertainty and anxiety. The need for active support from healthcare professionals, including dieticians and psychologists, is the greatest in the period immediately after diagnosis. Although stress and anxiety decrease in the year after diagnosis, the disease and its treatment continue to have impact on the lives of parents and children. Using the expertise of the psychologist or counselor in treatment was found to reduce the impact of diabetes on parents’ lives 28. To support this, routine screening by means of standardized questionnaires could be used to estimate the children’s as well as the parents’ resilience to cope with diagnosis and burden of disease management. Systematic screening has been shown to provide healthcare professionals
with crucial information on the level of emotional support needed. Parents in this study declared to need healthcare professionals to tailor care to individual needs of parents and child, for instance to the developmental level of the child. The parents reported that as their children grew older and gained in independence and autonomy, they preferred to take more responsibility for their own diabetes management. In addition, they preferred care tailored to their history regarding the disease. With time, parents become more experienced and independent in disease management. The needs of parents change from intensive guidance in the period following diagnosis to support in the case of aberrant situations and upon request. Shared decision making, with healthcare professionals making decisions with patients instead of for patients, might help in fine-tuning care and approach to individual needs and preferences. Although there is limited research on the effects of shared decision-making in pediatric medicine, studies involving adults report that patients generally prefer to be involved in the decisions about their treatment. The parents in the present sample expected that more shared decision-making would improve the fit of the treatment to their individual lives, which would lead to better adherence to treatment advice. The parents of a child with T1D have a need for concise and practical disease information, which was reported earlier. Parents indicated getting easily overwhelmed by the amount and the nature of information on the Internet, which potentially increased uncertainty and anxiety. In addition, parents had difficulties assessing the reliability of general information they retrieved from the Internet, as was also found by Nordfeldt, Hanberger, and Berterö, who reported that trust in and suitability of online public information were low in their sample. As such, parents require their healthcare professionals to guide them through the enormous pile of information available on the Internet, and specifically mentioned wanting information about ongoing trials and study results and how this information can be applied to everyday diabetes management. This information can ideally be provided and archived online to allow immediate access and to enable the diabetes team to update information and to provide a platform for parents and healthcare professionals to discuss how the information applies to everyday diabetes care. Parents explicated their need for local peer support. During the focus group interviews, the spontaneous exchange of experiences, tips, and worries between parents took up a great deal of time. Fellow parents of a child with T1D were considered potentially important sources of support to other parents. Peer support reduced the number of parent-child conflicts concerning diabetes in the families of a child with T1D and improved coping in the parents of chronically ill children. Peer support can ideally be organized online. Our study shows that local peer support is preferred over nationwide peer support and that parents greatly appreciate it being initiated and moderated by the local diabetes team. It is further notable that the parents in the present sample recognized a need for instrumental support (exchanging tips) and
emotional support (sharing worries). The clear distinction between instrumental and emotional support and its implications for organization of peer support is an understudied phenomenon in this population. Since value of peers is increasingly recognized in the field, this needs further investigation. Although instrumental peer support is regarded to be suitable for online delivery, parents seem to prefer emotional peer support being provided by face-to-face meetings. The provision of online peer support might lower the threshold for parents to engage in face-to-face meetings. Parents in our sample emphasized the importance of accessibility of healthcare professionals for patients with diabetes, as has also been shown in earlier studies. The results in this study support this, but highlight the need for reliability concerning communication of healthcare professionals. Accessibility is perceived as being supportive, when parents know how to contact their team and what to expect from their healthcare professionals regarding response time following a question. It was interesting that parents indicated reliability of high importance: parents do not mind when a relatively long time lapse is indicated by the team as long as they can count on their team to live up to their promise. So, teams who fail to respond to questions later than promised are experienced as less reliable. This suggests that it fits better to parents’ needs to use a larger time lapse between question and reply, than to promise a small time lapse, but repeatedly fail to achieve within that time lapse. By using the Internet, the accessibility of healthcare professionals could be improved. Most parents already use e-mail in their communication with their team. However, regular e-mail comes with certain security issues, and individual messages can get lost or deleted if not stored carefully. A secured online environment could archive all correspondence between parents and team automatically and safely, and make all correspondence transparent for members of the treatment team.

**Strengths and limitations**

The results in the present study have to be interpreted with some considerations in mind. The design warrants internal validity (by means of global respondent validation and multiple coding), external validity (by means of checking for revealed issues in literature), reliability (by means of audio recording interviews and verbatim transcription, the use of processing software, and again multiple coding), and process validity (by means of exploring focus group results during data gathering for saturation). However, despite this rigorous design, process validity could have improved when the authors had extensively analyzed every focus group interview prior to conducting the next one. This could have provided new information for fine-tuning of hypotheses during data collection. Given time constraints, the authors were forced to only explore focus group content. Also, in the second round of recruitment, participants were drafted by means of purposive recruitment, which means that participants with special interest in the subject of the study, “information-rich” cases, were recruited. Although this is common in qualitative research, it means that part of our sample was not
randomly selected, which threatens representativeness of the sample. However, since the majority of participants in our study were selected randomly, the bias is expected to be minimal.

**How might this information affect nursing practice?**

The input of the parents led to five strategies that diabetes care teams could address to improve the fit of diabetes care to parents’ needs and wishes. Diabetes teams should explicitly and frequently address the impact of the disease and its treatment on the lives of parents and children. Shared decision-making regarding disease management can be utilized in fine-tuning care and approach to individual needs and preferences, for instance to the level of independence of the individual child. Teams could facilitate local peer support, provide up-to-date disease information, and improve their accessibility. Parents recognized the potential value of using the Internet in pediatric diabetes care. A web-based patient portal is the sort of an Internet application that shows the best fit to their needs and preferences. A portal can ideally be used for creating a community that acts as a virtual extension of the diabetes clinic, providing a secured environment for patients alike to meet, exchange experiences and gain knowledge, and interact with their treatment team. This has already been shown to be highly appreciated by patients in other fields, like reproductive medicine and Parkinson disease. Its potential was also indicated in care for adolescents with T1D, and its applicability for meeting parents’ needs and preferences seems to be supported by this study. Since parents value peer support, the portal could enable this, also in combination with exchange of information among all users (parents and healthcare professionals), for instance through real-life chatting, a message board, or online forum applications. A portal also has the potential to facilitate the interaction with the treatment team, through a secured transparent mailing system, also allowing healthcare professionals to see each other’s responses to questions of parents to avoid contradictory advice. A portal could also provide an online library, with reliable information, presented as web links, online documents, and videos, contributed by all users and moderated by the healthcare team. The portal should be organized by the local medical teams and moderated by the nurse practitioner, and regarded as an add-on to usual diabetes care. It is important to note that parents prefer an online portal with a local reach over one with a nationwide reach, since they were mostly interested in local resources, local events, local policy regarding diabetes care, and local peer support. These findings will be leading in ongoing research, in which a web-based patient portal is developed and tested for efficacy and feasibility.
References


17. Plantin L & Daneback K (2009) Parenthood, information and support on the Internet. A literature review of research on parents and professionals online. *BMC Family Practice* 10, Article no. 34.


Teaming up: feasibility of an online treatment environment for adolescents with type 1 diabetes

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Abstract

Objective
To evaluate the feasibility of an online interactive treatment environment for adolescents with Type 1 Diabetes (T1D), called Sugarsquare, to supplement usual care.

Research design and methods
Sugarsquare provides easily accessible contact with the diabetes team, peer support, and treatment overview. Of 120 eligible patients, 62 adolescents aged 11 – 21 (M = 15.23, SD = 2.00) were assigned to a usual-care group (n = 31) or a usual-care + intervention group (n = 31). Feasibility was assessed in terms of acceptability, demand, practicability, integration, and efficacy in a 9-month study-period.

Results
Assessment of acceptability and demand revealed that 20 adolescents in the intervention group (65%) logged in at least once; 16 adolescents (52%) logged in repeatedly. Usage resulted in 5795 page-views, 3580 chat-messages, 427 forum-messages, and in 40 private interactions between 11 adolescents (35%) and professionals. Assessment of practicability revealed that all 13 professionals (100%) accessed the intervention. Slow processing speed and security procedures formed obstacles for usage. Assessment of integration showed that international standards for diabetes care (International Diabetes Federation/International Society for Pediatric and Adolescent Diabetes/American Diabetes Association) were met. Assessment of efficacy revealed improvement in the intervention group in evaluation of care (Patients’ Evaluation of Quality of Diabetes Care), $F(1,30)=5.35, p<0.05$, and quality of life, communication (PedsQL), $F (1,30) = 11.65, p <0.05$. The latter was correlated with posted chat-messages ($r = 0.42, p < 0.05$). No between-group differences were found.

Conclusions
This study shows that Sugarsquare is feasible in adolescents with T1D. It meets a demand in adolescents and can support professionals when organizing on-going care according to international standards. Results are promising and next steps are a full-scale randomized controlled trial and subsequent implementation in daily care.
Introduction

Adolescence is often considered to be the most difficult phase in life for dealing with Type 1 Diabetes (T1D) due to both physiological and psychosocial processes. The challenges for diabetes healthcare professionals in adolescents are to closely monitor and treat adolescents’ physical condition, to be sensitive to adolescents’ emotional responses and to support them in their T1D self-management. Review of recent literature reveals that several aspects of diabetes care are promising when it comes to improving glycemic control and self-management. Knowledge is one of the key-aspects. Increasing knowledge was found to improve glycemic control, self-management, and quality of life. This is especially the case when combined with peer support. In addition to knowledge, characteristics of communication between healthcare professionals and adolescents could positively affect self-management. Shared goal setting and shared decision-making have shown to help the adolescent develop effective self-management skills and enhances self-efficacy. Increasing adolescents’ contribution during consultations and direct patient-professional communication, instead of mediated by parents, have shown to improve adolescents’ adherence to and satisfaction with care, which was in turn found to be related to improved self-management and glycemic control. Another important facilitator of self-management seems to be peer support. Support by peers, and particularly by peers with diabetes is considered helpful in diabetes care. In their recent review, Palladino and Helgeson state, however, that studies on peer support in pediatric diabetes care are scarce and show mixed results. They conclude that peer support did improve self-care when support was targeted at specific self-care behaviors. This overview of the literature shows the importance of knowledge about diabetes, active communication between professionals and adolescent, and peer support on improving diabetes self management. The literature also shows that glycemic control in many adolescents remains suboptimal, despite efforts to improve diabetes care for adolescents and to support their disease management. The Internet is a medium that may help support adolescents in more effective self-management. During the last decade the role of the Internet in everyday life has increased significantly. Especially pediatric patients who need chronic care and their caregivers are expected to benefit from the potential of the Internet, as it can be effectively used for exchange of information and knowledge and lower the threshold for communication with healthcare professionals or peers. It is further noteworthy that adolescents with T1D, their parents and healthcare professionals generally support the idea of using Internet interventions in pediatric diabetes care, and that using the Internet can meet adolescents’ need for privacy. More research is needed, however, on feasibility and efficacy of Internet interventions in pediatric diabetes care and especially in those, which address multiple aspects of care, such as knowledge, patient-professional communication, and peer support. To fill this gap, a secured online intervention, called Sugarsquare, was
developed. Sugarsquare integrates the appealing aspect of using the Internet with providing easily accessible contact with healthcare professionals, peer support, and a treatment overview in a population of adolescents with T1D. In this article, the feasibility of Sugarsquare, is described including its efficacy in terms of improved self management and glycemic control. Studies on interventions show a variety of approaches when it comes to assessment of feasibility. For example, in recent studies feasibility was assessed as participants’ online activities, as the extent to which the intervention was acceptable to users, whether the inclusion was satisfactory and whether the intervention could be conducted as planned or as patients’ willingness and ability to use the intervention. In contrast to these limited interpretations of feasibility, we followed suggestions of Bowen and colleagues to focus on several areas of feasibility of an intervention. They distinguish between acceptability, demand, implementation, practicability, adaptation, integration, expansion, and efficacy. Which of the eight area of focus are assessed depends on the goal of the study and interest of the researchers. In this study, we addressed different aspects of feasibility in terms of acceptability and demand (actual usage), practicability (ability to reach and use the intervention), integration (fit with existing international guidelines for diabetes care), and efficacy, in order to answer the following research question:

What is the feasibility of an online treatment environment in a population of adolescents with T1D as an additive to regular outpatient pediatric diabetes care in terms of:
1. Acceptability (do recipients use the intervention?)
2. Demand (do recipients continue to use the intervention?)
3. Practicability (can recipients access the intervention?)
4. Integration (does the intervention fit with guidelines for pediatric diabetes care?)
5. Efficacy (what is the effect on adolescents’ self efficacy?)

**Research design and methods**

**Sample and procedure**
In March and April of 2009, 120 adolescents aged 11 – 21 were notified about the study through an informative letter and during consultations. To be included, adolescents had to be diagnosed with T1D and receive regular outpatient hospital-delivered diabetes care by the Children’s Diabetes Center Nijmegen (CD CN), Nijmegen, The Netherlands. Adolescents who were unable to read or fill out questionnaires because of language or cognitive impairment were excluded as well as adolescents who reported psychiatric problems. Written informed consent was obtained for all participants. Participants filled out a baseline questionnaire and were subsequently allocated to an experimental group and a control group. Allocation was
performed randomly by means of block randomization, using blocks of 2 and was conducted by the main researcher. All adolescents received care as usual, according to international standards for pediatric diabetes care. The intervention group additionally received access to the online interactive treatment environment, which replaced regular e-mail contact. After 9 months following the baseline-questionnaire, a post-test questionnaire was completed. During the 9-month study period, user activity of professionals and adolescents on the intervention was logged.

**Care as usual**
Care as usual was delivered according to international standards for pediatric diabetes care. Care was provided by a multidisciplinary team of healthcare professionals, consisting of physicians, nurse practitioners, dietitians, and psychologists, all experienced in providing diabetes care. Patients and parents are invited for consultations at the outpatient clinic three times per year. Patients are additionally invited for a group consultation once a year. Additional consultations can be requested. In between consultations, the diabetes team can be reached during office hours through telephone and e-mail and an emergency telephone number is staffed by a physician outside office hours to guarantee continuous access to care.

**Intervention**
The development of the intervention was based on positive results of a comparable intervention implemented in our hospital for couples in In Vitro Fertilization treatment and on a needs assessment in adolescents with diabetes by means of 13 interviews. Subsequently, an online treatment environment was developed, combining four components: information, patient-professional interaction, peer support, and a treatment overview. A draft template of the intervention was developed and piloted by a panel consisting of three adolescents with diabetes, one nurse practitioner and one physician. The final version of the intervention, Sugarsquare, is a secured online interactive treatment environment, which can be accessed through computers equipped with the right certificate (security access device), provided by the research team, and by using the appointed username-password combination. When logged on, users arrive at a homepage, which gives access to four applications (my diabetes, chat, forum, carelink) by means of clicking on the application name (Appendix I). The information on my diabetes and carelink is limited to the individual patient and the professionals. The other two applications (chat and forum) are semi-public, which means that every user has access to any input on chat and forum.

**My diabetes.** My diabetes is a personal secured page and provides a message board for private discussion with professionals. The application further consists of an individual treatment overview of basic data [e.g., weight and most recent hemoglobin A1c (HbA1c)], and treatment information (e.g., insulin dose and type)
Chat. The chat application allows users to interact in real-time. An overview of online users is given as well as an overview of the most recent messages.

Forum. The forum is an online bulletin board, containing a preset number of topics (e.g., news, school, parents). Users (both adolescents and professionals) can start a discussion within one of the topics or read and contribute to an existing discussion.

Carelink. The Carelink application consists of a web link to the Carelink website, on which data can be extracted from digital meters and pumps.

Professionals. A team of four diabetes nurse practitioners moderated the forum and chat applications on weekdays. A psychologist, a dietician, and two physicians moderated the forum and chat applications once a week or when requested by diabetes nurse practitioners.

Adherence of the professionals to the protocol was evaluated once every month.

Measures
Feasibility was assessed in terms of acceptability and demand, practicability, integration, and efficacy.

Acceptability and demand
Acceptability and demand were assessed in terms of the usage and repeated usage of the intervention by the patients in the trial indicated by logged user statistics.

Practicability
The interventions’ practicability was considered as the ability to log in and occurrence of constraints in delivery and was assessed in terms of the percentage of users in adolescents and professionals, its bounce percentage (percentage of login-errors) and other login-problems. The bounce-percentage was logged and participants were asked to report login-errors.

Integration
Integration was assessed in terms of the extent to which our web-based intervention promotes care that was consistent with recognized standards of diabetes care for adolescents including those published by the International Diabetes Federation (IDF) in collaboration with the International Society for Pediatric and Adolescent Diabetes (ISPAD) and the American Diabetes Association (ADA) \(^3,3^3\). See also Appendix I.

Efficacy
Efficacy was assessed in terms of change between baseline and follow-up assessments in adolescents regarding perceived diabetes self efficacy as primary outcome measure and regarding knowledge about diabetes and treatment, health-related quality of life and
appreciation of the diabetes care as secondary outcome measures using standardized questionnaires. All questionnaires were comprised especially for research in Diabetes care and have shown good psychometric values. The study used a pre-, post-test design and a control group.

**Diabetes self efficacy** was assessed in terms of adolescents' confidence in their diabetes self management and determined by means of the Confidence in Diabetes Self-care (CIDS) questionnaire. This questionnaire was validated in Dutch adult diabetes care and consists of 20 items, which can be answered on a 5-point Likert scale. Scores range from 20 to 100 with higher scores meaning better confidence.

**Disease knowledge** was measured using the Dutch version of the Diabetes Knowledge Questionnaire (DKT). This questionnaire was translated into Dutch by forward translation, backward translation and testing of applicability by a panel of diabetes care professionals. The final Dutch version consisted of 21 multiple choice questions. Raw data are transformed so that the range of scores is from 0 to 100 with higher scores meaning better knowledge.

