Women with type 1 diabetes during pregnancy and postpartum

Well-being and diabetes management

Karolina Linden

Institute of Health and Care Sciences
Sahlgrenska Academy at University of Gothenburg

UNIVERSITY OF GOTHENBURG

Gothenburg 2018

Cover photo by Gustaf Adolfsson

Women with type 1 diabetes during pregnancy and postpartum

karolina.linden@gu.se

ISBN 978-91-629-0432-6 (PRINT)
ISBN 978-91-629-0433-3 (PDF)
http://hdl.handle.net/2077/54536

Printed in Gothenburg, Sweden 2018
Printed by BrandFactory

For Max and Albert

Women with type 1 diabetes during pregnancy and postpartum

Well-being and diabetes management

Karolina Linden

Institute of Health and Care Sciences
Sahlgrenska Academy at University of Gothenburg
Gothenburg, Sweden

ABSTRACT

Type 1 diabetes mellitus (T1DM) is associated with increased medical risks during pregnancy and birth. To minimize the risks and increase the possibility of a healthy offspring, blood glucose levels near normal are required. This puts women with T1DM in a vulnerable situation in relation to pregnancy and childbirth, as it demands high levels of diabetes management.

The overall aim was to investigate well-being and diabetes management in women with T1DM during pregnancy and in the first six months postpartum.

Studies I, II and III mainly report on patient-reported outcome measures in terms of questionnaires. Studies I and III have an observational design and Study II was a randomized controlled trial. Study IV used a case study design and analysed data with both quantitative and qualitative methods.

In Study I, well-being and diabetes management in early pregnancy was explored. A higher degree of diabetes management correlated positively with self-perceived health and well-being and with less worry about diabetes distress and hypoglycemia. In Study II, a web-based support program during pregnancy and up to six months after childbirth was evaluated. The findings suggest that the web-based support and standard care was not superior to standard care alone in terms of general well-being or self-efficacy of diabetes management at six months postpartum and that few participants had a high activity level. In Study III, associations between well-being, diabetes management and breastfeeding postpartum were investigated. Participants with lower scores of general well-being and sense of coherence expressed a need for more professional support to manage their diabetes than they were offered. In Study IV, adherence to technological elements and study design in a web-based intervention were critically analysed. The results highlight that technology and study design matter and might mutually influence each other.

The findings confirm that well-being and diabetes management are closely linked during the childbearing period. Means of identifying a more vulnerable group of women with T1DM during pregnancy and new approaches to professional support after childbirth are needed.

Keywords: well-being, self-management, type 1 diabetes mellitus, pregnancy, postpartum, patient-reported outcome measurement, eHealth

ISBN: 978-91-629-0432-6 (PRINT) http://hdl.handle.net/2077/54536
ISBN: 978-91-629-0433-3 (PDF)

SAMMANFATTNING PÅ SVENSKA

Typ 1 diabetes är ett kroniskt tillstånd. Under graviditet medför det ökade risker för både fostret och kvinnan. För att minska riskerna eftersträvas jämna låga blodsockernivåer, något som kvinnorna kämpar hårt för att uppnå under dygnets alla timmar. På grund av de unika förutsättningar som det innebär att vara gravid vid diabetes krävs omfattande vårdinsatser under hela förloppet. Trots en högspecialiserad vård med ett flertal aktörer involverade behöver kvinnor med typ 1 diabetes ett utökat stöd under den barnafödande perioden, i synnerhet efter förlossning.

Avhandlingen syftar huvudsakligen till att undersöka välbefinnande och diabeteshanteringsförmåga hos gravida kvinnor med typ 1 diabetes och de första sex månaderna efter barnets födelse.

I Studie I utforskas välbefinnande och diabeteshanteringsförmåga i tidig graviditet. Resultatet analyserades med hjälp av beskrivande och jämförande statistik samt korrelationsanalyser. Resultatet visade att en högre diabeteshanteringsförmåga samverkade positivt med välbefinnande, självupplevd hälsa och var förknippat med färre diabetesrelaterade problem och mindre rädsla för hypoglykemi. Välbefinnande och diabeteshanteringsförmåga kan troligtvis förbättras genom att stärka kvinnornas kapacitet och ansvarstagande för att uppnå målvärde för HbA1c, så kallat långtidsblodsocker.

Studie II är en randomiserad kontrollerad studie, MODIAB-Web (MODerskap och DIABetes), som utvärderade ett webbaserat stöd som komplement till den ordinarie vården för kvinnor med typ 1 diabetes under tidig graviditet till sex månader efter barnets födelse. Analyserna utfördes med beskrivande och jämförande statistik. Resultatet visade ingen statistisk säkerställd skillnad gällande välbefinnande och diabeteshanteringsförmåga mellan interventionsgruppen som erhöll sedvanlig vård med tillägg av webbaserat stöd och kontrollgruppen som erhöll sedvanlig vård. Aktivitetsnivån i det webbaserade stödet var lägre än förväntat men en högre grad av användning visade ett positivt mönster för psykosociala utfallsvariabler.

I Studie III undersöks välbefinnande, diabeteshanteringsförmåga samt amning de första sex månaderna efter barnets födelse. Resultatet visade att vid två respektive sex månader efter barnets födelse så upplevde de flesta deltagarna ett relativt gott välbefinnande och en förhållandevis god

diabeteshanteringsförmåga trots frekventa hypoglykemier och instabila blodsockernivåer. Dock skattade en fjärdedel sin känsla av sammanhang som låg. Kvinnor med ett lägre välbefinnande upplevde att de saknade adekvat professionellt stöd. Metoder för att identifiera de som riskerar ett lägre välbefinnande behövs.

Studie IV är en kritisk analys av MODIAB-Web. Syftet var att diskutera utmaningar i att genomföra randomiserade kontrollerade studier med webbaserad teknik med fokus på socialt stöd och användning. Analyserna genomfördes med hjälp av beskrivande statistik och innehållsanalys samt utifrån en modell som åsyftar ökad användning. Resultatet visade att både studiedesign och tekniska aspekter påverkar användandet av webbaserad teknologi och därigenom det sociala stödet i interventionen. Baserat på erfarenheter från projektet ges rekommendationer för utveckling av webbaserat stöd inom ramen för en randomiserad kontrollerad studiedesign.

Sammanfattningsvis bidrog avhandlingen med ny kunskap gällande välbefinnande och diabeteshanteringsförmåga hos kvinnor med typ 1 diabetes under den barnafödande perioden. Det behövs metoder för att redan under graviditeten kunna identifiera en grupp av mer sårbara kvinnor samt utveckling av professionellt stödet efter hemkomsten ifrån BB. Vidare finns det inget som hindrar att ett sådant stöd skulle kunna erbjudas i ett webbaserat format men då krävs en kontaktyta mellan användaren och den professionella vårdgivaren inom stödet. Då teknikutvecklingen varit nästintill explosionsartad inom diabetesvården krävs ny forskning som undersöker välbefinnande i relation till kontinuerlig och intermittent glukosmätning under graviditet och i tidigt moderskap. Detta torde vara av stor vikt för kvinnornas diabeteshanteringsförmåga och således kunna påverka välbefinnandet.