**Health-related quality of life** was measured by means of the Pediatric Quality of Life Inventory diabetes module (PedsQL-dm). This frequently used questionnaire is validated in Dutch pediatric diabetes care and consists of 28 items, which can be answered using a 5-point Likert scale. Raw data are transformed so that scores range from 0 to 100 with higher scores meaning better quality of life.

**Adolescents' appreciation of our diabetes care** was assessed using the Patients' Evaluation of Quality of Diabetes (care (PEQD). The questionnaire was validated in Dutch adult diabetes care and consists of 14 items, which can be answered using a 5-point Likert scale. Raw data are transformed so that total scores range from 0 to 100 with higher scores meaning better appreciation of care.

Finally, as a measure of adolescents’ glycemic control, HbA1c levels [measured by DCA method (Siemens, Point of Care) (normal values: 20 – 42 mmol/mol (4.0 – 6.0%)] were gathered retrospectively by consulting patients’ medical files.

**Statistical analyses and sample size calculation**

Descriptive statistics of the Statistical Package for Social Sciences (SPSS 18.0) were used to describe participants’ demographics at baseline. Change over time was assessed by means of Generalized Linear Modeling (GLM) for repeated measures in SPSS, which controls for multiple testing. Pearson correlation coefficients were used for analyzing the relationship between user statistics and change over time. Alpha levels were set at 0.05 for all analyses. Sample size was calculated at a total study population of 80 participants. On the basis of previous studies an effect size of 0.955 is expected. A standard deviation of 6.56 and an alpha of 0.05, gives a power of 0.985, when 40 participants are allocated to the control group and 40 participants are allocated in the experimental group.
Results

Patients’ characteristics
Of 120 adolescents, 66 (55%) sent back their written informed consent and the baseline questionnaire. One adolescent was excluded because of psychiatric problems. Three adolescents were excluded, since they participated in the pilot, used for testing the intervention. The remaining 62 adolescents filled out a baseline questionnaire and were alternately assigned to a control group and an intervention group. The post intervention questionnaire was returned by 53 adolescents. Twelve adolescents (10 in the control group and 2 in the intervention group) failed to return the questionnaire and were regarded as drop-outs. Reasons for dropping out were transferring to adult care (n = 3), changing from hospital (n = 2), and losing interest in the study (n = 7). Table 1 shows our participants’ characteristics. No significant differences in characteristics were found between intervention and control group on age (F = 0.14, p = 0.71), gender ($\chi^2 = 2.54, p = 0.11$) and HbA1c (F = 0.15, p = 0.70) at baseline. Analysis revealed that drop-outs did not differ in age (F = 0.57, p = 0.45), gender ($\chi^2 = 1.37, p = 0.24$), and HbA1c (F=0.03, p=0.88) at baseline compared to adolescents who completed the study.

Table 5.1 Participants’ characteristics at baseline

<table>
<thead>
<tr>
<th>N</th>
<th>All</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>62</td>
<td>31</td>
<td>31</td>
</tr>
<tr>
<td>Age</td>
<td>M (SD)</td>
<td>15.23 (2.00)</td>
<td>15.13 (2.13)</td>
</tr>
<tr>
<td>Gender</td>
<td>F</td>
<td>40 (64.5%)</td>
<td>23 (74.2%)</td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>22 (35.5%)</td>
<td>8 (25.8%)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>% (mmol/mol)</td>
<td>8.65 (71)</td>
<td>8.54 (70)</td>
</tr>
</tbody>
</table>

HbA1c: hemoglobin A1c

Feasibility
Acceptability and demand
Twenty adolescents (65%) in the user group logged in at least once. As seen in Table 2, their usage during the 9-month study period resulted in 5795 page views, 3580 posted chat messages, and 427 posted forum messages. Of the 20 adolescents, 16 adolescents (52%) logged in repeatedly. These 16 repeated users could be divided into frequent users (at least once a week for 8 wk during the study period or at least once a week for 4 consecutive weeks), n=9 (29%), and incidental users (logging in repeatedly, yet less than once a week for 8 wk
during the study period or once a week for 4 consecutive weeks), n = 7 (23%). The remaining adolescents, n = 15 (42%), logged in only once (n = 4) or not at all (n = 11) during the study period (non-users). Table 2 also shows that the number of initiated private interactions with the professionals was 40. A total of 11 adolescents used this application; 6 of them accounted for 38 (95%) of the interactions.

Table 5.2 Total user data (in numbers) in intervention group in 9–month study phase

<table>
<thead>
<tr>
<th></th>
<th>Adolescents</th>
<th>Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page views (per month)</td>
<td>5795 (643.89)</td>
<td>3006 (334)</td>
</tr>
<tr>
<td>Chat visits (per month)</td>
<td>1050 (116.67)</td>
<td>253 (28.11)</td>
</tr>
<tr>
<td>Chat messages (per month)</td>
<td>3580 (397.78)</td>
<td>399 (44.33)</td>
</tr>
<tr>
<td>Initiated forum discussions (per month)</td>
<td>24 (2.67)</td>
<td>3 (0.33)</td>
</tr>
<tr>
<td>Forum messages (per month)</td>
<td>427 (47.44)</td>
<td>69 (7.67)</td>
</tr>
<tr>
<td>Initiated private discussions (per month)</td>
<td>24 (2.67)</td>
<td>47 (5.22)</td>
</tr>
<tr>
<td>Private messages (per month)</td>
<td>40 (4.44)</td>
<td>88 (9.78)</td>
</tr>
</tbody>
</table>

**Practicability**

As already indicated, Sugarsquare was accessed by 20 adolescents (65%). The bounce percentage was 5.4%, which was the percentage of failed attempts to log-in in adolescents who had successfully installed the certificate. Installation of the certificate was too complicated for 4 of 31 adolescents, resulting in non-usage in those 4 adolescents. All 13 professionals (100%) were able to login using existing local ICT-systems. Outdated browser software resulting in low processing speed and repeatedly removed security certificates from users’ accounts by the existing ICT updating systems were reported as barriers for usage by the professionals.

**Integration**

Using the intervention attributed to providing care according to the Global IDF/ISPAD Guideline for Diabetes in Childhood and Adolescence and ADA International Standards of Medical Care in Diabetes[^3][^33]. See also Appendix I.

**Efficacy**

Within group analyses revealed no differences in adolescents' confidence in their diabetes self management and their diabetes knowledge. However, the intervention group showed an improvement in adolescents’ evaluation of the quality of diabetes care, PEQD total scale score, F(1,30)=5.35, p=0.028, as well as on various items of the PEQD (Table 3). Adolescents in the
intervention group also showed an improvement in diabetes-related quality of life, regarding disease communication $F (1,30) = 11.65$, $p = 0.002$. Adolescents in the control group did not show significant change in any assessed measures. Adolescents in the intervention group who reported more improvement in quality of life regarding disease communication also posted higher numbers of chat messages, ($r=0.42$, $p<0.05$). Between group analyses revealed no significant differences in change over time between the intervention and the control group concerning HbA1c ($F(1,61)=0.16$, $p=0.693$), confidence in diabetes self management ($F (1,61) = 2.55$, $p = 0.118$), diabetes knowledge ($F (1,61) = 0.09$, $p = 0.768$), health-related quality of life ($F (1,61) = 0.12$, $p = 0.730$) and evaluation of diabetes care ($F (1,61) = 0.08$, $p = 0.781$).

### Table 5.3 Change over time in psychosocial variables in intervention group and control group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experimental group</th>
<th>Control group</th>
<th>F</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0 M(SD)</td>
<td>T1 M(SD)</td>
<td>N=31</td>
<td>N=29</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N=31</td>
<td>N=21</td>
</tr>
<tr>
<td>PEQD</td>
<td>68.28 (11.59)</td>
<td>72.45 (11.69)</td>
<td>5.35*</td>
<td></td>
</tr>
<tr>
<td>Waiting times</td>
<td>3.17 (0.90)</td>
<td>3.07 (0.90)</td>
<td>0.03</td>
<td>2.74 (0.93)</td>
</tr>
<tr>
<td>Duration of consultations</td>
<td>3.10 (0.89)</td>
<td>3.29 (0.71)</td>
<td>1.00</td>
<td>3.19 (0.83)</td>
</tr>
<tr>
<td>Time between appointments</td>
<td>3.13 (0.90)</td>
<td>3.43 (0.7)</td>
<td>2.41</td>
<td>3.23 (0.85)</td>
</tr>
<tr>
<td>Clarity of information</td>
<td>3.57 (0.94)</td>
<td>3.89 (0.83)</td>
<td>3.58*</td>
<td>3.58 (0.99)</td>
</tr>
<tr>
<td>Amount of information</td>
<td>3.50 (0.94)</td>
<td>3.68 (0.91)</td>
<td>0.71</td>
<td>3.42 (0.96)</td>
</tr>
<tr>
<td>Usefulness of information</td>
<td>3.17 (0.70)</td>
<td>3.64 (0.78)</td>
<td>7.16*</td>
<td>3.45 (0.85)</td>
</tr>
<tr>
<td>Opportunity to ask questions</td>
<td>4.10 (0.92)</td>
<td>4.21 (0.88)</td>
<td>1.06</td>
<td>3.90 (0.91)</td>
</tr>
<tr>
<td>Emotional support</td>
<td>3.37 (0.85)</td>
<td>3.71 (0.94)</td>
<td>5.62*</td>
<td>3.68 (1.11)</td>
</tr>
<tr>
<td>Medical technical competence</td>
<td>3.35 (0.90)</td>
<td>3.79 (0.74)</td>
<td>3.96</td>
<td>3.65 (0.92)</td>
</tr>
<tr>
<td>Continuity of diabetes care</td>
<td>3.41 (0.81)</td>
<td>3.64 (0.68)</td>
<td>3.55</td>
<td>3.26 (0.89)</td>
</tr>
<tr>
<td>Integration of care</td>
<td>3.27 (0.83)</td>
<td>3.29 (0.90)</td>
<td>0.16</td>
<td>3.10 (0.75)</td>
</tr>
<tr>
<td>Co-decide on diabetes treatment</td>
<td>3.47 (0.93)</td>
<td>3.68 (0.86)</td>
<td>4.73*</td>
<td>3.55 (0.81)</td>
</tr>
<tr>
<td>Ease of getting appointments</td>
<td>3.41 (0.97)</td>
<td>3.71 (0.94)</td>
<td>5.11*</td>
<td>3.32 (1.05)</td>
</tr>
<tr>
<td>Overall quality of diabetes care</td>
<td>3.60 (0.68)</td>
<td>3.68 (0.77)</td>
<td>1.15</td>
<td>3.55 (0.72)</td>
</tr>
<tr>
<td>CIDS</td>
<td>82.77 (9.06)</td>
<td>81.35 (9.28)</td>
<td>3.37</td>
<td>82.36 (8.42)</td>
</tr>
<tr>
<td>DKT</td>
<td>80.49 (9.23)</td>
<td>82.14 (10.32)</td>
<td>0.04</td>
<td>78.19 (10.77)</td>
</tr>
<tr>
<td>PedsQL</td>
<td>65.79 (13.83)</td>
<td>67.91 (13.31)</td>
<td>1.55</td>
<td>69.08 (11.12)</td>
</tr>
<tr>
<td>Diabetes symptoms</td>
<td>53.08 (16.01)</td>
<td>55.64 (15.30)</td>
<td>1.93</td>
<td>58.06 (13.43)</td>
</tr>
<tr>
<td>Treatment barriers</td>
<td>75.81 (19.21)</td>
<td>76.94 (19.13)</td>
<td>0.10</td>
<td>76.48 (16.56)</td>
</tr>
<tr>
<td>Treatment adherence</td>
<td>72.12 (15.29)</td>
<td>74.28 (15.67)</td>
<td>0.73</td>
<td>77.21 (12.58)</td>
</tr>
<tr>
<td>Worry</td>
<td>79.30 (19.23)</td>
<td>76.68 (18.86)</td>
<td>1.18</td>
<td>75.81 (22.09)</td>
</tr>
<tr>
<td>Communication</td>
<td>71.28 (21.63)</td>
<td>77.98 (22.01)</td>
<td>11.65*</td>
<td>73.92 (22.85)</td>
</tr>
<tr>
<td>HbA1c %/ mmol/mol</td>
<td>8.54 (1.49)/70</td>
<td>8.98 (1.91)/75</td>
<td>0.06</td>
<td>8.76 (1.83)/72</td>
</tr>
</tbody>
</table>
Conclusions

The aim of this study was to evaluate the feasibility of a secured online interactive treatment environment, Sugarsquare, in adolescents with T1D. Sugarsquare was found to be feasible. Acceptability and demand of Sugarsquare in the present study were high to moderate among adolescents and very high among the professionals, which indicates high acceptance by all recipients. Sugarsquare was accessible for professionals through existing ICT-systems. However, outdated browser software, and a reduced fit to our local ICT-system, affected usage of the intervention. Considering the negative effect of reduced fit to existing ICT systems on usage and acceptability suggested in literature, levels of usage of Sugarsquare were remarkably high. This suggests that an online intervention providing knowledge, easy accessible contact with the diabetes care team, peer support, and insight in treatment goals, clearly meets a demand in adolescents and professionals. Using the online intervention contributed to delivering care according to proposed Global IDF/ISPAD Guideline for Diabetes in Childhood and Adolescence and ADA Standards of Medical Care in Diabetes. Since treatment teams for diabetes care deliver their care according to global guideline and standards more and more, successful integration of an online interactive treatment environment in common practice is very likely. Efficacy was partly found. Adolescents who used Sugarsquare reported improvement in the evaluation of their received care. They also reported improved communication about diabetes with their diabetes care team. This was especially so in adolescents who used the chat application more often. This is remarkable, since the chat-application focuses mainly on peer contact. It is possible that discussing the disease with peers, or at least being able to do so, makes it easier to open up to professionals as well. Another possibility is that, since the professionals participated in some chat sessions, this lowered the threshold for adolescents to interact with the professionals in general. There was no significant change over time in HbA1c. However, closer examination of the data shows a slight but insignificant increase of HbA1c in the experimental groups and a slight and also insignificant decrease in the control group. On the basis of the sample of this study we could not speculate on reasons for this. It warrants expanding the number of participants in a next study to enable conclusions on effect on diabetes regulation and diabetes regulation in subgroups, e.g., drop outs compared to participants who completed the study. No between group differences were identified, possibly due to power problems. We did not reach the required sample size, which decreased the chance for finding potential effects. A second possible explanation concerns the login-procedure and limited fit to existing ICT structures, which might have influenced usage. It is arguable that easier login procedure and better fit would have lead to even higher individual frequency of use and more benefit in the access group. The results presented in this article have to be considered with some limitations in mind. The first limitation lies in the already mentioned limited number of participants. We did
not reach the required number of participants and we experienced a high dropout rate in the control group, a well-known phenomenon in trials testing in Internet interventions, which impeded comparison of the control and intervention group in the analyses.[29,36] This study further lacks assessment of effects of single applications. Our online interactive treatment environment consists of several applications: an online forum, a chat application, an overview of treatment plan and an application for interaction with the diabetes care team, which are combined on one platform. Assessing the value of single applications through multiple study-arms would have provided clear information on which (combination of) applications were most desirable and most effective.[39] This requires, however, a high number of participants in the total research population. Instead, we chose to assess users’ activity on the various applications, which we were able to associate with improvement on participants’ quality of life. Interesting result of this study is that it is feasible to build an online intervention meeting the guidelines of IDF/ISPAD and ADA. It meets demands in adolescents indicated by usage as well as repeated usage in a considerable part of the adolescents involved. Efficacy was only partly found. Finding efficacy in an innovative project like the one described in this article is difficult due to unforeseen technicalities and start up problems. However, the intervention improved communication between adolescent and team. As adolescents were able to view and manage their personal treatment overview, they were encouraged to take an active role in managing their disease. In addition, professionals could access all adolescents’ treatment overviews, and could attune their advice to previous advices of other team members, which promotes alignment of treatment advices from a multidisciplinary perspective. Sugarsquare, the online interactive treatment environment described in this study, combines disease knowledge, patient-professional interaction and peer support, and is a good example of how to use the Internet in improving ongoing pediatric diabetes care and patient-professional interaction. In a next phase, Sugarsquare should be tested by means of a full-scale randomized controlled trial and implemented in daily care.
References


### APPENDIX I

Integration of global IDF/ISPAD guideline for diabetes in childhood and adolescence according to the International Diabetes Federation (IDF) in collaboration with the International Society for Pediatric and Adolescent Diabetes (ISPAD) and standards for diabetes care according to the American Diabetes Association (ADA) 3,33.