LIST OF PAPERS

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

I. Linden, K., Sparud-Lundin, C., Adolfsson, A. & Berg, M. Well-Being and Diabetes Management in Early Pregnant Women with Type 1 Diabetes Mellitus. International Journal of Environmental Research and Public Health 2016; 13: 836.

II. Linden, K., Berg, M., Adolfsson, A. & Sparud-Lundin, C. Person-centred web-based support in pregnancy and early motherhood for women with Type 1 Diabetes Mellitus – a randomized controlled trial. Diabetic Medicine 2018; 35: 234-243.

III. Linden, K., Berg, M., Adolfsson, A. & Sparud-Lundin, C. Well-being, diabetes management and breastfeeding in mothers with type 1 diabetes – an explorative analysis. Sexual & Reproductive Healthcare 2018; 15: 77-82.

IV. Berg, M.*, Linden, K.*, Adolfsson, A., Sparud-Lundin, C. & Ranerup, A. A critical analysis of adherence to technological elements and study design – based on a web-based intervention for women with type 1 diabetes in pregnancy and early motherhood. *The first authorship is shared between Berg and Linden. *Submitted.*

CONTENTS

ABBREVIATIONS v
1 INTRODUCTION 1
2 BACKGROUND 2
2.1 Type 1 Diabetes Mellitus 2
2.2 Type 1 Diabetes Mellitus and Childbearing 3
2.2.1 Diabetes-related complications of pregnancy and childbirth 4
2.2.2 Healthcare during pregnancy, childbirth and postpartum 5
2.2.3 Well-being and diabetes management during pregnancy 6
2.2.4 Well-being and diabetes management postpartum 7
2.3 Web-based support for self-management 8
3 THEORETICAL STANDPOINTS 10
3.1 Well-being 11
3.2 Self-management 12
4 RATIONALE 15
5 AIM 16
5.1 Overall aim 16
5.1.1 Specific aims 16
6 METHODS 17
6.1 Research Design 17
6.1.1 The MODIAB-Web support intervention 19
6.1.2 Sample size estimation 23
6.2 Data collection 23
6.2.1 Participants and recruitment 23
6.2.2 Data sources 27
6.3 Data analysis 31
6.3.1 Statistical methods 31
6.3.2 Critical analysis 32
7 ETHICAL CONSIDERATIONS 34

8 RESULTS 35
8.1 Study I 35
8.2 Study II 35
8.3 Study III 38
8.4 Study IV 38
8.5 Summary 39
9 DISCUSSION 42
10 METHODOLOGICAL CONSIDERATIONS 48
11 CONCLUSIONS 52
12 FUTURE RESEARCH 53
ACKNOWLEDGEMENTS 54
REFERENCES 57

ABBREVIATIONS

EVGFP	Self-perceived health
HbA1c	Glycated haemoglobin A1c
PSD	Persuasive system design
SOC-13	The 13-item Sense of Coherence Scale
SWE-DES-10	The Diabetes Empowerment Scale Short version
SWE-HFS	The Swedish Hypoglycaemia Fear Survey
SWE-PAID-20	The Swedish Problem Areas in Diabetes Scale
T1DM	Type 1 diabetes mellitus
W-BQ12	The Well-Being Questionnaire Short form
WHO	The World Health Organization

1 INTRODUCTION

Diabetes mellitus type 1 (T1DM) complicates all aspects of childbirth. An abnormal blood glucose level may impact on the woman's chances of conception, the viability of the embryo, the health of the foetus, and the birth, as well as the risk involved with the woman's own health. In 1989, the World Health Organization (WHO) and International Federation of Diabetes stated in the Saint Vincent declaration that a target was to implement effective measures to *'achieve pregnancy outcomes in women with diabetes that approximate that of women without diabetes' (p.63)* (1). Although results have improved, this goal remains unmet (2).

This thesis focuses on supporting well-being and diabetes management in pregnant women and mothers with T1DM and the scope of this exploration is confined to six months postpartum. The term childbearing can be defined as the process of giving birth to children (3) and is used to describe the period from early pregnancy to motherhood. Self-management and diabetes management are used interchangeably where diabetes management is viewed as self-management of diabetes.

My work has been conducted in accordance with the International Confederation of Midwives' ethics and mission to promote well-being of women. My undertaking of this research has also been particularly inspired by four of their philosophical objectives (4), namely: to promote partnership with women, enhance informed decision-making, empower women to assume responsibility for their health, and build their self-confidence. For women with T1DM pregnancy, birth and early motherhood is a short but important time of life. During this period, different types of healthcare professionals are involved in care and it is my hope that the findings from this thesis will be relevant and useful to the whole diabetes team.

In this thesis all participants are referred to as women and mothers. However, we have not asked for their gender identity and acknowledge that this assumption may be incorrect.

2 BACKGROUND

The background introduces the condition T1DM, its prevalence, treatment and the pathophysiology in general and during pregnancy in particular, as well as healthcare during pregnancy, childbirth and postpartum. Further, it summarizes previous research regarding well-being and diabetes management during pregnancy and postpartum and introduces web-based support in these contexts.

2.1 Type 1 Diabetes Mellitus

T1DM is a chronic condition that prevents the body from producing insulin, a hormone that is needed to convert sugar, starches and other food to energy. This is caused by β-cell destruction in the pancreas. There are hereditary factors associated with T1DM but the cause of the condition is still unknown. Traditionally, T1DM has been believed to be associated with an auto-immune process (5). However, conflicting evidence indicates that diabetes onset may be caused by an inflammatory disease affecting the entire pancreas (6).

Persons with T1DM require insulin therapy for survival. The use of insulin as a treatment for diabetes was discovered during the 1920s (7). Insulin may be inserted into the body by multiple daily injections or by a continuous injection via an insulin pump. Onset of T1DM is most common during early childhood or adolescence but may also occur in adulthood (5). After Finland, Sweden has the second highest incidence rate of T1DM in 0-15 year olds in the world. Data suggests that 43.1 children per 100 000 children aged 0-15 have been diagnosed with T1DM (8) and research indicates that the incidence of T1DM is growing in Europe (9). According to the annual report from the Swedish National Diabetes Register, the prevalence of T1DM in the total Swedish population was 39 671 in 2015 (the register is almost but not fully comprehensive) (10).

The body's inability to produce insulin creates a range of problems. Ideally, blood glucose levels should be closely monitored and insulin dosage adjusted accordingly to control fluctuating levels – a balance that is difficult to achieve. Too much insulin may result in hypoglycemic episodes but too little may cause ketoacidosis, both acute and potentially fatal complications of diabetes (5). Blood glucose levels are normally checked by pricking a finger and sampling a drop of blood on a test stick inserted into a blood glucose

meter. However, since approximately 2005, real-time continuous blood glucose monitoring and shortly thereafter sensor-augmented pump therapy have been available. Since 2014, a new form of intermittent blood glucose monitoring has been introduced called flash glucose monitoring. A small sensor worn on the back of the arm is connected with a scanner and indicates trends and provides graphs over time. Flash glucose monitoring is more cost-effective than continuous blood glucose monitoring and sensor-augmented pump therapy (11).

Besides insulin therapy, diet and exercise are important factors in diabetes treatment and both factors influence blood glucose levels. Dietary factors may have a stabilizing effect on HbA1c, lower blood pressure levels and blood fat levels and might prolong the onset of diabetes-related complications (12). Exercise combined with a balanced diet and insulin intake might enhance glycemic control. It also has multiple health benefits, including better cardiovascular fitness and enhanced bone-health in persons with T1DM (13).

Over time, diabetes can damage the heart, blood vessels, eyes, kidneys, and nerves leading to severe illness such as myocardial infarction and/or stroke, high blood pressure, renal failure, retinopathy with or without blindness and diabetic wounds that may result in amputation of extremities. The risk of complications increases with time since the onset of diabetes. Achieving blood glucose levels as near as possible to normal reduces the risk (14).

2.2 Type 1 Diabetes Mellitus and Childbearing

The term childbearing appears to be used in different ways within the literature. In some studies it is only used to refer to pregnancy and birth, whilst in others childbearing is used to define the process of trying to conceive, pregnancy, birth and the first year of motherhood (15-17). In this thesis, childbearing is confined to pregnancy, birth and the first six months of motherhood.

Between 2003-2012, about 0.47% or 500 of the women who gave birth annually in Sweden had T1DM (18). This number can be put in relation to the 0.07% with a diagnosis of type 2 diabetes mellitus during pregnancy during the same timeframe (18) and the 2-3% of Swedish pregnant women that are expected to suffer from gestational diabetes (19). This thesis only focuses on women with T1DM.

Pregnancy was universally fatal for mother and child at the beginning of the century but expectations of better outcomes were raised in 1989 by the Saint Vincent declaration (20). Women with T1DM were previously discouraged from getting pregnant, especially if they suffered from cardiovascular complications. This is not common practice today. Pre-conception care is strongly encouraged to lower the risk of adverse outcomes (21).

Pregnant women with T1DM may administer their insulin by multiple daily injections with either short-acting and long-acting insulin analogues or subcutaneous intensive insulin therapy via a pump (22, 23). During pregnancy, the physiological need for insulin increases (up to two or three times more) and falls dramatically to pre-pregnancy levels or below after birth (22). There is insufficient scientific evidence regarding dietary recommendations during pregnancy for women with T1DM. However, a moderately carbohydrate-restricted diet with a low glycaemic index that includes carbohydrate counting appears to be safe and a good choice (24). A recent Cochrane review found no randomized controlled trials (RCTs) that evaluated the effects of exercise interventions aiming to improve maternal and foetal outcomes in women with pre-existing diabetes (25).

2.2.1 Diabetes-related complications of pregnancy and childbirth

Although the medical risks associated with T1DM have decreased over time (20) there is still a tangible risk of diabetes-related complications for the foetus/new-born and the pregnant woman/mother. The degree of complications appears to be associated with maternal glycaemia, where abnormal blood glucose levels increase adverse outcomes. The best chance of a normal pregnancy with a healthy offspring is to achieve normal blood glucose levels in early pregnancy (23, 26). The risk of severe hypoglycemia is increased during pregnancy and particularly in early pregnancy (27-29).

A Canadian study of over 1,000,000 births found that women with pre-existing diabetes had twice the rates of perinatal mortality and congenital anomalies compared to women without diabetes (30). In addition, a review published in 2013 (2) of 12 population-based studies found that the risk of adverse outcomes were two to five times higher in women with T1DM compared to the general maternity population.

Risks to the foetus/new-born include congenital malformations, growth anomalies, stillbirth, foetal macrosomia, shoulder dystocia and operational birth; neonatal complications such as hypoglycemia and respiratory distress, and perinatal mortality (2, 26, 30-36). Maternal risks include an increased likelihood of worsened diabetes-related vascular complications, miscarriages, pre-eclampsia and eclampsia, and of caesarean section and vacuum extraction/forceps vaginal birth (26, 31, 32, 35, 36).

2.2.2 Healthcare during pregnancy, childbirth and postpartum

The National Board of Health and Welfare is a government agency in Sweden under the Ministry of Health and Social Affairs which publishes national guidelines for chronic conditions. In the national guidelines for diabetes care, very little is stated in terms of T1DM and pregnancy. For example, *"blood glucose levels as close as possible to normal values"* should be aimed for to avoid macrosomia and diabetes-related abnormalities in the foetus, but no further guidelines as to what this entails are given (37). Care is organized regionally and there are differences in structure and setup depending on where in Sweden the woman lives. Frequent care is a necessity during pregnancy in order to monitor the health of the woman and the foetus. Women are encouraged to contact their health care provider when they first learn that they are pregnant (22). During pregnancy, in addition to general maternity care, the women typically have contact with a nurse or midwife specialized in T1DM, an obstetrician and an endocrinologist. This care may be specialized and given at one location or fragmented in a disconnected care chain (38). Maternity care is not limited to improving or maintaining physical health but also entails monitoring mental health and identifying those in need of professional psychosocial support. Assessment and treatment routines vary but counselling sessions by a trained welfare officer or psychologist are often provided to those with a great need (39). During labour and birth, a midwife and an obstetrician collaborates in caring for the woman and her child. The new-born is monitored for symptoms of hypoglycemia or other complications related to maternal diabetes that may need medical intervention. After discharge from the hospital, at least one follow-up visit is offered with the maternity care team. If contact with the ordinary diabetes team has been discontinued during pregnancy, their responsibility resumes after childbirth.

2.2.3 Well-being and diabetes management during pregnancy

Women with T1DM are in a vulnerable situation in relation to pregnancy and birth (38, 40-43). They are well aware of the risks that are associated with their diabetes. In qualitative studies, some pregnant women perceived this risk as high (44) and others have described feeling that their unborn child's survival and health were dependent on their ability to control and manage their diabetes. During pregnancy, a strict routine of controlled diet and physical activity with frequent monitoring of blood glucose levels is a necessity to manage daily life (41). Pregnant women struggle day and night to achieve normal blood glucose levels in an attempt to ensure that the foetus/child will be born healthy; they typically experience frequent hypoglycemic episodes and feelings of stress, worry and insecurity (38, 40, 41). When faced by these challenges, pregnant women with T1DM may alternate between 'mastering' and 'being enslaved by' their diabetes (40). Finding themselves in unfamiliar territory during pregnancy, these women rely heavily on the health care professionals' expertise to help them manage their diabetes (44) and will need extended support from their caregiver but also from their partner and other close family members (45). Such close contact with health care providers may mean that diabetes management becomes the main focus of the pregnancy due to emphasis on minimizing the risk of complications. Thus, the joy of pregnancy may be overshadowed, leaving women feeling disappointed and less able to enjoy the experience (44, 46). If care is provided by a disconnected diabetes organization, the pregnant woman runs the risk of becoming a messenger, informing one caregiver of what the other said, adding to the stressful situation (38).