<table>
<thead>
<tr>
<th>International guideline and standards for diabetes care</th>
<th>Does Sugarsquare contribute to treatment according to guideline standards?</th>
</tr>
</thead>
<tbody>
<tr>
<td>People with diabetes should receive medical care from a physician-coordinated team</td>
<td>Yes The physician-coordinated team uses the online interactive treatment environment to communicate with the adolescents</td>
</tr>
<tr>
<td>Such teams may include, but are not limited to, physicians, nurse practitioners, physician’s assistants, nurses, dietitians, pharmacists, and mental health professionals with expertise and a special interest in diabetes</td>
<td>Yes All disciplines in the multidisciplinary teams use the online interactive treatment environment</td>
</tr>
<tr>
<td>It is essential in this collaborative and integrated team approach that individuals with diabetes assume an active role in their care</td>
<td>Yes Adolescents are encouraged to ask questions or post comments addressing his or her treatment. The team can fit each other’s advices to one another’s</td>
</tr>
<tr>
<td>The management plan should be formulated as a collaborative therapeutic alliance among the patient and family, the physician, and other members of the healthcare team</td>
<td>Yes Adolescents are actively involved in their treatment and can alter their own treatment plan on their treatment sheet</td>
</tr>
<tr>
<td>A variety of strategies and techniques should be used to provide adequate education and development of problem-solving skills in the various aspects of diabetes management</td>
<td>Yes Adolescents are encouraged to give each other tips and learn how they deal with the disease</td>
</tr>
<tr>
<td>Implementation of the management plan requires that each aspect is understood and agreed to by the patient and the care providers and that the goals and treatment plan are reasonable</td>
<td>Yes Adolescents can write their own treatment plan and share and adapt it with online input of the team members</td>
</tr>
<tr>
<td>Any plan should recognize diabetes self-management education (DSME), including introduction of new therapies and technologies, on-going diabetes support and psychosocial support as an integral component of care</td>
<td>Yes The online interactive treatment environment is particularly aimed at ongoing support in-between consultations and aims at facilitating education and support by the treatment team and peers. Team members can easily introduce new therapies and technologies to the adolescents, e.g., by writing blogs</td>
</tr>
</tbody>
</table>
### International guideline and standards for diabetes care

**In developing the plan, consideration should be given to the patient’s age, school or work schedule and conditions, physical activity, eating patterns, social situation and cultural factors, and presence of complications of diabetes or other medical conditions.**

<table>
<thead>
<tr>
<th>International guideline and standards for diabetes care</th>
<th>Does Sugarsquare contribute to treatment according to guideline standards?</th>
</tr>
</thead>
<tbody>
<tr>
<td>In developing the plan, consideration should be given to the patient’s age, school or work schedule and conditions, physical activity, eating patterns, social situation and cultural factors, and presence of complications of diabetes or other medical conditions</td>
<td>Yes</td>
</tr>
</tbody>
</table>

| The Diabetes Care team provides ambulatory and hospital care, including emergency access to advice, hospitalization, care visits, and Quarterly HbA1c determination | Yes | The online interactive treatment environment is used as an additive to existing ambulatory and hospital care |
The Sugarsquare study: protocol of a multicenter randomized controlled trial concerning a web-based patient portal for parents of a child with type 1 diabetes
Abstract

Background
Type 1 Diabetes (T1D) demands a complicated disease self-management by child and parents. The overwhelming task of combining every day parenting tasks with demands of taking care of a child with diabetes can have a profound impact on parents, often resulting in increased parenting stress. Tailored disease information, easy accessible communication with healthcare professionals and peer support are found to support parents to adequately cope with the disease and the disease self-management in everyday life. Internet can help facilitate these important factors in usual pediatric diabetes care. Therefore, we will develop a web-based patient portal in addition to usual pediatric diabetes care and subsequently evaluate its efficacy and feasibility. The web-based patient portal, called Sugarsquare, provides online disease information, and facilitates online parent-professional communication and online peer support. We hypothesize that parenting stress in parents of a child with T1D will decrease by using Sugarsquare and that Sugarsquare will be feasible in this population.

Methods/design
We will test the hypotheses using a multicenter randomized controlled trial. Eligible participants are parents of a child with T1D under the age of 13. Parents are excluded when they have no access to the Internet at home or limited comprehension of the Dutch language. Participants are recruited offline from seven clinics in the Netherlands. Participants are randomly allocated to an intervention and a control group. The intervention group will receive access to the intervention during the twelve-month study-period; the control group will receive access in the last six months of the study-period. Self-reported parenting stress is the primary outcome in the present study. Data will be gathered at baseline (T0) and at six (T1) and twelve (T2) months following baseline, using online questionnaires. User statistics will be gathered throughout the twelve-month study-period for feasibility.

Discussion
Dependent on its feasibility and efficacy, the intervention will be implemented into usual pediatric diabetes care. Strengths and limitations of the study are discussed.
Background

Type 1 Diabetes (T1D) is a chronic metabolic disorder due to carbohydrate malfunctioning. The incidence of T1D in children is increasing in Europe, with incidence rates expected to raise by 100% in children aged 0 to 5 and by 70% in children aged 0 to 15 in the period from 2005 to 2020. In 2011, 17,800 new cases of T1D were diagnosed in Europe, increasing the number of children with T1D to 115,700, which makes it the region with the highest rates of children with T1D.

T1D comes with a complicated and intrusive treatment regime. Parents have to adapt their child’s lifestyle and their own to the demands of the disease, without withholding their child from typical life experiences. As such, raising a child with T1D can have great impact on parents’ wellbeing. Especially parents of young children with diabetes can show elevated levels of stress, anxiety and depressed mood, which can lead to an increase in conflicts within the family, and depressed mood and poor self management skills in the child.

Given the impact of the disease and its disease self-management, support provided by healthcare professionals is of great importance. Several aspects in pediatric diabetes care show promising results when it comes to supporting parents. A first important factor is education which, defined as providing knowledge and skills needed to perform diabetes self-care, manage crises and make lifestyle changes, was found to improve quality of disease management and treatment adherence by child and parents and to subsequently improve the child’s glycemic control.

Easy accessible communication with healthcare professionals is a second important factor in diabetes care. Tailored and supportive patient-professional communication was found to be associated with improved disease knowledge and quality of disease management of parents, including treatment adherence. Literature further points out that parents and patients prefer their healthcare professional to find a balance between exchanging technical information and providing emotional support.

A third important factor is peer-support, which was found to reduce parenting stress in parents of chronically ill children and to reduce the number of parent-child conflicts concerning diabetes in families of a child with T1D. Peer support is also related to better coping in parents of a chronically ill child. It is suggested that healthcare professionals should be actively involved in organizing peer contact, for example by facilitating peer support groups or by appointing mentor-peers.

These findings have major implications for healthcare professionals of the diabetes care teams. They are expected to provide tailored disease knowledge, be accessible to patients and facilitate peer support. The Internet can be of great assistance to them in facilitating the abovementioned factors. The role of Internet in everyday life has increased significantly during the last decade. Especially pediatric patients who need chronic care and their
caregivers are expected to benefit from the potential of the internet, as it can be effectively used for exchange of information and knowledge and lower the threshold for communication with healthcare professionals or peers. It is further noteworthy that adolescents with diabetes, parents and healthcare professionals generally support the idea of using Internet interventions in pediatric diabetes care. More research is needed, however, on efficacy and feasibility of Internet interventions in pediatric diabetes care and especially concerning interventions that combine multiple aspects of care, such as education, patient-professional communication and peer support.

In the present paper the background, rationale and design of a patient-initiated, multicenter study are described. In the study, a secured web-based patient portal, called Sugarsquare, is developed and evaluated in terms of efficacy and feasibility. The portal integrates the appealing aspect of using internet with providing tailored disease knowledge, easily accessible communication with healthcare professionals of the diabetes team and peer support in a population of parents of a child with T1D.

Hypotheses:
Usage of Sugarsquare in pediatric diabetes care leads to a decrease in parenting stress in parents of a child with T1D.
Sugarsquare is feasible in pediatric diabetes care for parents of a child with T1D.

Methods/Design

Setting and participants
The present study is conducted in seven clinics for pediatric diabetes care in the Netherlands, which, together, deliver care to approximately 750 children with diabetes under the age of 13. Eligible participants are parents of a child with T1D, who receives treatment at one of the seven clinics for diabetes care. Parents are excluded when their child reaches the age of 13 before start of the study. No access to the Internet at home and limited comprehension of the Dutch language are also reasons for exclusion.

Intervention

*Intervention development and patient participation*
The present study was initiated at parents’ explicit request for usage of Internet in care. The design and contents of the intervention was partly based on positive results of a comparable intervention implemented in our hospital for couples in IVF treatment and a comparable intervention implemented in our hospital for adolescents with T1D. To match design and contents of the intervention to parents’ preferences, seven focus groups were conducted among parents. Purpose of these focus groups was to map parents’ experiences, needs and
wishes concerning their child’s diabetes care. Also, healthcare professionals affiliated to the cooperating diabetes care teams filled out a questionnaire assessing their experiences providing diabetes care and their wishes for fitting the intervention to their workflow.

A test phase, consisting of a series of small pilots, was conducted in the cooperating clinics. Goal was to finetune the intervention and to repair bugs. This iterative process helped significantly to fit the intervention to parents’ preferences and to professionals’ workflow. The test phase ended when bugs were repaired and both parents and professionals felt the intervention was ready for use.

**Intervention**

The final version of Sugarsquare consists of a web-based patient portal, which provides disease information, easily accessible contact with the diabetes care team and peer support. In accordance to parents’ preferences, the intervention is organized locally. This means that every clinic has its own secured portal, which is only accessible to healthcare professionals of that particular clinic and parents of children treated at that clinic. Sugarsquare is accessible through the Internet and consists of three main sections:

**Section I: Social.** This first section includes online peer support and is accessible to all users (parents and healthcare professionals). Peer support is facilitated through a chat-application, a forum-application and a blog application. Parents and healthcare professionals are able to communicate in real time by using the chat-application. On the forum-application, healthcare professionals and parents can read and post messages, which are open to all users. Since all users contribute to the social section, it will grow out to have great educational value.

**Section II: Personal.** This second section applies to individual patients and the information exchanged there can therefore only be accessed by the parents of that particular patient and all healthcare professionals of the clinic. The section consists of an application for overview of treatment goals and an application for easy accessible private contact with the healthcare professionals. The treatment goals are composed during regular consultations with the nurse practitioner and can be accessed online by parents and healthcare professionals at any given moment. The application for easy accessible communication with healthcare professionals is used by parents for discussing the child’s treatment and wellbeing. Discussions are accessible to both parents and all professionals of the diabetes care team. This allows healthcare professionals to fine-tune their advice to previously given advices. This application is only used for non-urgent matters.

**Section III: Information.** The third section contains disease information, which is presented by means of downloadable documents and web links. Each diabetes care team prepares documents and selects web links. Parents can add web links to Sugarsquare as well, which the diabetes care team can choose to endorse after review. All posted information in this section is available to all users. A screenshot of the login page of Sugarsquare is presented in Figure 1.
Access, privacy and security
The main researcher activates the accounts for healthcare professionals and parents. They subsequently received an invitational e-mail with a request for acceptance of conditions. URL of the intervention, username and password are subsequently provided automatically. When registering, users enter their cell phone number. Sugarsquare is secured by means of a two-factor authentication, using a username-password combination and a personalized SMS-code in the login procedure.

Diabetes team
All participating clinics provide usual diabetes care by means of a multidisciplinary team, consisting of pediatric endocrinologists, nurse practitioners, dieticians and psychologists. The nurse practitioners of the diabetes care team moderate the forum daily, organize weekly chat sessions among participants, fill out the treatment overview during consultations and answer questions of participants posed on Sugarsquare. The pediatricians, dieticians and psychologists are involved upon request of nurse practitioners by writing blogs, answering specified questions of participants or participating in the forum or in chat sessions. Parents
who have access to Sugarsquare are requested to use the intervention as much as possible for regular non-urgent communication with the diabetes care team, instead of using conventional tools, such as e-mail or telephone. Besides replacement of communication through telephone and e-mail in case of non-urgent matters, care as usual will not be altered

**Study design and procedure**

*Design*
A 12-month, multicenter, randomized controlled trial (RCT) is conducted, in which participants are assigned to one of two conditions: 1) an intervention condition and 2) a waiting list control condition. Participants in the intervention group have access to the intervention during the entire 12-month study period. Participants in the control group are placed on a six-month waiting list. In the remaining six months they will have access to Sugarsquare.

*Procedures*
Eligible, potential participants are approached by their diabetes care team with hard-copy information (information letter, flyer, brochure and application form) about the study. Upon returning the application form, participants are randomized and are subsequently send a questionnaire. When participants have sent back their filled out baseline questionnaire, they are informed about the allocation. Participants who fail to return their baseline questionnaire are contacted by telephone by their diabetes care team, requesting them to send back the filled out questionnaire. After six months following baseline assessment, a second assessment is conducted, also by means of a questionnaire. After having sent back the second questionnaire, participants in the experimental group retain access. Participants in the control group are granted access after having sent back their second questionnaire. After twelve months following baseline assessment, a third assessment will take place, again by means of a questionnaire. Participants who fail to return their second or third questionnaire after request over telephone are considered as dropout. All procedures described in this study protocol are approved by the Ethics Committees of Human Experimentation of the Radboud university medical center and of the participating hospitals and are in accordance with the Declaration of Helsinki. Written informed consent will be obtained from all participants.

*Randomization & blinding*
Randomization takes place per center and is conducted using envelopes containing red and green cards. For every clinic, there are as many cards as there are participants in the research population. There are as many red cards as there are green cards. Every card is concealed in aluminum foil, so the color will not be visible in any way except when opening the envelope. For every included participant an envelope is picked. When the envelope contains a green card, the participant will be allocated into the experimental group. When the envelope
contains a red card, the participant will be allocated into the control group. Randomization is carried out by an independent researcher. This study is not blinded. Since patient-professional communication is part of the intervention, healthcare professionals know whether a participant is allocated in the experimental group. Parents themselves also know whether they are allocated in the experimental group or the control group. The main researcher is administrator of the intervention and is responsible for enrolment of participants in the intervention and for support during the study period.

**Sample size**

We aim to include 240 parents. This number of participants is calculated using a medium effect size (d = .5), an $\alpha$ of .05 (two-tailed test) and a $\beta$ of .10. The hypothesized effect size is realistic, when considering the paper of Leung et al. ([38]; see also Table 1), in which an effect size of 1.38 was described, using the PSI-SF. To reach adequate power (.90), 180 participants are included in the final analysis [39]. These participants are divided equally into an experimental group (N = 90) and a control group (N = 90). However, in recent studies on randomized controlled trials regarding E-health interventions, an average dropout rate of 25% was found [28]. This means that, when taking drop out into account and when aiming at 180 participants in the final analyses, at least 240 parents have to be included at the start of the study.

**Table 6.1 Means and standard deviations of the parent-reported measures of the PSI in other research [38]**

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
</tr>
<tr>
<td>Pre intervention</td>
<td>121.60 (17.16)</td>
<td>112.87 (14.35)</td>
</tr>
<tr>
<td>Post intervention</td>
<td>85.27 (19.91)</td>
<td>109.08 (14.98)</td>
</tr>
</tbody>
</table>

**Data-collection**

Data are collected through self-report questionnaires except for the medical data and user statistics. All questionnaires are sent at baseline, T1 (6 months following baseline) and T2 (12 months following baseline), through the Internet. All data are collected using Radquest. Radquest is software used for composing and storing questionnaires using a secured server and was developed by the department of Medical Psychology of the Radboud university medical center. Data derived from patients’ medical files are gathered by nurse practitioners of the diabetes care teams.
Study outcome measures

Background variables
Demographics are gathered through questionnaires on baseline only (see Table 2).

Table 6.2 Background variables used in the Sugarsquare study

<table>
<thead>
<tr>
<th>Background variables</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>Age and gender of the child</td>
</tr>
<tr>
<td></td>
<td>Onset and duration of diabetes</td>
</tr>
<tr>
<td></td>
<td>Pen or pump treatment</td>
</tr>
<tr>
<td></td>
<td>Age, gender and educational level of the primary parent</td>
</tr>
<tr>
<td></td>
<td>Social economic status of the parents</td>
</tr>
</tbody>
</table>

Primary and secondary outcome measures

Standardized questionnaires are used to gather data on primary and secondary outcome measures. Parenting stress is the primary study parameter. We aim to assess parenting stress by means of the Dutch version of the Parenting Stress Index short form (PSI-SF). The reliability and criterion validity of the Dutch PSI-SF are shown to be good. The PSI-SF consists of 25 items, which can be answered using a 6-point Likert-scale, ranging from ‘totally disagree’ to ‘totally agree’. An example of an item on the PSI-SF is ‘it is not always easy to accept my child the way he/she is’. The sum score on the PSI-SF can be categorized into normal, subclinical, and clinical based on standardized cut-off scores described in the manual. For an elaborate overview of secondary outcome measures, see Table 3. Most mentioned questionnaires (PEQD, DKT, CIDS, DFCS, PedsQL) have been developed and validated especially for research in diabetes care. The general questionnaires (GHQ-12, SDQ, MMAS) have demonstrated good psychometric properties in the general pediatric population.

Feasibility

In present literature, a variety of approaches to assess feasibility can be found. As to use a more standardized measure, Bowen and colleagues suggest focusing on several areas of feasibility of an intervention: They distinguish between acceptability, demand, implementation, practicability, adaptation, integration, expansion and efficacy. Which of the eight area of focus are assessed depends on the goal of the study and interest of the researchers. In this study we concentrate on practicability, acceptability, demand and integration (see Table 4). For assessment of feasibility, individual user data, such as frequency of logins and number of messages posted on the forum, are logged automatically and digitally (see also Table 4). These user data can subsequently be associated with potentially reported
change over time. This will give insight in efficacy of the separate applications. In addition to actual usage, data on users’ experiences with and evaluation of the separate applications on the intervention are gathered, using a questionnaire on T2.