Aspects of well-being during pregnancy have also been studied quantatively. A study exploring changes in health-related quality of life, anxiety and depression symptoms during pregnancy in women with pre-gestational diabetes mellitus (type 1 n=110, type 2 n=27) found a slight improvement in mental quality of life and a deterioration in physical quality of life between 8 to 33 gestational weeks. Mental health parameters such as depressive symptoms were stable and a slight reduction of anxiety was measured (47). Some previous studies have measured well-being and quality of life during pregnancy in women with pre-gestational diabetes but their sample size has often been relatively small (of women with T1DM), making it hard to draw conclusions (48-50). Other studies did not specify the type of diabetes that the participants had (51). An Israeli study (52) showed that women with pre-gestational diabetes (n=53, type unspecified) raised more intense negative emotions such as fear, disappointment or guilt than positive emotions such as

hope, exhilaration or pleasure compared to a group of women without diabetes who underwent a normal course of pregnancy (n=49). However, their well-being appeared unaffected and measures were within the normal range during the second trimester (52).

2.2.4 Well-being and diabetes management postpartum

After childbirth, an Italian study found a drop in measures of both physical and psychological well-being compared with the third semester of pregnancy in mothers with T1DM (n= 30) (53). Qualitative research from Sweden portrays feelings of uncertainty and exposure early postpartum. Mothers with T1DM struggle with looking after their child and managing their diabetes and may set their own needs aside in favour of the baby's (54). A qualitative Australian study of women seeking peer support online indicated manifestations of depressed mood and diabetes-specific distress postpartum (42). A Swedish study comparing mothers with T1DM with a matched control group (CG) without diabetes or other long-term illness (T1DM n=108; CG=104) found that mothers with T1DM were more sensitive to unexpected disruptions in their daily routines and more worried about their health at both two and six months postpartum (55). Moreover, they reported lower levels of vitality and general well-being than women in the control group at six months after childbirth, as well as lower general health at two and six months. Better well-being in mothers with T1DM at two months was explained by the lesser extent to which breastfeeding influenced diabetes management. This factor, along with longer duration of diabetes, explained better well-being at six months postpartum (56).

Mothers with diabetes are navigating new territory in trying to establish breastfeeding without the frequent professional support that surrounds them during pregnancy (54). The frequency of breastfeeding varies between countries but mothers with T1DM appear to initiate breastfeeding to a lesser extent and to breastfeed for a shorter period of time compared to mothers without diabetes (57-62). This discrepancy does not seem to be associated with the mothers' actual condition of T1DM but rather to factors that are influenced by their T1DM (57, 62-64). A study with participants from 15 countries explained lower breastfeeding rates in mothers with T1DM compared to those of the general maternal population as related to lower gestational age in new-borns, high rates of caesarean sections, and younger

age and education in mothers with T1DM (63). Similar results were found in a Swedish study (57).

A literature review of 14 studies aiming to identify breastfeeding practices that encourage women with diabetes to breastfeed categorized the needs of women and identified supportive practices according to Maslow's Hierarchy of Needs. It states that breastfeeding as the first feed and exclusive breastfeeding are beneficial in meeting the physiological needs of both mother and infant. Further, the mothers' safety and security needs can be met by having food nearby and someone to contact if need arises. An early first breastfeeding can support feelings of love and belonging, and the new mother's self-esteem can be boosted by informed multidisciplinary support. The review concluded that self-actualization or success has been attained by breastfeeding mothers with diabetes (65).

2.3 Web-based support for self-management

During childbearing, women use the Internet as a source of information and reassurance (66-69). A grounded theory study researching life transitions in young women with T1DM found that meaningful personal interactions and social support over the Internet can strengthen autonomy and well-being (70). In a Swedish study from 2011 of 105 mothers with T1DM, 71% used the Internet to search for information concerning pregnancy, childbirth and parenthood, with 12% searching every day and 29% one or more times a week. Forty-seven of the 105 women (45%) stated that they had felt a great need or quite a great need for web-based support focused on pregnancy, birth, and parenthood (71).

Web-based health interventions are often behaviourally based and optimized for delivery via the Internet (72). According to Eysenbach (2001) they hold potential to educate and empower the user and to promote partnership between the patient and the healthcare professional, where decisions are made in a shared manner (73). This is in line with person-centred care, a holistic approach to delivering care in a respectful manner through an empowering relationship (74). A Cochrane review from 2005 found that web-based interventions (defined as Interactive Health Communication Applications) can improve knowledge, social support, health behaviours and clinical outcomes in persons with chronic conditions (75). In patients with type 2 diabetes, web-based interventions providing social support have proven successful in improving self-management behaviours and

psychosocial outcomes, as well as clinical measures (76). Web-based interventions have also indicated positive effects on clinical measures, education and attitudes in relation to preconception care education for women with diabetes (77).

Web-based interventions have the potential to provide fundaments for social support. Social support plays an important role in the adaptation to major life events such as the transition from pregnancy to motherhood (78). Women have a continuous need of social support during pregnancy, childbirth and postpartum. Health care professionals have a unique position to educate about the need for support and mobilize it during this period (79).

Social support affects both health and well-being (80-83) and may have a buffering effect against stress (83). Cobb (1976) defines social support as *"information leading the subject to believe that he is cared for and loved, esteemed, and a member of a network of mutual obligations (p. 300)"* (84). Social support is always well-intended by the provider of the support, is given consciously and provided in an interpersonal context that is characterized by trust, caring and respect (85).

According to House (86), social support is composed of interpersonal transactions of four different aspects. *Emotional support* is the offering of empathy: to care about as well as show concern and interest in a peer. *Instrumental support* involves the provision of tangible aid such as money or direct assistance to a person in need. *Informational support* involves offering advice and making suggestions that a person can use to address problems. It also includes sharing information that can be of importance to peers. *Appraisal support* is characterized by constructive feedback and information that is useful for self-evaluation purposes. All four aspects may be found within social support independently or combined.

Based on House's (86) approach, health care professionals may offer web-based support containing aspects of social support in their professional role facilitating self-management. To exemplify: aspects of *instrumental support*, *informational support* and *appraisal support* may be given directly in a web-based support. Whilst *emotional support* may be offered when using the web-based support along with a clinical consultation, if the web-based support is not designed for the health care professional to take an active part.

3 THEORETICAL STANDPOINTS

This thesis is conducted in Health Care Sciences, which is a broad research discipline that includes theory building and methodological development, as well as intervention studies and other research related to human health (87). One aim of Health Care Science is to provide knowledge about health and effects of health that may benefit an individual, their surrounding environment, groups or society (88). A goal for Swedish maternity care is to promote health in pregnant women, their unborn children and later new-borns. An important aspect of this care is to strengthen the women in becoming parents (39). My work entails supporting well-being and diabetes management in women with T1DM through their transition to motherhood.