**Table 6.3 Primary and secondary outcome measures used in the Sugarsquare study**

<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenting stress</td>
<td>Parenting Stress Index short form (PSI-SF)</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
</tr>
<tr>
<td>Parents’ psychosocial wellbeing</td>
<td>General Health Questionnaire (GHQ-12)</td>
</tr>
<tr>
<td>Parents’ satisfaction of quality of diabetes care</td>
<td>Patients’ Evaluation of Quality of care Diabetes (PEQ-D)</td>
</tr>
<tr>
<td>Parents’ knowledge about diabetes (care)</td>
<td>Diabetes Knowledge Test (DKT)</td>
</tr>
<tr>
<td>Parents’ treatment adherence</td>
<td>Morisky Medicine Adherence Scale (MMAS)</td>
</tr>
<tr>
<td>Parents’ confidence in diabetes self-care</td>
<td>Confidence In Diabetes Self-care questionnaire (CIDS)</td>
</tr>
<tr>
<td>Diabetes related conflicts</td>
<td>Diabetes Family Conflict Scale (DFCS)</td>
</tr>
<tr>
<td>The impact of diabetes on the family</td>
<td>Pediatric Quality of Life Inventory family impact scale (PedSQL FIS)</td>
</tr>
<tr>
<td>The child’s quality of life</td>
<td>Pediatric Quality of Life Inventory generic scale parent report (PedSQL generic)</td>
</tr>
<tr>
<td>The child’s health-related quality of life</td>
<td>Pediatric Quality of Life Inventory diabetes module parent report (PedSQL-DM)</td>
</tr>
<tr>
<td>The child’s psychosocial well-being</td>
<td>Strength and difficulties questionnaire parent report (SDQ)</td>
</tr>
</tbody>
</table>

**Table 6.4 Feasibility measures used in the Sugarsquare study**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practicability (can they use it?)</td>
<td>Percentage of users who logged in at least once</td>
</tr>
<tr>
<td></td>
<td>Inventory of difficulties logging in</td>
</tr>
<tr>
<td></td>
<td>Inventory of downtime (inaccessibility)</td>
</tr>
<tr>
<td>Acceptability (do they use it?)</td>
<td>Percentage of users who logged in at least once and used all applications</td>
</tr>
<tr>
<td></td>
<td>Duration of usage</td>
</tr>
<tr>
<td>Demand (do they continue to use it?)</td>
<td>Percentage of users who logged in repeatedly</td>
</tr>
<tr>
<td>Integration (does it fit with the treatment?)</td>
<td>Evaluation of international guidelines for diabetes care (ISPAD/IDF/ADA)</td>
</tr>
<tr>
<td></td>
<td>when using Sugarsquare</td>
</tr>
</tbody>
</table>
Other outcomes
Information on the child’s glycemic control (HbA1c) and the number of hospital admissions of 24 hours or over in case of keto-acidosis or severe hypoglycemia, throughout the entire study-period are derived from the child’s medical files (see Table 5).

Table 6.5 Other measures used in the Sugarsquare study

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical parameters</td>
<td>HbA1c</td>
</tr>
<tr>
<td></td>
<td>Hospitals admissions due to glycemic disruptions</td>
</tr>
</tbody>
</table>

Analyses

Descriptive statistics
Demographics of the research sample will be analyzed descriptively. Secondly, differences at baseline between subpopulations and clinics will be assessed by using analysis of variance (ANOVA).

Primary analysis
To compare differences between treatment and control group on our primary outcome measure on T0 and T1, analyses of covariance (ANCOVA) will be performed on T1 data, using T0 data as covariates. Effects for clinic differences will be taken into account. A sensitivity analysis will be conducted by means of a multiple imputation analysis (based, among others on HbA1c scores of the population at T1) and an analysis based on a Last Observation Carried Forward (LOCF) imputation.

Secondary analysis
Similar analyses are conducted for exploring effects on secondary outcome measures and medical parameters. Data on T2 is regarded as follow-up.

Feasibility
For feasibility, user data will be explored, by means of descriptive statistics. Association of user data with individual characteristics on baseline, change on primary and secondary outcome measures and medical parameters will be explored, using Pearson Correlations Coefficients and univariate ANOVA.
Discussion

This paper describes the protocol for a multicenter randomized controlled trial, by which the efficacy and feasibility of a web-based patient portal will be evaluated, in a population of parents of a child with T1D. The web-based patient portal, called Sugarsquare, integrates the appealing aspect of using the Internet with providing education, easy accessible contact with the diabetes team, and peer support. We hypothesize that the intervention will decrease parenting stress in parents of a child with T1D and will be feasible in the research population. Sugarsquare provides patients and healthcare professionals with an innovative and easy-accessible tool. Sugarsquare is expected to support parents in coping with and learning about diabetes through exchange of experiences and ideas with peers and to ease communication between parents and healthcare professionals. It is also expected to be feasible as it contributes to the multidisciplinary character of diabetes care by making all communication between healthcare professionals and parents visible for and accessible to all involved healthcare professionals. Combining those aspects in one intervention is an important strength of our study. A second strength of this study is that it incorporates patient participation in the development of the intervention. By exploring needs and wishes of the users and by extensive piloting of the intervention, we were able to fine-tune the intervention to users’ preferences\textsuperscript{17,52}. This will contribute to usability of the intervention and to its generalizability when implementing the intervention in daily care. A third strength of this study is the design of the feasibility assessment using domains proposed by Bowen\textsuperscript{51}. This design will enable us to link usage of different sections or applications in the intervention to change in different domains. This design is, on the other hand, also a vulnerability. A design using one arm for every section or application would make it easier to assess the separate contribution of individual sections or applications. However, a web-based patient portal such as Sugarsquare highly depends on the number of users\textsuperscript{31}. In the Netherlands, Diabetes care is organized locally, resulting in a great number of diabetes teams with relatively small populations. To get enough users in the intervention group, we could only take on two arms in the present study: 1) an experimental arm and 2) a control arm. Another vulnerability is the chance for dropout. Studies on internet-delivered interventions often suffer from high dropout rates, which can significantly interfere with finding potential efficacy of the intervention\textsuperscript{28}. To minimize interference, we took a drop-out rate of 25\% into account in the sample size calculation. However, we can still be confronted with problems regarding power in the intention-to-treat analysis.

In conclusion, a significant portion of parents of a child with T1D reported high levels of parenting stress. Disease education, easy accessible communication with the diabetes care team and peer support help in reducing stress. Although these modes of support are suitable for delivery through the Internet, effects of web-based delivery of these aspects in pediatric
diabetes care are hardly described in literature. The present study aims to contribute to the knowledge on effects of a web-based patient portal on parenting stress and its feasibility in a population of parents of a child with T1D. Depending on its efficacy and feasibility, the intervention will be attuned in light of results of the study and additionally be implemented in usual pediatric diabetes care.
References


Sugarsquare, a Web-Based Patient Portal for Parents of a Child With Type 1 Diabetes: Multicenter Randomized Controlled Feasibility Trial

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Abstract

Background
Raising a child with Type 1 Diabetes (T1D) means combining the demands of the disease management with everyday parenting, which is associated with increased levels of distress. A Web-based patient portal, Sugarsquare, was developed to support parents, by providing online parent-professional communication, online peer support and online disease information.

Objective
The first aim of this study was to assess the feasibility of conducting a multicenter, randomized controlled trial in Dutch parents of a child with T1D. The second aim was to assess the feasibility of implementing Sugarsquare in clinical practice.

Methods
The parents of 105 children (N=105) with T1D below the age of 13 participated in a 6-month multicenter randomized controlled feasibility trial. They were randomly assigned to an experimental (n=54, usual care and Sugarsquare) or a control group (n=51, usual care). Attrition rates and user statistics were gathered to evaluate feasibility of the trial and implementation. To determine potential efficacy, the parenting stress index (PSI-SF) was assessed at baseline (T0) and after 6 months (T1).

Results
Of a potential population of parents of 445 children, 189 were willing to participate (enrollment refusal=57.5%, n=256), 142 filled in the baseline questionnaire (baseline attrition rate=25%, n=47), and 105 also filled in the questionnaire at T1 (post randomization attrition rate during follow-up=26%, n=32). As such, 24% of the potential population participated. Analysis in the experimental group (n=54) revealed a total of 32 (59%) unique users, divided into 12 (38%) frequent users, 9 (28%) incidental users, and 11 (34%) low-frequent users. Of the total of 44 professionals, 34 (77%) logged in, and 32 (73%) logged in repeatedly. Analysis of the user statistics in the experimental group further showed high practicability and integration in all users, moderate acceptability and demand in parents, and high acceptability and demand in health care professionals. Baseline parenting stress index scores were related to the parents’ frequency of logging on ($\rho=.282$, $P=.03$) and page-views ($\rho=.304$, $P=.01$). No significant differences in change in parenting stress between experimental and control group were found ($F_{3,101}=.49$, $P=.49$).
Conclusions

The trial can be considered feasible, considering the average enrollment refusal rate, baseline attrition rate and postrandomization attrition rate, compared to other eHealth studies, although lower than hypothesized. Implementing Sugarsquare in clinical practice was partly feasible, given moderate demand and acceptability in parent users and lack of potential efficacy. Parents who reported higher levels of parenting stress used Sugarsquare more often than other parents, although Sugarsquare did not reduce parenting stress. These results indicate that Web-based interventions are a suitable way of providing parents of children with T1D with additional support. Future studies should determine how Sugarsquare could reduce parenting stress, for instance by adding targeted interventions. Factors potentially contributing to successful implementation are suggested.

Background

Type 1 Diabetes (T1D) is a chronic metabolic disorder with a complex daily treatment regime, requiring patients to carry out a variety of health-related self-care behaviors, such as monitoring blood glucose levels, administering insulin, adhering to a diet, and exercising. In case of young children, parents are responsible for ensuring that these disease management tasks are performed. Having to combine these complex self-management tasks with regular parenting tasks in everyday life can have a profound impact on parents, indicated by elevated levels of stress and depressive symptoms in parents of a child with T1D, especially in those with young children and with children with a more recent diagnosis. Family and parental functioning are related to well being, self-care skills, and glycemic control in children, which makes it important that diabetes teams are aware of the impact of the disease and its treatment on parents. Studies show that parents need easy access to their diabetes care team, local peer support, and tailored information about the disease and its management provided by their own diabetes team. This positively affects their quality of life and helps them adequately cope with the disease.

New technologies such as the Internet can help diabetes teams in delivering these aspects. Despite the great potential of the Internet and parents’ positive attitude toward using Internet in care, there has been little research into the efficacy and feasibility of Internet interventions for the parents of chronically ill children, especially interventions that combine multiple aspects of care. This is unfortunate, considering that chronically ill patients and their parents can benefit from using the Internet, because it facilitates the exchange of knowledge and information between patients and health care professionals. There are several challenges, when it comes to implementing and testing an
Internet intervention in a clinical research context. eHealth studies are specifically subject to low retention rates (evaluation dropout), which are often the result of study-specific factors and low adherence rates (nonintervention usage) that are mostly intervention specific. These rates can lead to a loss of participants and thus to lack of statistical power. Achieving successful recruitment is particularly problematic when multiple practices are involved, as practices often differ at an organizational level and local recruiters often have limited resources for recruitment.

**Randomized Controlled Trial**

To gain knowledge about the feasibility of conducting a randomized controlled trial (RCT) and implementing an Internet intervention in usual care for parents of a child with T1D, we developed a Web-based patient portal, called Sugarsquare. Sugarsquare was specifically developed according to parents’ needs and preferences and is hypothesized to enable diabetes teams to improve their accessibility, facilitate local peer support, and provide tailored information. An explorative, multicenter study was conducted to answer the following research questions:

1. Is conducting an RCT concerning Sugarsquare feasible in a population of parents of a child with T1D in terms of:
   - potential participants: what is the number of eligible parents?
   - Is conducting an RCT concerning Sugarsquare feasible in parents?
   - enrollment refusal rate: what is the proportion of parents who refuse participation?
   - baseline attrition rate: what is the proportion of parents who drop out before baseline?
   - follow-up attrition rate: what is the proportion of parents who drop out during the trial?

2. Is implementing of Sugarsquare in daily clinical practice feasible in a population of parents of a child with T1D in terms of:
   - practicability: are recipients able to use Sugarsquare?
   - acceptability: do recipients use Sugarsquare?
   - demand: do recipients continue to use Sugarsquare?
   - integration: is Sugarsquare consistent with international guidelines for pediatric diabetes care?
   - potential efficacy: is usage associated with change in parenting stress
Design and Setting of the Study

The participants for this study were recruited from 7 medical centers in the Netherlands, with a potential of 445 parents, from May 2012 to January 2013. Eligible participants were the parents of a child with T1D (one parent per child) younger than 13 years of age, had access to the Internet at home, and were able to comprehend the Dutch language. The children had to be treated in one of the participating centers during the entire course of the study. Participants were randomly assigned to one of two conditions: (1) an intervention condition and (2) a usual care control condition. Participants in the intervention condition had access to the intervention for 6 months in addition to care as usual. Participants in the control group received care as usual during that period. An extensive report of the offline recruitment of participants, the randomization and the procedure of the data collection is described in the Sugarsquare study protocol [31]. The study described in this study was part of a larger project [31], of which all procedures were approved by the Ethics Committees of Human Experimentation of the Radboud University Medical Center and the participating hospitals and are in accordance with the Declaration of Helsinki.

Intervention

The final version of Sugarsquare consists of a Web-based patient portal providing online parent-professional communication, peer support, and disease information. Sugarsquare was developed at parents’ explicit request and is based on a previous comparable intervention for adolescents with T1D [8,31,40]. Seven focus group interviews with parents [8,31] and a questionnaire for health care professionals affiliated to the cooperating centers were used to tailor the intervention to the preferences of both parents and health care professionals. In a series of pilots, involving parents and professionals participated, the intervention was further fine-tuned and facilitators and barriers were identified. The test phase ended when bugs were repaired and both parents and professionals felt the intervention was ready for use. In accordance with parents’ preferences, the intervention was organized locally, so that each center for diabetes care has its own secured portal, which is only accessible to health care professionals of that particular center and to the parents of the children treated at that clinic. Sugarsquare is accessible through the Internet and has the following two main sections.

Section I: General

The first section provides online peer support and disease information and is accessible to all users (parents and health care professionals). Peer support is facilitated through a chat application, a forum application, and a blog application. Disease information is provided by means of downloadable documents and Web links.

Section II: Personal

The second section is specific to individual patients and can only be accessed by the parents...
of that particular patient and their diabetes team. The section contains an overview of treatment goals and an application for easily accessible private contact between parents and health care professionals. This application is only used for nonurgent matters. The intervention has been described in the study protocol\textsuperscript{31}. In the final version of Sugarsquare, disease information is incorporated in Section I, instead of Section II as described in the study protocol. Sugarsquare is secured by means of a 2-factor authentication, requiring a username-password combination and a personalized SMS code in the login procedure. Health care professionals of the local diabetes teams were appointed as coordinators for the local recruitment of participants and the local implementation of Sugarsquare.

**Care as Usual**

All children received care as usual, according to International Guidelines for Pediatric Diabetes Care\textsuperscript{18,50}, provided by a multidisciplinary team of pediatric diabetologists, diabetes nurse practitioners, dietitians, and psychologists. Parents and children were invited to visit the outpatient center for consultations with the pediatric diabetologist and nurse practitioner 4 times a year. Dietitians and psychologists were available on request by parents, children, or physicians. The diabetes care team could be contacted during business hours by telephone and email. An emergency telephone number could be accessed outside office hours to guarantee continuous access to care. Children of participants in both conditions (experimental and control) received care as usual during the entire study period. As such, Sugarsquare was used in addition to care as usual. During the study period, the parents in the experimental group could contact the diabetes care team via the portal instead of by telephone or email in case of nonurgent matters. The telephone number for emergencies was maintained.

**Measures**

Feasibility of the RCT was assessed in terms of the number of potential participants, the proportion of parents who refused participation, and the attrition rates. Demographic data of all the participants who were included in the final analyses were gathered at baseline. For assessment of feasibility of the intervention, expressed in terms of practicability, acceptability, and demand\textsuperscript{40,51}, individual user data of all participants in the experimental group, such as frequency of logins and number of messages posted on the forum, were logged digitally. For feasibility in terms of integration, we assessed whether Sugarsquare was of added value for working according to International ISPAD (International Society for Pediatric and Adolescent Diabetes) and or IDF (International Diabetes Federation) and ADA (American Diabetes Association) Guidelines for Diabetes Care\textsuperscript{18,50}, by checking 9 key-elements for diabetes care, derived from these guidelines. For feasibility in terms of potential efficacy, parenting stress was assessed by means of the Dutch version of the parenting stress
index-short form (PSI-SF) on T0, T1, and T2. The reliability and criterion validity of the Dutch PSI-SF are shown to be good. The PSI-SF consists of 25 items answered on a 6-point Likert scale, ranging from “totally agree” to “totally disagree.” An example of an item on the PSI-SF is “it is not always easy to accept my child the way he or she is.” The sum score on the PSI-SF can be categorized into normal, subclinical, and clinical based on standardized cutoff scores described in the manual. Parenting stress was assessed at the start of the study (T0=baseline), at 6 months after the start of the study (T1), and at 12 months after the start of the study (T2=follow-up). Also, at the end of the study we asked the local Sugarsquare coordinators, who were health care professionals and part of the local diabetes teams, to evaluate the study and identify facilitators and limitations for the implementation.

Information about the child’s glycemic control (HbA1c) and the number of hospital admissions (lasting over 24 h) for keto-acidosis or severe hypoglycemia were used to explore the potential efficacy of the portal. These data were taken from the child’s medical files.

Questionnaires for demographics and parenting stress were administered by means of a Web-based, secured survey program, called Radquest, which generates a closed survey system. The registered participants received an email with a Web link to the survey, which was paired with a unique user id. All items had to be answered and participants were able to change the answers until the participant submitted the completed survey. The data generated from the survey were stored on a secured server. Some participants preferred filling in a hardcopy questionnaire, which was sent to them by post. For an elaborate overview of all measures, see Table 1.

**Analyses**

Demographic data were analyzed descriptively, and differences at baseline between the experimental group and the control group were assessed using an analysis of variance (ANOVA).

For feasibility, user data were analyzed by means of descriptive statistics. To compare differences in change in parenting stress between the experimental group and the control group, an analysis of covariance (ANCOVA) was performed on T1 data, using T0 data as covariate and the condition (experimental vs control) as fixed factor. A sensitivity analysis was conducted by means of a multiple imputation analysis (based on HbA1c scores at T1) to account for missing data. To test robustness of the results, a conservative analysis based on a Last Observation Carried Forward (LOCF) imputation was performed. Associations between user data and parenting stress at baseline were explored using Spearman ρ for nonparametric correlation due to high skewness of user data and a univariate ANOVA. Data on T2 were regarded as follow-up and were not analyzed in this study.
**Power Calculation**

We calculated that the data of 180 parents would be needed for the final analysis in order to reach a medium effect size \(d=0.50\), with a Cronbach alpha of .05 (two-tailed test) and a beta of .10\(^{31}\). On the basis of recent literature, a declination rate of 25% (\(n=80\)) and a dropout rate of 25% (\(n=60\)) was hypothesized\(^{31,34}\). As such, we would need to approach 320 parents in order to reach a minimum of 240 parents at the start of the study to have data for 180 participants in the final analysis\(^{31}\).
Results

Feasibility of the randomized controlled trial: enrollment and dropout

All the parents of children with T1D, who were treated in 1 of the 7 cooperating centers for pediatric diabetes care, were invited by mail to participate in the study. The total population consisted of the parents of 445 children. A total of 189 parents of 189 children were willing to participate. The remaining 256 potential participants refused participation (enrollment refusal rate=57.5%). Frequently mentioned reasons for not participating were a lack of time, no interest in additional care and having to temporarily increase the focus on diabetes.

A number of 142 parents filled in the baseline questionnaire. As such, 47 parents (baseline attrition rate=25%) dropped out before filling out the first questionnaire. Mentioned reasons for dropping out were a loss of interest and a lack of time. Subsequently, 105 parents also filled in the questionnaire at T1, meaning that 32 (postrandomization attrition rate during follow-up=26%) participants dropped out during the course of the study. Participants dropped out due to losing interest, a lack of time or because they changed from treatment center. As such, 23.6% (n=105) of the potential population successfully participated in the study (see also Figure 1).

Demographics

The demographic statistics of the 105 participants are displayed in Table 2. A one-way, between-group ANOVA revealed no significant differences in any of the variables at baseline between the centers.

Feasibility of the Intervention

Data from the 54 participants in the experimental group and who therefore had access to Sugarsquare were used for the feasibility analysis and for the analysis relating user data and baseline scores on questionnaires. A proportion of 59% (n=32) of the parents who had access, used Sugarsquare during the trial (Table 3). Of the 32 unique parent users, 11 (34%) logged in repeatedly, at least once every 2 weeks and 9 (28%) logged in incidentally (3 times or more, but under once every 2 weeks), and 16 (41%) logged in once or twice during the study period. Table 3 also shows that 34 (77%) of 44 professionals who had received access at the start of the study, logged in and 32 (94%) logged in again. Thus, overall, 73% (n=32) of the professionals accessed Sugarsquare more than once. All users (parents and professionals) viewed all applications at least once when they logged in. The applications for forum (#page views=2838) and contact with the treatment team (#page views=2795) were viewed more often than the applications for information (#page views=415) and chat (#page views=683). Users reported no downtime, although 2 users reported that they sometimes could not
access Sugarsquare, due to technical problems with the users’ telecom providers. Some parents (n=8) said that the two-step security procedure as a hassle. Sugarsquare attributed to provision of care according to all 9 key elements, derived from the Global IDF or ISPAD and ADA Guidelines for Diabetes care in Childhood and Adolescence (see also Multimedia Appendix II) 18,50. According to the Sugarsquare coordinators, there were 3 factors that limited implementation. These factors were the two-step login procedure, the lack of customized instructions for health care professionals and the randomization on individual level. The local Sugarsquare coordinators and the multidisciplinary approach of the team were suggested as 2 factors that positively affected implementation.

**Figure 7.1 Flowchart of Inclusion of Participants.**
Table 7.2 Demographics and baseline scores of the participants.

<table>
<thead>
<tr>
<th></th>
<th>Experimental group</th>
<th>Control group</th>
<th>Total group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>54</td>
<td>51</td>
<td>105</td>
</tr>
<tr>
<td>Gender (M/F/filled in together)</td>
<td>49/5</td>
<td>44/5/2</td>
<td>93/10/2</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>lower secondary education (n/%)</td>
<td>2 (4%)</td>
<td>4 (8%)</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>middle secondary education (n/%)</td>
<td>3 (5%)</td>
<td>4 (8%)</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>higher secondary education (n/%)</td>
<td>24 (44%)</td>
<td>19 (37%)</td>
<td>43 (41%)</td>
</tr>
<tr>
<td>middle tertiary education (n/%)</td>
<td>9 (17%)</td>
<td>2 (4%)</td>
<td>11 (11%)</td>
</tr>
<tr>
<td>higher tertiary education (n/%)</td>
<td>9 (17%)</td>
<td>19 (37%)</td>
<td>28 (27%)</td>
</tr>
<tr>
<td>academia (n/%)</td>
<td>7 (13%)</td>
<td>3 (6%)</td>
<td>10 (10%)</td>
</tr>
<tr>
<td>Child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age in years (M/SD)</td>
<td>9,1 (2,9)</td>
<td>8,9 (2,5)</td>
<td>9 (2,7)</td>
</tr>
<tr>
<td>Gender (F/M)</td>
<td>30/24</td>
<td>27/24</td>
<td>57/48</td>
</tr>
<tr>
<td>HbA1c in mmol/mol (M/SD)</td>
<td>64 (13,77)</td>
<td>62 (7,77)</td>
<td>63 (10,62)</td>
</tr>
<tr>
<td>HbAc in % (M/SD)</td>
<td>7,98 (1,17)</td>
<td>7,86 (0,71)</td>
<td>7,92 (0,97)</td>
</tr>
<tr>
<td>Insulin therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injections (n/%)</td>
<td>10 (19%)</td>
<td>15 (29%)</td>
<td>25 (24%)</td>
</tr>
<tr>
<td>Pump (n/%)</td>
<td>44 (82%)</td>
<td>36 (71%)</td>
<td>80 (76%)</td>
</tr>
</tbody>
</table>

Potential Efficacy

With regard to parenting stress, 82 (78%) parents (control and experimental condition) reported average or below average levels of parenting stress compared with Dutch healthy controls, 19 (18%) reported slightly elevated levels, and 4 (4%) reported very high levels of parenting stress (see also Table 4).

The analysis revealed no significant differences in change in parenting stress over time between the two groups ($F_{3,101}= .49, P=.49$), or between centers ($F_{3,101}= .31, P=.91$), and nor was there an interaction between groups and centers ($F_{3,101}= 1.16, P=.34$). Similar results were obtained in an ANCOVA (Table 5) without the factor center and a sensitivity analysis, conducted by means of a multiple imputation analysis. Since no change was found, a conservative analysis using LOCF was not conducted. We also found no significant differences in change over time in HbA1c levels between the experimental group and the control group ($F_{3,101}= .040, P=.84$).
Baseline Parenting Stress Levels and Portal Usage

The analysis revealed that parenting stress at baseline was significantly correlated with the frequency of logging in ($\rho=.282$, $P=.03$; Table 6) and the number of pages viewed ($\rho=.304$, $P=.02$). It seems that the greater stress parents experienced, the more parents logged in and the more pages they viewed.
Discussion

Principal Findings
This study investigated the feasibility of conducting a trial and implementing an Internet intervention in a population of parents of children with T1D, in daily clinical practice. It revealed that eHealth has the potential to create a platform for shared, daily disease management between professionals and parents. Sugarsquare seems to attract parents with relatively high stress levels. The participation rate and dropout rate in the RCT were average, compared with other trial studies and results indicated that conducting a trial concerning Sugarsquare was feasible. The implementation of Sugarsquare in clinical practice was partly feasible, given the high practicability in all users, moderate acceptability and demand in parent users, high acceptability and demand in professional users, high level of integration and lack of potential efficacy. It is interesting to note that parents reporting higher levels of parenting stress were more likely to use Sugarsquare compared with parents reporting lower levels. This is consistent with a recent study by Balkhi and colleagues [26], who reported that parents with higher stress levels more frequently visited diabetes-related online forums than did parents with lower stress levels. As no association between HbA1c and usage was found, it is assumed that general parenting stress is associated with usage and not stress related to

Table 7.4 Distribution of parenting stress index (PSI) scores for the total group.

<table>
<thead>
<tr>
<th>PSI-scores</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal stress scores</td>
<td>82 (78%)</td>
</tr>
<tr>
<td>Elevated stress scores</td>
<td>19 (18%)</td>
</tr>
<tr>
<td>High stress scores</td>
<td>4 (4%)</td>
</tr>
</tbody>
</table>

Table 7.5 Results of the ANCOVA in Parenting Stress and HbA1c

<table>
<thead>
<tr>
<th></th>
<th>Experimental</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0 M(SD)</td>
<td>T1 M(SD)</td>
</tr>
<tr>
<td>PSI</td>
<td>48.13 (19.46)</td>
<td>51.35 (22.32)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>63.74 (12.77)</td>
<td>63.06 (8.98)</td>
</tr>
</tbody>
</table>

Table 7.6 Correlations of parenting stress at baseline and frequency of log-ins and page views.

<table>
<thead>
<tr>
<th>Parenting stress (baseline)</th>
<th>#logins</th>
<th>#pageviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>ρ=.282, P=.030</td>
<td>ρ=.304, P=.019</td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER 7

medical condition of the child. However, it is quite possible that the parents who did not use Sugarsquare might do so if they have a temporary need for additional support or information, for instance if their child becomes ill, at onset of puberty or if they are planning a trip abroad. Our enrollment refusal rate (57.5%) and baseline attrition rate (25%) fell within the ranges described in the review by Karlson and Rapoff (2009), who found the refusal rates in eHealth studies to be ranging from 0% to 75% (mean 37%) and baseline attrition rates ranging from 0% to 35% (mean 4%) 53. From this perspective, the rates in this study are reasonable. Still, we expected a lower enrollment refusal rate, since the intervention was requested by parents and fitted to their preferences by means of focus group interviews. It could be that the questionnaires, which had to be filled in by the parents on several occasions, discouraged potential participants 54. It is also possible that, due to the research context, parents perceived this study as an externally driven project, which conflicted with their preference for a center-driven intervention 8 and might have negatively influenced their willingness to cooperate 55. Our study was further confronted with an average postrandomization attrition rate during follow-up (26% vs 0-54%, mean 20% in Karlson and Rapoff) 34,53. The eHealth studies are subject to low enrollment and high dropout rates. In order to resolve the issue of low enrollment, Lernmark and colleagues 56 suggested that clarity should be provided about what participants are expected to invest and about the potential added value of the study results for the individual participant, their clinic or care in general. Baxter and colleagues 57 suggested that interaction between researchers and participants is vital for keeping participants committed after they decide to participate. During the study, possibilities to improve the trial and implementation were identified. First of all, customized instructions for when and how to use Sugarsquare, would have helped them fit Sugarsquare into their daily workflow and encourage parents to use Sugarsquare 58,69,60. Also, Sugarsquare was used in a research context and randomization took place on an individual level. As such, only a part of the population in each center participated in this study. This meant that health care professionals had to work using two procedures simultaneously, making their work very complex and intensive and complicating the integration of Sugarsquare in their workflow of everyday 61,62. The research context also had a negative effect on the amount of interaction on Sugarsquare, since only a relatively small population of parents had access to the platform. Implementation would have been more successful if randomization was conducted on center level, which would have meant that a center would have used Sugarsquare for its entire population or not at all. Factors that might have contributed to the success of the trial and the implementation were also identified. The teams all appointed a team member dedicated to Sugarsquare, who coordinated local recruitment and implementation, and monitored Sugarsquare usage. This might have supported the teams in integrating the intervention in usual care, given the results of studies in the past reporting increased awareness in the team for usage of innovative interventions 44,59,62. Also, the multidisciplinary
approach of the Diabetes teams in our study might have contributed to the implementation of Sugarsquare, since literature shows that members of multidisciplinary teams are used to working toward shared, organizational goals, which makes it easier to implement changes into their workflow. Sugarsquare has a broad focus and consists of multiple, general, potentially feasible applications. These characteristics fit to the needs of the parents, as expressed in the focus groups. However, because of this broad focus, it is difficult to establish which applications (information, peer contact, contact with staff) contributed to usage and to potential effect. As such, mechanisms of change could not be identified. Future studies could apply multiple study arms to adequately assess the value of single applications, which would increase the number of participants required. Another way of identifying potential working mechanisms and the value of single applications would be to collect qualitative data. This is expected to provide more insight into both and future researchers should consider collecting qualitative data in their study. In this study, we used a generic questionnaire to assess parenting stress, considering its broad use in pediatrics and the lack of a diabetes-specific one. Although generic parenting stress measures can be helpful for assessing stressors and distress, they might not be sensitive to issues specific to the parents of children with an illness or specific disease-related issues and, as such, failed to properly assess potential change in those domains. Future studies could consider using an instrument designed for parents of a child with T1D or, in case this is lacking, an instrument for parents of pediatric patients, such as the Pediatric Inventory for Parents (PIP) or the recently validated pediatric parenting stress index (PPSI). The direct effect of the small sample size in this study is expected to be limited, since the sensitivity analyses did not show different outcomes compared with the completers analysis. However, indirectly, the limited number of participants in the local centers may have decreased the interaction on the local Sugarsquares and, with that, generalizability of the results. Future studies can avoid this by using randomization on center level. Sugarsquare can be considered as a promising tool for diabetes teams, virtually extending their diabetes center. It contributes to usual care, because it offers parents and professionals a secured, Web-based platform for parent-health care professional communication, moderated peer support, and tailored disease information. In addition, it especially attracts parents who experience higher parenting stress levels. Given the complications that arose when Sugarsquare was used together with conventional communication tools, it is recommended that Sugarsquare be used as the sole medium for regular communication between parents and diabetes team. Appointing a dedicated Sugarsquare manager and using adequate instructions for the involved professionals are also hypothesized to contribute to the integration of Sugarsquare in care as usual. In order to increase usage by parent users and to improve their acceptance of Sugarsquare in daily care, diabetes teams could continuously add new content to Sugarsquare. This is expected to keep Sugarsquare interesting and to invite parent users to post information as well. It is also
important that all team members post information, which shows parent users that Sugarsquare is accepted by the whole team. This might lower the threshold for parent users to use and accept Sugarsquare. This has been found to be workable in 9 centers for diabetes care in the Netherlands, which have implemented Sugarsquare in usual care. In a recent study on the implementation of an eHealth intervention regarding online assessment of quality of life, it was noticed that successful implementation is affected by many factors acting on different aspects of implementing an intervention. In general, they distinguish between factors on the level of the existing IT-structures (eg, usability, compatibility), organization (eg, support, expectations of management for usage), and the intervention itself (eg, easy to use, technical problems). As attrition rates as well as limited implementation are general challenges in eHealth, future studies should pay more attention to these factors. Another issue in the field of eHealth is that the financial costs of maintenance of interventions have yet to be included in systems for health care costs. The main problem that arises from this issue is the high number of interventions that are not implemented after a trial. When starting an intervention study, we advise researchers to start with a single center trial for exploration of feasibility and potential efficacy. When feasibility and potential efficacy are demonstrated, a multicenter implementation could be conducted, potentially combined with assessment of efficacy using a historic design.

Conclusions
This study concerned a generic intervention, based on parents’ preferences and needs, serving different aims, especially regarding shared disease management between parents and professionals. Our next step is to further develop the potential of Sugarsquare to serve as a platform for provision of more mechanism-focused interventions, targeted to reduce parenting stress, for instance, by providing online information or online cognitive behavior therapy. More generally, eHealth has possibilities to support monitoring of physical and psychosocial well being, facilitate peer contact, interaction between patients and health care professionals and exchange of data. Sugarsquare can serve as central portal through which these applications or interventions can be accessed.
References


Appendix II

Integration of global IDF/ISPAD guideline for diabetes in childhood and adolescence according to the International Diabetes Federation (IDF) in collaboration with the International Society for Pediatric and Adolescent Diabetes (ISPAD) and standards for diabetes care according to the American Diabetes Association (ADA) 18,25

<table>
<thead>
<tr>
<th>International Guideline and Standards for Diabetes Care</th>
<th>Does Sugarsquare contribute to treatment according to Guideline and Standard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>People with diabetes should receive medical care from a physician-coordinated team.</td>
<td>yes</td>
</tr>
<tr>
<td>Such teams may include, but are not limited to, physicians, nurse practitioners, physician’s assistants, nurses, dietitians, pharmacists, and mental health professionals with expertise and a special interest in diabetes.</td>
<td>yes</td>
</tr>
<tr>
<td>It is essential in this collaborative and integrated team approach that individuals with diabetes assume an active role in their care.</td>
<td>yes</td>
</tr>
<tr>
<td>The management plan should be formulated as a collaborative therapeutic alliance among the patient and family, the physician, and other members of the health care team.</td>
<td>yes</td>
</tr>
<tr>
<td>A variety of strategies and techniques should be used to provide adequate education and development of problem-solving skills in the various aspects of diabetes management.</td>
<td>yes</td>
</tr>
<tr>
<td>Implementation of the management plan requires that each aspect is understood and agreed to by the patient and the care providers and that the goals and treatment plan are reasonable.</td>
<td>yes</td>
</tr>
<tr>
<td>Any plan should recognize diabetes self-management education (DSME), including introduction of new therapies and technologies, on-going diabetes support and psychosocial support as an integral component of care.</td>
<td>yes</td>
</tr>
<tr>
<td>International Guideline and Standards for Diabetes Care (^{18,25})</td>
<td>Does Sugarsquare contribute to treatment according to Guideline and Standard?</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>In developing the plan, consideration should be given to the patient’s age, school or work schedule and conditions, physical activity, eating patterns, social situation and cultural factors, and presence of complications of diabetes or other medical conditions.</td>
<td>yes</td>
</tr>
<tr>
<td>The Diabetes Care team provides ambulatory and hospital care, including emergency access to advice, hospitalization, care visits and Quarterly HbA1c determination.</td>
<td>yes</td>
</tr>
</tbody>
</table>
General discussion
Our studies showed the feasibility of the implementation of a web-based intervention, Sugarsquare, in daily pediatric diabetes care. The intervention was based on adolescents’ and parents’ needs for good accessibility of the diabetes team, moderated peer support and personalized care. These needs were used as a starting point for the development of Sugarsquare, which facilitated online patient-professional interaction, online moderated peer support and online personalized disease and treatment information. The feasibility study did not provide definitive information concerning the effect of using Sugarsquare on various psychosocial domains. A possible explanation is that Sugarsquare did not clearly focus on mechanisms of change. This needs further investigation.