The journey from early pregnancy to childbirth and parenthood in women with type 1 diabetes can be described as one of life's greatest life transitions. According to Meleis (89), life transitions are characterized by their own uniqueness, complexities, and multiple dimensions. Transition to motherhood is an ongoing process that typically starts in early pregnancy and continues through the first months post-partum. Transition to motherhood is typically a time of joy but also of uncertainty, trial and error. Active engagement in the pregnancy and new motherhood facilitates personal growth and transformation of self. However, this process may be disrupted by health scares during pregnancy or separation between mother and new-born, such as admittance of the baby to a neonatal ward (90).

For women with T1DM, the transition to motherhood might be more complex due to the threat of potential diabetes-related complications. Worry and anxiety in relation to prospective risks and occurred complications might overshadow some of the process. Well-being and diabetes management appear to be closely related and especially so during this transition period. The risks involved with being pregnant and having T1DM demand well-functioning diabetes management to maintain well-being. On the other hand, the woman may need a certain degree of well-being to be able to face the challenges related to pregnancy yet still maintain good diabetes management. Thus, well-being and diabetes management appear to be key components in the transition to motherhood for women with T1DM. In the following section, well-being and self-management will be explored in general and in relation to diabetes.

3.1 Well-being

Different aspects of well-being have long been a common outcome measure in health research (91). Well-being is mentioned in the WHO's constitution principles: "*Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (p.225)"* (92). However, there appear to be a multitude of opinions regarding what well-being entails. Dodge et al. (93) state that quality of life is often wrongfully used interchangeably with well-being. They argue that quality of life should be seen as a dimension of well-being rather than a definition of the concept. On the other hand, well-being can be viewed as a key component of quality of life. Nevertheless, the concepts appear to be related but not interchangeable. Thomas states that well-being is difficult to define (94) and this statement appears to have merit.

In a literature review, Dodge and colleagues describe two historically dominant views of well-being: either a medicalized view, with well-being seen as a lack of psychological distress and/or dysfunction or well-being as positive functioning (93). Shah and Marks (2004) state that: "*Well-being is more than just happiness. As well as feeling satisfied and happy, well-being means developing as a person, being fulfilled, and making a contribution to the community (p. 9)*" (95).

In terms of diabetes and well-being, Bradley and Gamsu state that physical and psychological well-being are independent from each other (96). Their approach to well-being appears to mix a medicalized view with positive functioning. This highlights the complexity of living with a chronic condition such as T1DM. The medical implications of T1DM will always be present and are therefore difficult to disregard but they do not define the person with the condition. Coping with diabetes and its physical implications has an impact on well-being but it is not necessarily an obstacle to achieving well-being.

In conclusion, Dodge and co-workers define well-being as: "*the balance point between an individual's resource pool and the challenges faced (p.230)*" (93).

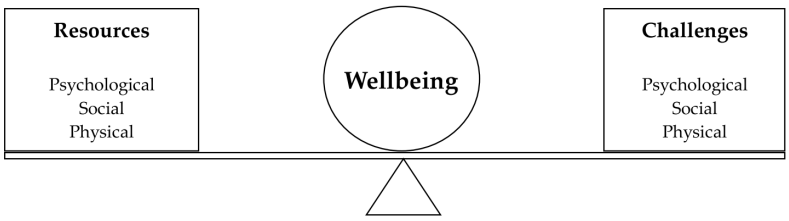

Figure 1. A definition of well-being (Dodge et al. 2012, p. 230). Reprinted with permission by R. Dodge.

Dodge et al. claim that well-being is stable as long as the person has the psychological, social and physical resources to meet a challenge but dips if the person faces more challenges than they have resources (93). Women with T1DM face multiple physical but also psychological challenges during pregnancy and postpartum (45) and thereby have an increased risk of deteriorating well-being.

3.2 Self-management

Diabetes is unique in that much of the day-to-day responsibility for care rests with the individuals who have the disease. People living with T1DM learn to manage their diabetes early after onset. Self-management of T1DM is a constant process that starts in childhood and adolescence if the onset of diabetes occurs before adulthood. It includes many activities related to giving insulin, monitoring metabolic control, regulating diet and exercise etc. (97, 98). Self-management of diabetes is the cornerstone of diabetes care and to achieve it the patient needs ongoing education and support (99). However, persons with diabetes might be reluctant to discuss self-care with their health care provider (100) and the concept is not exempt from paternalistic power structures.

Multiple definitions of self-management exist and the concept is used in different ways depending on discipline and context. Barlow et al. (101) define self-management as an individual's ability *"to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition (p. 178)"*. In relation to power imbalances between a patient and a health care professional, Grady and Gough state that self-management provides an opportunity for a person to actively identify challenges and solve problems connected to their condition rather than being a passive recipient of health education (102). In this context, the term empowerment is often used as a contradictive term to compliance with self-management strategies. Empowerment can be seen as a process emerged from a supportive educational relationship between the patient and the health care provider rather than the 'provision' of information (103). The aim of the process is for patients to gain control of their resources and obtain power over their health, much like the desired outcome of sufficient self-management. It has been said that health care professionals can facilitate self-management by providing social support (104). Professional provision of social support likely contributes to the process of empowerment. However, far from all relationships between a patient and a healthcare professional are empowering and the concept is to some degree idealistic.

Lorig and Holman (105) operationalize self-management in chronic conditions as consisting of three tasks (defined by Corbin & Strauss 1988 (106)): *medical management* (i.e. in relation to diabetes, this entails taking insulin and monitoring blood glucose levels); *role management* (i.e. creating new meaningful life behaviours. In relation to diabetes this may entail continuing with daily life activities but being aware of how diabetes influences them and managing accordingly): and *emotional management* (i.e. dealing with the emotions that come from understanding that a chronic condition alters one's view of the future. In terms of T1DM this may be feelings such as fear of long term complications).

Further, Lorig & Holman (105) state that these three tasks may be achieved with six self-management skills. *Problem solving* is the foundation for self-management education (and interventions) and all programs must be based on patient-perceived problems. This entails that the person is able to define their problem, generate a possible solution themselves or assisted by suggestions from peers or health care professionals, implement the solutions and evaluate the result. *Decision making* is part of problem solving but it also includes making decisions in response to changes in disease condition. To make informed decisions, a person needs enough and specific information. An example may be recognizing symptoms of hypoglycaemia and knowing

how to act in response. *Resource utilization* is a basic skill that, according to Lorig & Hallman, is often overlooked in self-management education. Healthcare professionals often list potential resources but give no direction on how to utilize them. For example, if referring a person to a web-page, the health care professional should show the person how to work the page. It also means encouraging the person to seek out information from multiple sources while at the same time maximizing the chance of getting a good answer quickly. *The formation of a patient-provider partnership* is another key element in achieving self-management. Traditionally, the health care provider diagnosed and treated disease but in self-management of chronic conditions the health care provider is utilized as a partner, a teacher and a professional supervisor. The patient takes an active part in the care and reports symptoms of and trends in their condition and participates in treatment decisions. *Action planning* or taking action is a decision that includes skills in how to change a behaviour. Creating an action plan is an example of this. The action plan should be created to fulfil a short term goal (1-2 weeks) and should be realistic and doable. For example, this might mean taking a brisk walk around the block before breakfast to avoid high blood glucose levels. The final skill is *self-tailoring*. This skill combines all other self-management skills as the person applies them to themselves. This entails skills for making behavioural changes, decision making and solving problems (105).