The studies in this thesis supported other studies, which reported that children and adolescents with Type 1 Diabetes (T1D) have more psychosocial problems than their healthy peers and that their parents have parenting stress levels that are comparable to those of parents of healthy children [1,2,3]. In many cases, health care professionals were not fully capable of making an accurate estimation of the psychosocial health of child and parents based on the information available to them. Our analyses revealed that the estimations of psychosocial problems made by healthcare professionals differed from patient-reported outcomes and parent-reported outcomes in 50% of the cases.

Our studies also described that, from the perspective of adolescents and parents, the diabetes team served as a major source of diabetes related social support. The diabetes team played an important role in the way children, adolescents and parents deal with the disease in everyday life. The adolescents with T1D and the parents of children with T1D stressed the importance of easy access to their diabetes team as well as personalized care, fitted to their individual and continuously changing circumstances. Both parents and adolescents also indicated a need for local, moderated peer support for adolescents with T1D and for parents of children with T1D.

The first version of Sugarsquare was developed for adolescents with T1D and was feasible in terms of practicability (can recipients use it?), acceptability (do recipients use it?) and integration (does it fit with guidelines for clinical practice?). Feasibility in terms of demand (do recipients continue to use it?) was found in a subgroup. Sugarsquare was related to improved quality of life in adolescents, in terms of their perceived ability to communicate about the disease with their diabetes team. The implementation in clinical practice of the second version of Sugarsquare, which was aimed at parents of children with T1D, was partly feasible. Practicability was high in all users, whereas acceptability and demand were moderate in parent users. Acceptability and demand were high in professional users. Our analyses revealed a high level of integration of Sugarsquare in usual care, since working with Sugarsquare meets the guidelines for clinical practice. Analyses also showed a lack of potential efficacy in reducing parenting stress. However, the parents with higher levels of parenting stress used Sugarsquare more often than the parents with lower levels of parenting stress.
Since psychosocial problems in patients and parents are related to deteriorated disease management, it is important to adequately monitor their psychosocial health, in order to allocate patients and parents to additional care. Moreover, monitoring psychosocial health can be considered as an intervention in itself. For instance, studies by De Wit and colleagues revealed that monitoring quality of life using patient-reported outcomes and discussing the results of the outcomes lead to an improvement in quality of life. A study by Haverman and colleagues showed that monitoring patient-reported outcomes positively affected the communication of psychosocial issues during consultations. Our studies revealed the possible added value of patient-reported outcomes and parent-reported outcomes by means of standardized questionnaires to clinical estimations of physicians and nurse practitioners, when screening for psychosocial problems in children with T1D and their parents. Despite great agreement on the importance of screening, implementing it in daily practice is still a challenge.

Besides the added value of patient and parent reported outcomes to the monitoring of psychosocial health, patients and their parents can provide valuable information contributing to the improvement of quality of care. The subsequent evaluation of Sugarsquare showed that it was feasible to implement such a web-based patient portal in usual diabetes care. It met a need in both adolescents as well as parents of children with T1D, and, as such, healthcare professionals could use a web-based patient portal as an online extension to their diabetes care clinic in daily clinical practice. Although healthcare professionals as well as their patients are often very enthusiastic beforehand about new technologies, implementing them in their usual care daily practice has proved to be difficult. An important reason for a disappointing uptake is a mismatch between the intervention and expectations of users. In our study, we specifically started the development by asking our potential participants what they missed in their provided care and what they would expect of a web-based intervention. We developed Sugarsquare with these preferences in mind. A second important reason why eHealth interventions potentially fail to be used in regular care is the fear of potential users concerning technical difficulties, malfunctions and low usability in both patient and professional users. To minimize these flaws, we tried out Sugarsquare extensively before starting the first trial. Fixes and software-updates were implemented during both trials. Although this process changed the technicalities during the trials at the back-end, it did not affect contents and applications. A third important reason why the implementation of eHealth interventions is complex is the lack of an implementation plan for the period following the trial and the unexpected cost and time of keeping the intervention in the air and software up to date. As such, we composed a small business model in which we described that the centers pay a monthly contribution for the usage of Sugarsquare. We also reserved a small amount of the research-budget to train local Sugarsquare-coordinators. Ownership of Sugarsquare was adopted by a software-company.
**Strengths and limitations**

The strengths of the studies in this thesis are the translation of the input from parents and adolescents into an Internet intervention, Sugarsquare, and the implementation of Sugarsquare in daily diabetes care. The assessment of the implementation was described in a detailed manner. The description of the different steps in the implementation process, contributed to the context in which the results of the analyses for feasibility and potential efficacy could be interpreted. This assessment also revealed the rather small research population in the trials, which is a limitation in our studies. Diabetes care in the Netherlands is quite fragmented. This meant that, in our first trial, in which we used a single center design, we had to deal with a total potential population of 120 adolescents. The second trial was performed multicenter, which was expected to lead to a much larger study population. Although this was the case in the potential population, the final number of participants in the multicenter trial was still disappointing, although in line with other studies.\(^{18,19}\)

An important strength of Sugarsquare is its generic character and the close link to daily clinical practice. This strength is, however, a limitation as well. Since we focused on implementation and feasibility, our studies did not investigate potential working mechanisms and the different applications of the intervention (patient-professional interaction, interactive treatment plan, peer support) were not tested separately on their efficacy in changing outcomes.

For assessing the main outcomes, we used the Parenting Stress Index to assess parenting stress. The lack of change in parenting stress in our study might be explained by the fact that we used a generic tool to measure parenting stress. We chose this instrument for its good psychometric properties and the opportunity for comparing the outcomes with literature concerning other illnesses. Since this instrument was not developed with disease related parenting stress in mind, it is possible that this generic instrument did not tap the specific problems that arise when parenting a child with T1D. It could be that a tool designed specifically for parents of children with diabetes or another (chronic) illness, such as the Pediatric Inventory for Parents (PIP)\(^{20}\) might reveal that disease related parenting stress is indeed elevated in our population.

**Implications for clinical practice**

Sugarsquare provides healthcare professionals with a tool that helps them support their patients with their daily disease management. Patients and parents are confronted with disease management on a 24/7 basis, whereas traditional care is generally limited to quarterly face-to-face consultations. Sugarsquare complements traditional care, since it is available 24 hours a day. Professionals can reply on a daily basis, making integrated care on daily basis available.

An important potential of Sugarsquare lies in the fact that it can be used as a central platform for bridging the gap between patient and care. Besides providing patient-patient and patient-
professional communication, Sugarsquare offers healthcare professionals the opportunity to provide applications delivering, tailoring or improving care to their patients.

**Implications for future research**

The development of Sugarsquare fits with the model for development of Internet interventions, proposed by Ritterband and colleagues. This model focuses on nine major components, which have to be taken into account when developing an Internet intervention (see also figure 8.1).

The first component suggested in the model, environment, was a very important factor in our studies. Since our intervention had to be accessible 24/7, and therefore had to fit seamlessly in the patients’ environment, the design of the intervention was based on needs and preferences of patients and parents. The intervention was further designed to be integrated in the existing healthcare system and to fit to the workflow of professionals. A peer support application was included as part of the intervention to integrate a community mode. We used quantitative and qualitative measures to investigate user characteristics (most important user characteristics, and preferences and needs), which were leading in the development of the website design and choice for support, and lead to adequate website use. We were, however, unable to achieve significant symptom improvement. Referring to the model, a possible reason for the lack of improvement is that Sugarsquare did not clearly focus on mechanisms of change. In order to fully grasp the mechanisms of change behind disease management and disease management tasks, it is worthwhile positioning them in a theoretical framework.

A useful framework for positioning the self-management tasks is the Theory of Planned Behavior (TPB), developed by Schiffter & Ajzen in 1985, and which fits the model of Ritterband and colleagues. The theory was based on the assumption that behavior performance depends on three factors. First of all, according to TPB, behavior performance depends on ones belief that the intended behavior helps to realize a desired goal (behavioral beliefs). The second factor affecting behavior performance is the acceptance of the intended behavior by that person’s social environment (normative beliefs). The third factor is ones belief that he or she can perform the intended behavior (control beliefs). Ajzen included an extra condition later on: actual behavioral control. This is the level to which one is actually capable of performing the behavior, emphasizing the importance of realistic and shared goal setting.

These conditions, described by Ajzen can be applied to disease management. In order to perform a certain action in the context of disease management, the patient has to belief that the action, for instance measuring blood glucose, will help him or her achieve a goal, which can be achieving good glycemic control. The patient also has to belief that measuring his or her blood glucose is acceptable behavior for his or her social environment (peers, parents, professionals). The adolescent who beliefs that her classmates will accept that she measures blood glucose levels in class will be more inclined to do so than the adolescent who does not.
Finally, the patient needs to believe that he or she is able to perform that action. For example, the child whose parents have always counted carbohydrates for him might have a hard time believing that he can do it himself. Patients have to feel confident that they can perform the tasks needed for adequate disease management.

Sugarsquare can affect the attitude towards the behavior of patient and parents by increasing disease knowledge through a shared online treatment plan and a platform for communication about disease management behavior. Although knowledge through education on its own is not enough to accomplish behavior change, it is widely recognized as the first step in doing so and was found to lead to better treatment adherence.\textsuperscript{25,26,27}

Another potential advantage of Sugarsquare is that it facilitates moderated peer support among patients and their parents, which can affect the normative beliefs that the intended

\textbf{Figure 8.1 Model of Internet interventions}\textsuperscript{21}
behavior is acceptable to peers (subjective norm). In contrast to studies regarding peer support in the past, which showed mixed results, recent studies revealed that moderated and targeted peer support could facilitate the exchange of practical advice that is applicable in daily diabetes management and could potentially assist in coping with the disease. It would be very interesting to investigate whether this can also be achieved by using the peer support applications on Sugarsquare.

Sugarsquare has the potential to support perceived behavioral control in patients or their parents through the possibility of closely shared monitoring of the disease management process and quick, solution-focused, positive feedback, for instance through professional-moderated text messaging, both of which have shown to improve treatment adherence.

**Figure 8.2 Theory of Planned Behavior diagram**

**Conclusions and prospects**

Our studies have contributed to the field of diabetes-related eHealth, by demonstrating the development of an Internet intervention, Sugarsquare, a web-based patient portal for online provision of patient-professional interaction, moderated peer support, facilitation of individualized disease information and the evaluation of its feasibility in pediatric diabetes care.

Our results show that it is possible to develop a web-based patient portal, based on a combination of the input from patients and parents and literature. The results from the feasibility studies showed that performing a trial using a web-based patient portal in regular care was feasible, despite a somewhat disappointing number of participants. Sugarsquare can potentially improve psychosocial health, given the improvement in quality of life in the
adolescent research population and since it attracted parents with relatively high levels of parenting stress. In order to fully address this potential, targeted interventions could be added to Sugarsquare.

As such, the potential of Sugarsquare lies in its possibilities for extension. This could ideally be done by combining an online screening tool, thereby potentially solving the challenge to increase the uptake of psychosocial screening 12, with targeted, theory-driven, online interventions. Outcomes of the screening tool can highlight potential psychosocial risks, which can subsequently be tackled by targeted online interventions. There are several good functioning online screening tools, such as the KLIK profile by Haverman and colleagues, which taps disease-specific issues 36,37. This would make Sugarsquare a central platform from which applications can be accessed for patient-professional communication, moderated peer support, disease information, monitoring and identifying psychosocial problems and targeted interventions. In order to strengthen the limited evidence concerning the effect of online interventions on diabetes-related behavior change, it is important to use a theory as a framework for the development of such an intervention. As we have shown above, the Theory of Planned Behavior could act as one.
References


27. Corace K & Garber G (2014) *When knowledge is not enough: changing behavior to change vaccination results*. Human vaccines & Immunotherapeutics 10, 2623-2624.


34. Swoboda CM, Miller CK & Wills CE (2016) *Setting Single or Multiple Goals for Diet and Physical Activity Behaviors Improves Cardiovascular Disease Risk Factors in Adults With Type 2 Diabetes: A Pragmatic Pilot Randomized Trial*. Diabetes Educator 42, 429-43.


Appendices

Summary
Samenvatting
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Summary

In this thesis we focused on improving regular diabetes care for adolescents with Type 1 Diabetes (T1D) and parents of a child with T1D. It comprised three main topics: 1) screening for psychosocial problems in adolescents with T1D and their parents, 2) needs and preferences of adolescents with T1D and parents of a child with T1D concerning their diabetes care, and 3) the development and evaluation of an Internet intervention: a web-based patient portal, Sugarsquare, aimed to provide support in management of the diabetes.

In chapter 1, the general introduction, we described the potential impact of T1D and the complex disease management on the everyday life of patients and their families. The interaction between psychosocial wellbeing and disease management was emphasized as well as the role of healthcare professionals in supporting patients and parents. The Internet is a medium that is increasingly used to facilitate and strengthen the role of health care professionals in supporting patients and parents in their daily disease management. The potential of the Internet lies in its possibilities for exchange of information, and for facilitating patient-patient and patient-professional interaction. We conclude the general introduction with our research questions and the aim of this thesis.

In chapter 2, we described our investigation of the assessment of psychosocial problems in children with T1D and their parents. We were especially interested in comparing clinical estimations regarding risks for psychosocial problems made by nurses and pediatricians with outcomes of risk assessment by standardized questionnaires. By doing so, using a cross-sectional design, we aimed to gather information about the potential additional value of using standardized questionnaires. We included 110 children with T1D (aged 4–16), their parents, and their healthcare professionals in this study. The children filled out the Strengths and Difficulties Questionnaire (SDQ) and the Pediatric Quality of Life Inventory, Diabetes Module (PedsQL-diabetes). Parents filled out the Strengths and Difficulties Questionnaire parent-report (SDQ parent-report) and the Parenting Stress Index (PSI). Independently, nurses and pediatricians filled out a short questionnaire to assess their clinical estimations of the children’s psychosocial problems and quality of life, and parents’ levels of parenting stress. Reports of children and parents were compared to clinical estimations. We discovered that children in our sample showed more psychosocial problems and lower health-related quality of life than their healthy peers. We also learned that in approximately half of the children, risk estimations by healthcare professionals and by patients and parents were in agreement. In 10% of the children, however, no psychosocial problems were present according to professionals’ estimations, although patients and parents reported psychosocial problems. In 40% of the children, psychosocial problems were present according to professionals’
estimations, although parents and patients did not report psychosocial problems. This tells us that professionals seem to tend towards overestimating psychosocial problems in their patients. Extending the assessment of psychosocial problems with routine screening on patient-reported outcomes, using validated questionnaires, could provide additional information about the psychosocial wellbeing of patients and their parents which can potentially assist in tailoring care to the needs of the individual child and parents.

Chapter 3 focuses on adolescents with type 1 diabetes. Research shows that care is most effective when it is tailored to the individual patient’s needs and wishes. In order to gain a better understanding of adolescents’ needs and wishes, we aimed to describe their experiences with coping with diabetes and with the preferred support from their diabetes team. We were also interested in their opinion about improving care by using the Internet. As such, 16 adolescents aged 13 to 19, who were diagnosed with T1D, and treated in a tertiary care diabetes center were interviewed. The interviews focused on 1) the problems adolescents encountered in their diabetes disease management, 2) whether current diabetes care addresses these problems and 3) improvement of care by implementing a web-based patient portal (yet to be developed). All interviews were recorded on audio and transcribed verbatim, and subsequently analyzed following steps of thematic content analysis. We discovered that adolescents were very much able to formulate their ideas about diabetes, diabetes disease management and diabetes care. They described to experience diabetes as an unpredictable disease, especially in stressful events. Having the disease made them feel different from their peers without diabetes. They were content with the level to which they were involved in their treatment and the way the diabetes team approaches them, although less satisfied about accessibility of physicians in case of non-urgent matters. Adolescents expected that using a web-based patient portal could improve the organization of diabetes care and accessibility of their diabetes team and facilitate peer support.

In chapter 4, we concentrated on the parents of children with T1D and their needs and preferences concerning pediatric diabetes care as well as their opinion on the potential value of using the Internet in care. Seven focus group interviews with parents of 34 children (aged 2-12) with T1D, in 7 different centers for diabetes care revealed that the provision of tailored care, disease information, peer support, and accessibility of healthcare professionals were parents’ major needs. In order to tailor care, according to the parents, diabetes teams should focus on the impact of the disease, parents’ experience, and the child’s development. They also stated that using the Internet in regular diabetes care has the potential to satisfy these needs, particularly by facilitating online patient-professional interaction and online peer support.
In *chapter 5*, we described the evaluation of the feasibility of a web-based patient portal Sugarsquare, in an adolescent population. Sugarsquare, provided online disease information, and facilitated online patient-professional communication and online peer support. A total of 62 out of 120 eligible patients participated in the evaluation. Their age ranged from 11 to 21 years (M=15.23, SD=2.00). The participants were assigned to a usual care group (n=31) or a usual care+intervention group (n=31). Feasibility was assessed in terms of acceptability (do recipients use the intervention?), demand (do recipients continue to use the intervention?), practicability (can recipients access the intervention?), integration (does the intervention fit with guidelines for pediatric diabetes care?), and efficacy (what is the effect on adolescents’ self efficacy?). The study revealed that implementing Sugarsquare was acceptable (65% of the adolescents logged in at least once and 52% repeatedly). Usage resulted in 5795 page-views, 3580 chat-messages, 427 forum-messages, and in 40 private interactions between 11 adolescents (35%) and professionals. Assessment of practicability revealed that all 13 professionals (100%) accessed the intervention. Slow processing speed and security procedures formed obstacles for usage. Assessment of integration showed that international standards for diabetes care (International Diabetes Federation/International Society for Pediatric and Adolescent Diabetes/American Diabetes Association) were met. Assessment of efficacy revealed improvement in the intervention group in evaluation of care (Patients’ Evaluation of Quality of Diabetes), $F(1,30)=5.35$, $p<0.05$, and quality of life in terms of communication with health care professional (PedsQL), $F(1,30)=11.65$, $p<0.05$. The latter was correlated with posted chat-messages ($r=0.42$, $p<0.05$). No between-group differences were found. We concluded that Sugarsquare is feasible in adolescents with T1D. It meets a demand in adolescents and can support professionals when organizing 24/7 care according to international standards. Results are promising and next steps are a full-scale randomized controlled trial and subsequent implementation in daily care.