Self-efficacy in relation to self-management

Self-efficacy theory was introduced by Bandura in 1977 (107) and its content can briefly be described as the belief that one can carry out a behaviour or action that results in a desired outcome. It may be measured by asking someone how confident they are in carrying out a behaviour under specific circumstances. Lorig and Holman (105) state that enhanced self-efficacy is one mechanism that positively influences health status in those successful in their self-management of chronic conditions.

4 RATIONALE

Due to the great need for optimal glycemic control during pregnancy, extensive health care resources are essential for women with T1DM in order to promote a better outcome for both mother and child. Despite this, their health care needs are insufficiently met by the current health care system during the childbearing period, especially during early motherhood after discharge from postpartum maternity care. Previous studies have identified a need for additional support during this tumultuous time. Active social support from peers through sharing of common experiences and from health care professionals through evidenced-based information, shared decision making and joint responsibilities for diabetes management, is likely to assist transition to motherhood in women with T1DM. It appears likely that well-being and diabetes management are closely interlinked during the childbearing period. Although some research regarding well-being and diabetes management during pregnancy and postpartum exists, it is important to explore their association to each other in more detail. Further studies are therefore needed to explore and investigate well-being and diabetes management in women with T1DM during transition to motherhood. This thesis also evaluates if and how web-based support for mothers with T1DM can increase the women's personal capacity, including knowledge, and thereby strengthen their well-being and autonomy during pregnancy and early motherhood. Further, a critical perspective is taken on the design and evaluation of web-based intervention studies.

5 AIM

5.1 Overall aim

The overall aim was to investigate well-being and diabetes management in women with T1DM during pregnancy and in the first six months postpartum.

5.1.1 Specific aims

Study I — To 1: explore well-being and diabetes management in women with T1DM in early pregnancy and 2: investigate associations among perceived well-being, diabetes management, and maternal characteristics.

Study II — To report on the effectiveness of this web-based support in terms of improved self-efficacy of diabetes management and general well-being in women with Type 1 diabetes during pregnancy and up to six months after childbirth (primary outcomes), and also with regard to self-perceived health, sense of coherence, glycaemic control, diabetes distress and fear of hypoglycaemia (secondary outcomes). A further aim was to explore the use of the web-based support.

Study III — To explore and investigate associations between well-being, diabetes management and breastfeeding in mothers with T1DM up to six months postpartum.

Study IV — To critically analyse and discuss the challenges of doing an RCT using web-based technology including technology for social support.

6 METHODS

Experiences can be researched using multiple scientific methods and from both a qualitative and a quantitative paradigm. In this thesis, quantitative methods are used in Studies I, II, III and partly in Study IV. This implicates assumptions of an ontological nature; that reality does exist and there are natural causes resulting in effects. From an epistemological perspective, the researcher is viewed as independent from the participants and findings are not influenced by the researcher. Objectivity is sought and biases are controlled as much as possible. Evidence is obtained through quantification of representative samples (108). The results in this thesis are mainly based on patient-reported outcome measures. The use of patient-reported outcome measures represents a shift in traditional medical research from solely clinical measures of health and treatment outcomes to gaining insight directly from the patient. The use of patient-reported outcome measures has the potential to improve adherence to treatment and provide a better understanding as to what problems the patient may encounter, allowing treatment decisions to be altered accordingly (109). Although, the data from questionnaires is analysed with quantitative methodology, it has been argued that patient-reported outcome measures are more in line with a hermeneutical approach to understanding and interpreting meaning (110). This is an important cornerstone within Health Care Sciences, where people's experiences and responses to health and illness, as well as their strategies for managing consequences of threats to health are central.

6.1 Research Design

This thesis is built on four studies, all originating from the same data collection. An overview of the respective study methods is presented in Table 1.

All data used in the studies is retrieved from the research project MODIAB-Web (MOtherhood and DIABetes), an RCT evaluating a web-based support. RCTs are considered to be high in the evidence hierarchy of design for cause-probing questions, second to systematic reviews of RCTs and non-randomized trials (108).

Study I has an observational design using a correlational method aiming to find associations between variables. Although the data is retrieved from the participants in the RCT, the sample is used as a composite group.

The second study (Study II) reports on the main outcomes of the RCT. It was conducted in accordance with the CONSORT statements to ensure methodological rigor and avoid bias (111).

The third study (Study III) has an observational design and uses a correlational method. As in Study I, the data is retrieved from the participants in the RCT and the sample is used as a composite group.

The last study (Study IV) has a case study design (112) and uses the Persuasive System Design (PSD) model (113) as a framework for deductive analysis. It aims to provide an in-depth and critical analysis of the content of the intervention, as well as its research design.

Table 1. Overview of the studies in the thesis presented under each respective Study.

	Study I	**Study II**	**Study III**	**Study IV**
Design	Observational study	Experimental randomized controlled trial	Observational study	Qualitative explorative case study
Data collection	Questionnaires	Questionnaires, user statistics from a web-based intervention, medical data	Questionnaires	Data from the web-based intervention MODIAB-Web including user statistics and narratives from the forum for peer support
Participants	Women with type 1 diabetes mellitus (n=168)	Women with type 1 diabetes mellitus (n=174)	Women with type 1 diabetes mellitus (n=155)	Women with type 1 diabetes mellitus (n=69)
Data analysis	descriptive statistics, comparison between groups, rank correlations	descriptive statistics, comparison between groups	descriptive statistics, comparison within groups over time, rank correlations	descriptive statistics, qualitative content analysis, critical analysis

6.1.1 The MODIAB-Web support intervention

A need for extended support regarding self-care for women with T1DM through pregnancy and early motherhood was identified through earlier research (38, 40, 41, 46, 51, 54, 57, 58, 63, 70, 71, 114-117). The research group wanted to find a way to strengthen the women's own capabilities and decided to utilize the principles of person-centred care as a starting point. Person-centred care offers a broader scope of medicine (74), where a patient

is viewed as a capable person: decision-making based on the patient's narration is shared between the person and the healthcare professional in a partnership that is reflected in the documentation (118). The planning and development of the MODIAB-Web intervention took place before the start of the research undertaken in this thesis.

The development of a web-based support with scope for documentation and shared-decision making was initiated (119). The development process was inspired by participatory design (120) and involved researchers, mothers with T1DM, health care professionals with different expertise (nurse specializing in neonatal care, nurse-midwives specialized in diabetes and breastfeeding, physicians specializing in medical diabetic care, obstetrics and neonatal care and a dietician), and web-designers (119). Details of the intervention is given in the study protocol (121) and will be briefly summarized in the following sections. The MODIAB-Web support intervention consisted of three parts:

1. Specific maternity information in relation to T1DM based on evidence and developed with mothers with T1DM and other experts. The information was reviewed for cultural suitability and edited for a lay audience (122).

2. A self-care diary for self-reporting of blood glucose levels, insulin intake, diet, physical activity and daily mood. Information could be inserted via a mobile phone or a computer. Inserted values could be viewed in tables or as diagrams. Content and functionality were tested in a focus group during the development process (123).

3. A discussion forum for peer support where participants could share experiences and narratives. The posts were moderated by the research group. To boost interaction, a woman with T1DM who had experienced pregnancy and motherhood participated as study facilitator in the forum for peer support in the first year.

In addition, an FAQ section and links to useful web resources were provided. The web-based support could be accessed from a smartphone or a web browser. Graphs could not be accessed in mobile phone view but all other content was available, including the logging of blood glucose levels, insulin dose, food and activity. Healthcare professionals did not have access to the

web-based support but a user could choose to log in to the web-based support during a health care visit and share her documentation on a computer screen.

Introducing participants to the web-based support involved a brief presentation of the different parts by the study-midwife. In addition, an introductory video showing the different features of the support was available, as was contact information for the research group to answer questions and provide technical support. Screenshots of the web-based support are provided in Figure 2 and Figure 3.

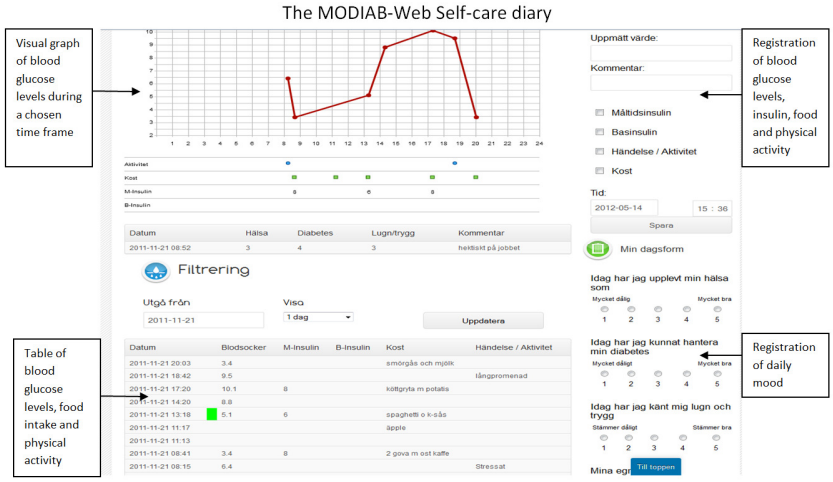

Figure 2. Screenshot of the MODIAB-Web self-care diary (retrieved from www.modiab.se).

Example of information text in the MODIAB-Web intervention

Figure 3. Screenshot of the MODIAB-Web evidence based information (retrieved from www.modiab.se).

The intervention group received web-based support in addition to usual care while the control group received usual care. What constituted usual care varied slightly between the study centres but general care is described in the background section of this thesis.

At the initiation of the RCT in 2011 to 2012, personal use of smartphones was not widespread. The research project provided smartphones to those in the intervention group for use free of charge during their participation in the study. The need for this decreased significantly during the later months of 2012 and by the end of the research project it no longer existed.

6.1.2 Sample size estimation

To maximise chances of detecting a statistically significant effect and avoid a type II error (a false negative result) a power analysis is recommended. The likelihood of detecting a potential difference increases with greater power but greater power requires larger samples. To estimate the sample size for comparison between two independent groups, the standard deviation, a clinically relevant difference, the significance level and the power must be specified (108). In the MODIAB-Web study sample, size estimation was based on the main outcome variables: 1) general well-being measured by the Well-Being Questionnaire Short form (W-BQ12) and 2) self-efficacy in diabetes management measured by the Diabetes Empowerment Scale Short version (SWE-DES-10). In order to detect a clinically relevant difference of 1.25 in general well-being between the intervention group and the control group, a group size of 68 subjects was needed to reach a statistical power of 80%, assuming an SD of 2.5 in each group, with a significance level of 0.05. Likewise, to detect a difference of 0.2 in diabetes management, a group size of 68 subjects was needed to reach a statistical power of 80%, assuming an SD of 0.40 in each group, with a significance level of 0.05. To compensate for 10% lost to follow-up, a total sample size of 160 was estimated.

6.2 Data collection

6.2.1 Participants and recruitment

The participants were recruited from six hospital-based antenatal clinics in western and central Sweden. The enrolment of participants started in two centres in November 2011. Another four centres were successively included: one was added in June 2012, another in October 2012 and finally two more were included in June 2013. To be eligible for inclusion, the pregnant women had to be registered at one of the participating study centres, be literate and Swedish-speaking, over 18 years of age and have a diagnosis of T1DM.

Women who suffered a miscarriage before randomization or had previously participated in the study were excluded, apart from randomized women who suffered a miscarriage in the first trimester. Those who miscarried earlier but became pregnant again were connected to the group to which they were randomized in the earlier pregnancy (intervention or control), and all data was collected on the new pregnancy.

In total, 288 pregnant women with T1DM were assessed for eligibility. Of these, 95 declined participation and 19 were excluded (2 because of previous participation, 14 because of miscarriage, and 3 were not invited), leaving 174 participants for group allocation. Recruitment of participants took place between November 2011 and December 2014 and data collection was completed in March 2016. The flow of participants for Studies I, II and III is illustrated in Figure 4.

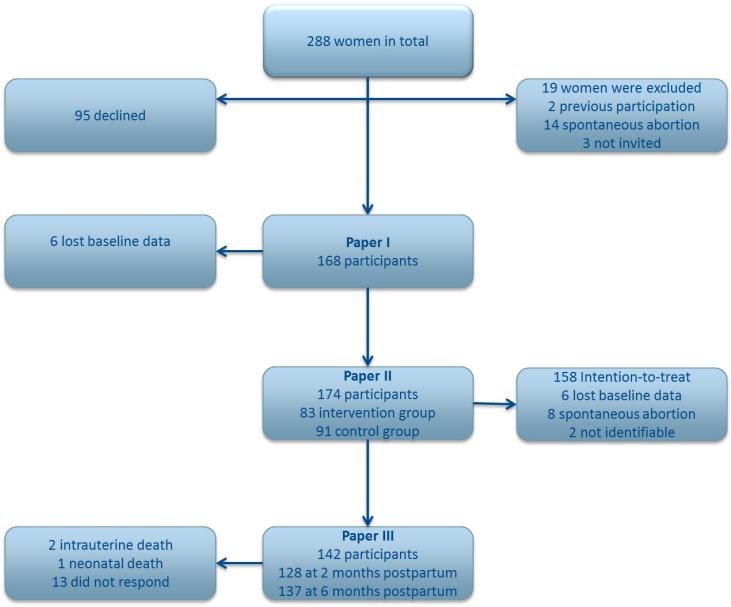

Figure 4. Flowchart of the participants in Studies I, II and III.