In *chapter 6* and *chapter 7* we focused on parents. First, in *chapter 6*, we described the development of a web-based patient portal and the protocol for the evaluation of its feasibility and potential efficacy in a population of parents of a child with T1D. In the previous studies we learned that T1D and the complicated disease management has a profound impact in everyday life. Tailored disease information, easy accessible communication with healthcare professionals and peer support can help adolescents with T1D and parents of a child with T1D adequately cope with the disease in everyday life. Given the positive view of adolescents and parents on using the Internet in regular pediatric diabetes care, we transformed the web-based patient portal for adolescents to a portal for parents of children with T1D. This portal provided online disease information, and facilitated online parent-professional communication and online peer support. We hypothesized that Sugarsquare would be feasible in a population of parents of a child with T1D. We also hypothesized that using Sugarsquare would decrease parenting stress in parents of a child with T1D.
In chapter 7, we described the evaluation of Sugarsquare, in a population of parents of a child with T1D, providing online parent-professional communication, online peer support and online disease information. The first aim of this study was to evaluate whether it was feasible to conduct a multicenter, randomized controlled trial. Feasibility of the trial was assessed in terms of potential participants (what is the number of eligible parents?), enrollment refusal rate (what is the proportion of parents who refuse participation?), baseline attrition rate (what is the proportion of parents who drop out before baseline?), and follow-up attrition rate (what is the proportion of parents who drop out during the trial?). The second aim was to evaluate whether it was feasible to implement Sugarsquare in clinical practice. Feasibility of the implementation was assessed in terms of practicability (are recipients able to use Sugarsquare?), acceptability (do recipients use Sugarsquare?), demand (do recipients continue to use Sugarsquare?), integration (is Sugarsquare consistent with international guidelines for pediatric diabetes care?) and potential efficacy (is usage associated with change in parenting stress?). In order to determine the feasibility of the trial and implementation, a 6-month trial was conducted. Participants were randomly assigned to an experimental (usual care and Sugarsquare) or a control group (usual care). The parenting stress index (PSI-SF) was assessed at baseline (T0) and after 6 months (T1). Of a potential population of parents of 445 children, 189 were willing to participate (enrollment refusal=57.5%, n=256), 142 filled in the baseline questionnaire (baseline attrition rate=25%, n=47), and 105 also filled in the questionnaire at T1 (post randomization attrition rate during follow-up=26%, n=32). As such, 24% of the potential population participated. Analysis in the experimental group (n=54) revealed a total of 32 (59%) unique users, divided into 12 (38%) frequent users, 9 (28%) incidental users, and 11 (34%) low-frequent users. Of the total of 44 professionals, 34 (77%) logged in, and 32 (73%) logged in repeatedly. Analysis of the user statistics in the experimental group further showed high practicability and integration in all users, moderate acceptability and demand in parents, and high acceptability and demand in health care professionals. Baseline parenting stress index scores were related to the parents’ frequency of logging on (ρ=.282, P=.03) and page-views (ρ=.304, P=.01). No significant differences in change in parenting stress between experimental and control group were found (F3,101=.49, P=.49). As such, the trial can be considered feasible, considering the average enrollment refusal rate, baseline attrition rate and post randomization attrition rate, compared to other eHealth studies, although higher than hypothesized. Implementing Sugarsquare in clinical practice was partly feasible, given the moderate demand and acceptability in parent users and lack of potential efficacy. We can also conclude that parents who reported higher levels of parenting stress used Sugarsquare more often than other parents, although Sugarsquare did not reduce parenting stress. These results indicate that Sugarsquare can be used to provide parents of children with T1D with additional support.
In Chapter 8, the general discussion, we presented the implications of our study-results from a clinical and research perspective. Our studies have contributed to the field of diabetes-related eHealth, by demonstrating the feasibility of the implementation of an Internet intervention, Sugarsquare, a web-based patient portal. Sugarsquare provided online patient-professional interaction, individualized disease information and moderated peer support, with the potential to improve psychosocial wellbeing. The strengths of the studies in this thesis are the translation of the input from parents and adolescents into an Internet intervention, Sugarsquare. Another strength was the implementation of Sugarsquare in daily diabetes care and the detailed description of the different steps in the implementation process, which contributed to the context in which the results of the analyses for feasibility and potential efficacy could be interpreted. An important strength of Sugarsquare is its generic character and the close link to daily clinical practice. This strength is, however, a limitation as well. Since we focused on implementation and feasibility, our studies did not investigate potential working mechanisms and the different applications of the intervention (patient-professional interaction, interactive treatment plan, peer support) were not tested separately on their efficacy in changing outcomes. Other limitations were the rather small research population in the trials, and the usage of a generic tool to measure parenting stress. We made some suggestions to further develop the potential of Sugarsquare by adding targeted interventions to Sugarsquare focussing on the mechanisms of change behind disease management and disease management tasks. One way of doing so, is by positioning the disease management tasks in a theoretical framework, such as the Theory of Planned Behavior (TPB). The TPB assumes that behavior performance depends on one’s belief that the intended behavior helps to realize a desired goal (behavioral beliefs), the acceptance of the intended behavior by one’s social environment (normative beliefs), one’s belief that he or she can perform the intended behavior (control beliefs), and one’s capability of performing the intended behavior (actual behavioral control). Adequate allocation of patients or their parents to such theory-driven, targeted interventions, depends on good monitoring of psychosocial problems. Our studies revealed the added value of patient-reported and parent-reported outcomes, assessed using standardized questionnaires to the clinical estimations of physicians and nurse-practitioners, when screening for psychosocial problems in children with T1D and their parents. There are several good functioning screening tools consisting of standardized questionnaires, such as the KLIK profile by Haverman and colleagues, which taps diseasespecific issues and can be used online. Sugarsquare offers the possibility to combine theory-driven, targeted interventions with psychosocial screening online. Outcomes of the

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1 See also the work by Ritterband and colleagues (2009) and Hanlon (2017).
2 See also the work by Schifter & Ajzen (1985) and Ajzen (2006)
3 Haverman, Engelen, van Rossum, Heymans & Grootenhuis (2011)
screening tool can highlight potential psychosocial risks, which can subsequently be tackled by targeted online interventions. This would make Sugarsquare a central platform, based on both theory and patient preferences, from which applications for peer-support, patient-professional communication, monitoring and identifying psychosocial problems and targeted interventions can be accessed, bridging the gap between patients and care.
Samenvatting

In deze thesis hebben we ons gericht op het verbeteren van reguliere diabeteszorg aan adolescenten met Type 1 Diabetes (T1D) en ouders van kinderen met T1D. De onderzoeken in deze thesis bestonden uit drie hoofdonderwerpen: 1) de screening van psychosociale problemen in adolescenten met T1D en hun ouders, 2) de beschrijving van wensen en voorkeuren van adolescenten met T1D en ouders van een kind met T1D betreffende hun diabetes zorg en 3) de ontwikkeling en evaluatie van een Internet interventie: een web-based patiënten portaal, Suikerplein, gericht op het faciliteren van steun in de diabetes management.

In hoofdstuk 1, de algemene introductie, beschreven we de potentiele impact van T1D en de complexe ziektemanagement op het alledaagse leven van patiënten en hun gezin. De interactie tussen het psychosociaal welbevinden van kinderen, jongeren en hun ouders en de ziektemanagement werd benadrukt evenals de rol van gezondheidszorgprofessionals in de steun aan patiënten en ouders. Het internet is een medium dat steeds meer wordt gebruikt om de rol van de gezondheidszorgprofessionals in de ondersteuning van patiënten en hun ouders in het dagelijkse ziektemanagement te faciliteren en versterken. Het potentieel van het Internet vormen de mogelijkheden voor het uitwisselen van informatie en het faciliteren van patiënt-patiënt en patiënt-professional interactie. We sloten onze algemene introductie af met onze onderzoeksvragen en het doel van deze thesis.

In hoofdstuk 2 beschreven we onze studie naar de inschatting van psychosociale problemen bij kinderen met T1D en hun ouders. We waren met name geïnteresseerd in de vergelijking van de klinische inschatting van het risico op psychosociale problemen door verpleegkundigen en artsen met de uitkomsten van risicobepaling door middel van gestandaardiseerde vragenlijsten. Met deze studie, waarin we een cross-sectioneel design gebruikten, trachten we de potentiële toegevoegde waarde van gestandaardiseerde vragenlijsten te bepalen. We includeerden 110 kinderen met T1D (in de leeftijd van 4-16 jaar), hun ouders en hun gezondheidszorgprofessionals. De kinderen vulden de Strengths and Difficulties Questionnaire (SDQ) en de Pediatric Quality of Life Inventory, Diabetes Module (PedsQL-diabetes) in. De ouders vulden de Strengths and Difficulties Questionnaire parent-report (SDQ parent-report) en de Nijmeegse Opvoedings Stress Index Kort (NOSIK/PSI-SF) in. Onafhankelijk daarvan vulden verpleegkundigen en artsen een korte vragenlijst in, waarin zij bevraagd werden naar hun klinische inschatting van de psychosociale problemen en kwaliteit van leven van de kinderen en de opvoedingsstress van hun ouders. De uitkomsten van de vragenlijsten werden vergeleken met de klinische inschatting. We vonden dat kinderen in onze onderzoekspopulatie meer psychosociale problemen en een
lagere gezondheid-gerelateerde kwaliteit van leven rapporteerden dan hun leeftijdgenoten zonder T1D. We ontdekten ook dat voor wat betreft de helft van de kinderen, de inschatting van artsen en verpleegkundigen overeenkwam met de zelfrapportage met behulp van gestandaardiseerde vragenlijsten. Bij 10% van de kinderen, daarentegen, kwamen volgens artsen en verpleegkundigen geen psychosociale problemen voor, hoewel patiënten en hun ouders die niet rapporteerden. Bij 40% van de kinderen, kwamen volgens artsen en verpleegkundigen psychosociale problemen voor, hoewel patiënten en hun ouders die niet rapporteerden. Blijkbaar neigden gezondheidszorg professionals naar overschatten van psychosociale problemen bij hun patiënten. De inschatting van psychosociale problemen met behulp van screening van door patiënt gerapporteerde outcomes, gebruikmakend van gevalideerde vragenlijsten, kan aan gezondheidszorgprofessionals aanvullende informatie bieden over de psychosociale gezondheid van patiënten en hun ouders wat in potentie kan helpen om zorg af te stemmen op behoeften het individuele kind en ouders.

In hoofdstuk 3 richtten we ons op adolescenten met T1D. Onderzoek laat zien dat zorg het meest effectief is wanneer het wordt afgestemd op de wensen en behoeften van de individuele patiënt. Om meer inzicht te krijgen in de wensen en behoeften van adolescenten, beschreven we hun ervaringen met het omgaan met diabetes en de steun van hun behandelteam en hun mening over verbetering van hun diabeteszorg door gebruik te maken van het Internet. Om die redenen interviewden we 16 adolescenten met T1D in de leeftijd van 13 tot 19, die werden behandeld in een tertiair gespecialiseerd diabetes behandelcentrum. De interviews richtten zich op 1) problemen die adolescenten ondervonden in hun diabetes management, 2) de mate waarin binnen de huidige diabetes zorg aandacht was voor deze problemen, 3) verbetering van zorg door implementatie van een (nog te ontwikkelen) web-based patiëntenportaal. Alle interviews werden opgenomen op audio recorders en verbatim beschreven en daarna geanalyseerd volgens stappen van de thematic content analysis. We ontdekten dat adolescenten zeer wel in staat waren om hun ideeën over diabetes, diabetesmanagement en diabeteszorg onder woorden te brengen. Zij omschreven hun diabetes als een erg onvoorspelbare ziekte, vooral in stressvolle situaties. Het feit dat zij de ziekte hebben, maakte dat zij zich anders voelden dan hun leeftijdsgenoten zonder diabetes. Ze waren tevreden over de mate waarin ze betrokken werden in hun behandeling en de wijze waarop het diabetes team hen benaderde. Ze waren echter minder tevreden over de bereikbaarheid van hun arts in geval van niet-urgente zaken. Adolescenten verwachtten dat gebruik van een web-based patiëntenportaal de organisatie van de zorg kan verbeteren, evenals de bereikbaarheid van hun diabetes team en dat het lotgenotencontact kan faciliteren.

In hoofdstuk 4 concentreren we ons op de ouders van kinderen met T1D en hun wensen en behoeften betreffende pediatrische diabeteszorg evenals hun mening over de potentiële
waarde van gebruik van het Internet in de zorg. Zeven focus groep interviews werden gehouden, waaraan de ouders deelnamen van 34 kinderen met T1D in de leeftijd van 2-12 jaar. Uit de data van de focus groep interviews, die werden gehouden in zeven verschillende behandelcentra voor diabeteszorg, kon worden opgemaakt dat zorg op maat, informatie over de ziekte, lotgenotencontact en bereikbaarheid van gezondheidszorgprofessionals de belangrijkste behoeften waren van ouders. Om zorg op maat te leveren, zouden de diabetes teams, volgens ouders, moeten afstemmen op de impact van de ziekte, de ervaring van ouders en de ontwikkeling van het kind. Zij gaven ook aan dat gebruik van het Internet in de reguliere diabeteszorg deze behoeften in potentie kan vervullen, met name door het faciliteren van online patiënt-professional interactie en online lotgenotencontact.

In hoofdstuk 5 beschreven we de evaluatie van de haalbaarheidsstudie van een web-based patiënten portaal, Suikerplein, in een populatie van adolescenten met T1D. Suikerplein voorzag in online informatie over de ziekte en faciliteerde online communicatie tussen patiënt en gezondheidszorgprofessional en online lotgenotencontact. In totaal namen 62 van de 120 patiënten die in aanmerking kwamen deel aan de evaluatie. De leeftijd van de deelnemers varieerde van 11 tot 21 jaar (M=15.23, SD=2.00). De deelnemers werden ingedeeld in een usual care groep (n=31) of een usual care+interventie groep (n=31). Haalbaarheid werd beoordeeld in termen van acceptatie (gebruiken participanten de interventie?), vraag (blijven participanten de interventie gebruiken?), integratie (past Suikerplein binnen de richtlijnen voor pediatrische diabetes zorg?), en preliminair effect (wat is het effect op self-efficacy van adolescenten?). De studie onthulde dat Suikerplein werd geaccepteerd (65% van de adolescenten logde ten minste een keer in en 52% logde herhaaldelijk in). Gebruik resulteerde in 5795 page-views, 3580 chat-berichten, 427 forum-berichten en 40 afgeschermd interacties tussen 11 adolescenten (35%) en professionals. Onderzoek liet verder zien dat alle 13 gezondheidszorgprofessionals (100%) de interventie gebruikten. Een lage verwerkingssnelheid en de veiligheidsprocedures van Suikerplein vormden obstakels voor gebruik. Onderzoek naar integratie liet zien dat aan internationale standaarden voor diabeteszorg (International Diabetes Federation/International Society for Pediatric and Adolescent Diabetes/American Diabetes Association) werd voldaan. Onderzoek naar preliminair effect onthulde een verbetering in de interventiegroep voor wat betreft evaluatie van de zorg (gemeten met de PEQ-D), F(1,30)=5.35, p<0.05, en kwaliteit van leven in termen van communicatie met gezondheidszorgprofessionals (gemeten met de PedsQL), F(1,30)=11.65, p<0.05. De laatste was eveneens gecorreleerd met geplaatste chat-berichten (r=0.42, p<0.05). Er werden geen verschillen gevonden tussen groepen. We concludeerden dat gebruik van Suikerplein haalbaar was in de populatie van adolescenten met T1D. Het voorzag in een vraag van adolescenten en kon professionals ondersteunen in het organiseren van 24/7 zorg volgens internationale richtlijnen. Resultaten waren veelbelovend en als volgende stappen
werden genoemd het ondernemen van een volledige gerandomiseerde gecontroleerde trial en aansluitend een implementatie in de reguliere dagelijkse diabetes zorg.

In hoofdstuk 6 en hoofdstuk 7, hebben we ons gericht op ouders van kinderen met T1D. In hoofdstuk 6 beschreven we de ontwikkeling van een web-based patiënten portaal en het protocol voor de haalbaarheidsstudie en de evaluatie van potentiele effect in een populatie van ouders van een kind met T1D. In de voorgaande studies leerden we dat T1D en de complexe ziektemanagement een grote impact op het leven van alledag kan hebben. Informatie over diabetes op maat, toegankelijke communicatie met gezondheidszorgprofessionals en lotgenotencontact kunnen adolescenten met T1D en ouders van een kind met T1D mogelijk helpen om in het alledaags leven op een adequate manier met de ziekte om te gaan. Aangezien adolescenten en ouders positief stonden ten aanzien van het gebruik van Internet in reguliere pediatrische diabeteszorg, transformeerden we het web-based patiënten portaal voor adolescenten in een portaal voor ouders van kinderen met T1D. Dit portaal bood online informatie over diabetes en faciliteerde online ouder-professional communicatie en online lotgenotencontact. We veronderstelden dat gebruik van Suikerplein in een populatie van ouders van een kind met T1D haalbaar zou zijn. We veronderstelden eveneens dat gebruik van Suikerplein een afname in opvoedingsstress zou teweegbrengen.

In hoofdstuk 7 beschreven we de evaluatie van Suikerplein in een populatie van ouders van een kind met T1D. Suikerplein voorzag in online informatie over diabetes, online ouder-professional communicatie en online lotgenotencontact. Het eerste doel van deze studie was evalueren of het haalbaar was om een gerandomiseerde, gecontroleerde trial uit te voeren in meerdere centra. Haalbaarheid werd beoordeeld in termen van potentiele participaten (wat is het aantal ouders dat in aanmerking komt om te participeren?), weigerpercentage (wat is het percentage ouders dat niet wil meedoen?), uitvalpercentage op baseline (wat is het percentage ouders dat uitvalt voor baseline?), en uitvalpercentage bij follow-up (wat is het percentage ouders dat uitvalt tijdens de trial?). Het tweede doel was het evalueren of het haalbaar was om Suikerplein te implementeren in de reguliere pediatrische diabetes zorg. Haalbaarheid werd beoordeeld in termen van uitvoerbaarheid (zijn gebruikers in staat om Suikerplein te bereiken?), acceptatie (gebruiken participaten de interventie?), vraag (blijven participanten de interventie gebruiken?), integratie (past Suikerplein binnen de richtlijnen voor pediatrische diabetes zorg?), en preliminair effect (wat is het effect op opvoedingsstress bij ouders). Om de haalbaarheid van de trial en de implementatie te toetsen werd een trial van 6 maanden uitgevoerd. Participanten werden ad random toegewezen tot een experimentele groep (reguliere zorg + Suikerplein) of een controle groep (reguliere zorg). De NOSIK (Nijmeegse Opvoedings Stress Index Kort) werd afgenomen op baseline (T0) en na 6 maanden (T1). Van een potentiele populatie aan deelnemers van ouders van 445 kinderen,
waren ouders van 189 kinderen bereid deel te nemen (weigeringspercentage=57.5%, n=256). Van hen vulden de ouders van 142 kinderen de baseline vragenlijst in (baseline uitval percentage=25%, n=47), en 105 vulden ook de vragenlijst op T1 in (uitvalpercentage bij follow-up=26%, n=32). Uiteindelijk nam 24% van de potentiele populatie deel. Analyse van de data uit de experimentele groep (n=54) liet zien dat er 32 (59%) unieke gebruikers waren, die konden worden ingedeeld in 12 (38%) frequente gebruikers, 9 (28%) incidentele gebruikers en 11 (34%) laagfrequentie gebruikers. Van de in totaal 44 professionals, logden er 34 (77%) eenmalig in en 32 (73%) herhaaldelijk. De analyse van de gebruikersstatistieken in de experimentele groep lieten verder een hoge mate van uitvoerbaarheid en integratie zien in alle gebruikers, matige acceptatie en vraag in ouders en hoge acceptatie en vraag in gezondheidszorgprofessionals. Opvoedingsstressscores op baseline waren gecorreleerd aan de frequentie waarmee ouders inlogden ($\rho=.282$, $P=.03$) een page-views ($\rho=.304$, $P=.01$). Er werden geen significante verschillen gevonden in verandering in opvoedingsstress tussen de experimentele en controle groep (F3,101=.49, $P=.49$). Kortom, de trial kan worden beschouwd als haalbaar, aangezien het weigeringspercentage, baseline uitval percentage en de follow-up uitvalpercentage, vergeleken met andere eHealth studies gemiddeld te noemen, hoewel wat hoger dan verwacht. Implementatie van Suikerplein in reguliere diabetes zorg was gedeeltelijk haalbaar gebleken, gezien de matige vraag en acceptatie bij de ouders en gebrek aan potentieel effect. We concludeerden verder dat ouders die hogere niveaus van opvoedingsstress rapporteerden, Suikerplein meer gebruikten dan andere ouders, hoewel Suikerplein de opvoedingsstress niet reduceerde. Deze resultaten wijzen erop dat Suikerplein kan worden gebruikt om aanvullende steun te faciliteren voor ouders van kinderen met T1D.

In hoofdstuk 8, de algemene discussie, presenteerden we de implicaties van onze studieresultaten vanuit een klinisch en onderzoeksperspectief. Onze studies hebben bijgedragen aan het veld van diabetes gerelateerde eHealth, door het demonstreren van de haalbaarheid van de implementatie van een Internet interventie, Suikerplein, een web-based patientenportaal. Suikerplein voorzag in online interactie tussen patiënt en gezondheidszorgprofessional, geïndividualiseerde informatie over diabetes en gemedierd lotgenotencontact, met het potentieel om psychosociaal welbevinden te verbeteren. Een sterk punt van de studies in deze thesis was de vertaling van de input van ouders en adolescenten naar een Internet interventie, Suikerplein. Een ander sterk punt was de implementatie van Suikerplein in dagelijkse diabetes zorg en de gedetailleerde beschrijving van de verschillende stappen in het implementatieproces, wat bijdroeg aan de context in welke de resultaten van de analyses voor haalbaarheid en potentieel effect vonden worden geïnterpreteerd. Een ander belangrijk sterk punt van Suikerplein was haar generieke karakter en de directe link met de dagelijkse praktijk. Dit punt was echter ook een beperking. Omdat we hebben gefocust op implementatie en haalbaarheid, hebben we geen onderzoek gedaan
naar de potentiele werkingsmechanismen en het effect van de verschillende applicaties van de interventie (interactie tussen patiënt en gezondheidszorgprofessional) op verandering in uitkomsten. Andere beperkingen waren de relatief kleine onderzoekspopulaties in de trials en het gebruik van een generiek instrument om opvoedingsstress te toetsen. We hebben enkele suggesties gedaan om het potentieel van Suikerplein door te ontwikkelen, door middel van het toepassen van gerichte interventies aan Suikerplein die focussen op de mechanismen voor verandering achter de ziektemanagement en ziektemanagement taken. Een manier om dit te doen, is door de ziektemanagement taken in een theoretisch raamwerk te plaatsen zoals de Theory of Planned Behavior (TPB). Binnen de TPB wordt aangenomen dat vertonen van gedrag afhangt van het geloof dat het betreffende gedrag bijdraagt aan het behalen van een doel (behavioral belief), acceptatie van het gedrag door de sociale omgeving (normative beliefs), de overtuiging dat het mogelijk is om het gedrag te vertonen (control beliefs), en de mate waarin iemand in staat is om het gedrag te vertonen (actual behavioral control). Adequate verwijzing van patiënten of hun ouders naar dergelijke op theorie gebaseerde, gerichte interventies, hangt af van goede monitoring van psychosociale problemen. Onze studies lieten de aanvullende waarde zien van zelfrapportage door patiënt en ouders, met behulp van gestandaardiseerde vragenlijsten, op de klinische inschatting van artsen en verpleegkundigen, bij het screenen naar psychosociale problemen in kinderen met T1D en hun ouders. Er zijn verschillende goed functionerende screeningtools, die bestaan uit gestandaardiseerde vragenlijsten, zoals het KLIK profiel door Haverman en collega’s, die ziektespecifieke onderwerpen behandelt, en die online kan worden gebruikt. Suikerplein biedt de mogelijkheid om op theorie gebaseerde, gerichte interventies te combineren met online screening naar psychosociale problemen. Uitkomsten van de screeningtool kunnen potentiele psychosociale risico’s aan het licht brengen, die kunnen worden aangepakt door de gerichte online interventies. Dit zou van Suikerplein een centraal platform maken, gebaseerd op zowel theorie als voorkeuren van patiënten, van waaruit applicaties voor interactie tussen patiënt en gezondheidszorgprofessional, lotgenotencontact en identificatie van psychosociale problemen en gerichte interventies kunnen worden benaderd en waarmee het gat tussen patiënt en zorg wordt verkleind.

1 Zie ook het werk van Ritterband en collega’s (2009) en Hanlon (2017)
3 Haverman, Engelen, van Rossum, Heymans & Grootenhuis (2011)
Dankwoord

Ik begin dit hoofdstuk van mijn proefschrift met een dankwoord alle kinderen, jongeren en hun ouders die de inspiratie vormden voor de onderzoeken in dit proefschrift. Het inzicht dat zij verschaften is het fundament waarop dit proefschrift staat. Met de resultaten die ik beschreef, hoop ik bij te dragen aan de kennis van de nog vaak onderschatte psychosociale aspecten die een rol spelen bij het hebben van diabetes type 1. De toekomst zal uitwijzen of deze kennis terug te zien zal zijn in de diabeteszorg van alledag.

Een andere bron van kennis en inspiratie vormen mijn (co)promotoren. Beste Chris, bedankt voor je geduld en geloof in mij, zelfs op de voor veel promovendi bekende momenten van zelftwijfel. Ik heb veel inspiratie gehaald uit de wijze waarop jij je klinische werk en onderzoek op hoog niveau combineert. Je was voor mij de juiste begeleider op het juiste moment. Beste Kees, bedankt voor de support in de afgelopen jaren. Ik waardeer je humor en tomeloze energie waarmee je onze overleggen kleurde. Bedankt voor de nodige ontspanning en de biertjes in Buenos Aires en Toronto! De wijze waarop jij het overzicht over onze projecten behield, Judith, was van grote waarde. Waar wij, in ons enthousiasme, soms te snel wilden gaan, liet je ons reflecteren over mogelijke obstakels en tidspaden. Dit heeft de kwaliteit van de onderzoeken en dit proefschrift verbeterd. Beste Nienke, jouw kennis over de (psychosociale) wereld van de diabetes is goud waard geweest. Ik waardeer je toewijding voor je werk en je passie voor het vak. Het perspectief dat jij bracht, vulde aan op wat wij reeds vormden.

Verder bedank ik professor Jan Kremer voor zijn inspiratie en aanwijzingen in de start van mijn promotietraject. Hans Markx bedank ik voor zijn begeleiding in de analyses van mijn kwantitatieve data en Rogier Donders voor zijn begeleiding in de analyses van de kwantitatieve data. Ik bedank Wouter Tuil voor de samenwerking in de ontwikkeling van Suikerplein. Tom en Tessa: bedankt voor de dappere gezamenlijke pogingen om eHealth-onderzoek naar een hoger niveau te tillen. Beste mensen van Buur: bedankt voor de werkplek, de broodnodige cafeïne en ontspannende momenten.

Beste kamergenootjes door de jaren heen: Sanne, Annemiek, Jose, Simone, Marloes, Eelke, Kim, Sylvia, Maaike, Judith & Kaya bedankt voor jullie gezelschap, (h)erkenning, steun, (herhaalde) peptalks en wandelingen door het park. De afgelopen jaren waren uitdagend en leuk en soms saai, langdradig en eentonig. Jullie voegden daar inspirerend aan toe. Ik weet waar, ik weet wanneer: Ik zal er zijn!

Beste Hetty en Jan, bedankt voor de ruimte die jullie mij gaven mijn proefschrift af te ronden. Bedankt ook voor de kans om datgene waar ik de afgelopen jaren over gedacht, gelezen en
geschreven heb, nu zelf te mogen doen. Beste Fleur, Evelien, Giesje, Minke en Yvonne, dank voor de samenwerking in de afgelopen jaren. Onze gezamenlijke pogingen de psychosociale diabeteszorg international op een hoger plan te tillen en lokaal een plaats te geven binnen de reguliere geestelijke gezondheidszorg zal slagen, daar ben ik van overtuigd. Aan jullie kwaliteit, betrokkenheid en doorzettingsvermogen zal het niet liggen!

Lieve pap en mam, bedankt voor jullie steun. Dankzij jullie heb ik me de afgelopen jaren in kunnen zetten voor mijn vak. Jullie hebben er altijd voor gezorgd dat ik de keuzes kon maken die ik wilde maken. Jullie hebben er altijd voor gezorgd dat er een weg terug was, als dat (weer eens) een keer niet de juiste keuze was. Van jullie heb ik geleerd door te zetten en na vallen weer op te staan. Zonder dat alles was dit mij nooit gelukt.

Lieve Marjo, Kitty, Benjamin, Ties en Julia, bedankt voor jullie blijvende interesse. Ik kan me voorstellen dat wat ik doe bij tijd en wijle vaag, zweverig, saai, ingewikkeld en langdradig was. Jullie bleven vragen hoe het ervoor stond en of het al wat op schoot. Hoewel ik daar soms ook geen antwoord op kon geven, was het erg fijn om te merken dat jullie aan me dachten. Ik hoop dat het nu wat duidelijker is wat ik de afgelopen jaren heb gedaan. Bedankt dat jullie daar samen met mij bij stil willen staan.

Lieve vriendjes en vriendinnetjes, Nikolai, Sanne, Marc, Albert, Maggie, Wes, Anissa, Maarten en Marlies, bedankt voor jullie steun en begrip als ik weer eens niet mee ging naar een concert of festival en mijn saaie werk voor liet gaan. Bedankt ook voor jullie interesse, ook al was het soms ver van jullie bed. Bedankt voor het aanhoren van mijn geklaag als het weer eens niet opschoot. Bedankt vooral voor de steun in de afgelopen paar maanden waarin de laatste loodjes duidelijk het zwaarst bleken. Zonder jullie was ik nu niet zo ver…

En aan het einde van de dag zijn jullie er altijd: Marieke, Sam en Luka.

Sam en Luka, jullie onvoorwaardelijke liefde heeft me de afgelopen jaren geïnspireerd en gemotiveerd om het beste uit mezelf te halen. Ik verwonder me elke dag om jullie onnavolgbare humor, streken en fantasie. Bedankt, lieverds, voor het o-zo hartelijke ontvangst na elke lange dag.

Lieve Marieke, van alle bedankjes blijkt deze het moeilijkst in woorden uit te drukken. Achter elke succesvolle man staat een sterke vrouw. Ik houd niet van clichés, maar deze is zeker waar. Bedankt voor je begrip, steun en wijze raad. Deze is ook een beetje van jou…
List of publications

Published original articles


Published abstracts


Boogerd EA, Verhaak CM & Noordam K (2010) *Digital Sugarsquare leads to better appreciation of care and better communication between caregiver and adolescent with diabetes.* *Pediatric Diabetes* 11 (suppl s14).


Curriculum Vitae


In 2008 startte Emiel het onderzoeksproject Suikerplein, gericht op eHealth voor jongeren met Type 1 Diabetes, bij de afdeling Medische Psychologie van het Radboudumc. In 2012 werd het project uitgebreid naar ouders van kinderen met Type 1 Diabetes. In de periode van 2007 tot 2011 was Emiel als universitair docent verbonden aan de opleiding Pedagogische wetenschappen en onderwijskunde van de Radboud Universiteit. Vervolgens was hij van 2011 tot 2012 bij het Radboudumc als psycholoog werkzaam binnen binnen de fertiliteitszorg. Van 2012 tot 2017 was Emiel als orthopedagoog werkzaam aan een onderwijsinstelling voor voortgezet onderwijs.

Sinds 2016 is Emiel werkzaam als psycholoog bij MemphysGGZ en Diabeter binnen de generalistische basis GGZ en specialistische GGZ voor kinderen en volwassenen met Type 1 Diabetes. Aldaar is hij in opleiding tot Orthopedagoog-Generalist (NVO) en Cognitief Gedragstherapeut (VGCT).

Emiel is getrouwd met Marieke. Samen hebben zij twee kinderen: Sam en Luka.
APPENDICES

PHD PORTFOLIO

Name Phd candidate Emiel A. Boogerd
Phd period 2012-2018
Department of Medical Psychology
Promotors Prof. JB Prins
Prof. C.Noordam
Co-promotors Dr. CM Verhaak
Dr. NM Maas- van Schaaijk
Graduate School Radboud Insitute for Health Sciences

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d) Other
- Journal club Pediatric Psychology - member 2010-2012 2
- EHealth working group - chair 2009-2015 3
- Advisory committee BKO - member 2009-2011 2

TEACHING ACTIVITIES

e) Lecturing
- Radboudumc teaching staff 2014 2
- Guest lecturer Tilburg University 2013 0.5
- Nascholing Radboudumc, dept Medical Psychology 2013 0.8
- Guest lecturer Tilburg University 2012 0.5

f) Supervision of internships / other
- Supervision research intern 2010 4
- Supervision research intern 2011 4
- Supervision research intern 2012 4
- Supervision research assistant 2012-2014 5

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*oral presentation/*poster presentation
Screenhot forum

**Forum**

**Forumoverzicht**

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Deel hier je ervaringen en vragen die je wilt delen.

Het forum wordt dagelijks beheerd en wordt gerегistreerd op meewer samen op het forum. Er zijn geleidelijke reacties en het forum bevat een lijst met voorbeelden.

Voor specifieke vragen of ervaringen met pompschakeling.

Voor ervaringen met en vragen over behandeling door middel van spuiten.

Voor vragen over of ervaringen met voeding bij diabetes.

Voor vragen over of ervaringen met jongeren forum.

In de dichtst liggende leden van het forum.
uitnodiging

U bent van harte uitgenodigd voor het bijwonen van de openbare verdediging van mijn proefschrift "Shared Disease Management in Pediatric Diabetes Care. The Role of E-Health in Patient-Professional Communication and Patient-Patient Interaction" op maandag 24 september 2018 om 16.30 uur precies in de aula van de Radboud Universiteit Nijmegen, Comeniuslaan 2, 6525 AG Nijmegen.

U bent ook van harte uitgenodigd voor de receptie ter plaatse, na afloop van de verdediging.

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José & Ties
Emiel.gaat.promoveren@gmail.com