Study I

Of the 174 participants included in the study, baseline data was lost in six cases, making the total number of participants 168. The participants were regarded as a composite group regardless of group allocation in the RCT.

Study II

The 174 participants were allocated to the intervention group (n=83) or the control group (n=91). In the intervention group, baseline data were lost in two cases and three women had a miscarriage, leaving 78 participants for intention-to-treat analysis. In the control group, baseline data were lost in four cases, two participants identity was not registered correctly, and five women had a miscarriage, leaving 80 participants for intention-to-treat analysis. Participants were included in the per-protocol analysis for the intervention group (n=59) if they had at least two individual log-ins to the web-based support and had answered the questionnaire at six months postpartum, and for the control group (n=70) if they had answered the questionnaire at six months postpartum.

Group allocation

The participants were randomly allocated (1:1) to either the intervention group or the control group by a study midwife at one of the participating study centres. To allow for equal distribution between the groups, block randomization in blocks of ten (five to the intervention group and five to the control group) was used. Closed envelopes were prepared with a unique code consisting of a first code letter identifying each centre, a second code letter identifying which group it belonged to (intervention or control) followed by a consecutive number. The study midwife registered the participant's personal information and the obtained code letters/numbers in a key. The key connecting the code with the woman's personal information was stored in a safe location at the study centre, in accordance with that specific hospital's policy.

Study III

Of the 158 participants included in the intention-to-treat analysis, two suffered from intrauterine foetal deaths and one from a neonatal death. They were excluded from further data collection for ethical reasons, making the possible number of participants 155. Of these, 128 (82.5%) answered the questionnaires at two months and 137 (88.4%) at six months after childbirth. The participants were regarded as a composite group regardless of group allocation in the RCT.

Study IV

In Study IV the MODIAB-Web RCT is used as a case for a critical analysis. The 69 participants in the intervention group who had made at least one individual log-in to the web-based support were included in the analysis.

The demography of the participants in Studies I, II and III is presented in Table 2.

Table 2. Demography of the participants in Studies I, II and III.

	Study I	**Study II**		**Study III**
		Intervention group	Control group	
Total number	n=168	n=78	n=80	n=137
Age	30.8 (4.6), 31.0 (20.0; 45.0)	31.4 (4.8), 31.0 (20.0; 41.0)	30.2 (4.2), 30.0 (23.0; 42.0)	31.0 (4.5), 31.0 (20.0; 42.0)
Education				
Primary school	3 (1.8%)	1 (1.3%)	2 (2.5%)	3 (2.2%)
Secondary school	55 (33.1%)	24 (31.2%)	26 (32.5%)	41 (30.1%)
University	108 (65.1%)	52 (67.5%)	52 (65.0%)	92 (67.6%)
Diabetes duration	17.0 (8.3), 16.5 (0.3; 35.0)	16.9 (8.9), 17.0 (0.3; 35.0)	16.9 (7.5), 16.0 (2.0; 35.0)	17.0 (8.1), 17.0 (0.3; 35.0)
Parity				
Primi para	90 (54.2%)	41 (52.6%)	47 (58.8%)	78 (56.9%)

Mean (Standard deviation), Median (Min; Max) or number (percent)

6.2.2 Data sources

Socio-demographic data was collected at baseline assessment. Medical data was collected from electronic medical records and user data from the intervention was obtained by Google analytics. Questionnaires were distributed at baseline (in the first or early second trimester), in late pregnancy (around 32 gestational weeks) and at two and six months after childbirth. If the questionnaire was not returned within ten days, a reminder was given either by telephone or by mail.

Questionnaires

This study uses patient-reported outcome measures in terms of questionnaires. The use of questionnaires allows for comparison between groups and within groups over time. Due to respondents differing in reading level and ability to communicate in writing, it is important that the questions are clear and simple to understand. Quality in questionnaires can be assessed through *reliability* and *validity* that is assessed through psychometric evaluation.

Reliability refers to the amount of error that occurs systematically or randomly in any measurement or, in other words, the consistency of the measurement (108, 124). One way to assess reliability is to measure a questionnaire's *internal consistency* that refers to whether multiple items that intend to measure the same general construct yield similar scores. Other common assessments are inter-rater and intra-rater reliability.

Validity refers to whether a questionnaire measures what it is intended to measure. There are multiple ways of evaluating validity. Two of these are face validity and content validity. *Face validity* refers to whether the questionnaire appears to measure the target construct, for example, if it 'looks valid' to the person answering. Good face validity is said to have a positive effect on participation. However, face validity alone is not considered strong evidence of validity. *Content validity* refers to whether a questionnaire has an appropriate sample of items and whether they represent all facets of a given construct (108).

The questionnaires were distributed to the participants by post except for the baseline assessment, which was handed out by the study midwife. All used questionnaires are described in the following section.

The Well-Being Questionnaire Short form (W-BQ12)

The well-being questionnaire is a generic instrument generating a score for general well-being. It was developed in patients with diabetes and the original instrument consists of 22 items (96). The short version of the well-being questionnaire (W-BQ12) is a 12-item questionnaire resulting in three sub-scores: *negative well-being* (range 0-12) where the higher the score, the greater the sense of negative well-being, *energy* (range 0-12) where the higher the score, the greater the energy level, and *positive well-being* (range 0-12) where the higher the score, the greater the sense of positive well-being. The negative well-being score is reversed and then added to the energy and positive well-being scores to produce a total score for general well-being (range 0-36), where the higher the score, the greater the general well-being (125, 126). It has a Cronbach's alpha of >0.88 (126) and its validity is considered to be good. The instrument has been validated for use in patients with high risk pregnancies (127). No cut-off limits have been presented.

The Diabetes Empowerment Scale Short version (SWE-DES-10)

The diabetes empowerment scale, short Swedish version (SWE-DES-10) (62) has 10 items divided into four factors: *goal achievement*, *self-awareness*, *stress management* and *readiness to change.* It uses five-point Likert scales ranging from strongly disagree to strongly agree. Higher values indicate stronger empowerment with a total score of 1-5. No general cut-offs have been presented. This validated instrument is based on the Swedish 23-item version (which originates from the American Diabetes Empowerment scale). SWE-DES is considered acceptable in terms of reliability; Cronbach's alpha ranges from 0.68 to 0.91 in the 23-item version of the scale (128, 129). The English short version contains 8 items and has a Cronbach's alpha of 0.84-0.85 (130). In this thesis, diabetes empowerment is interpreted as a measure of self-efficacy in diabetes management.

Self-perceived health (EVGFP)

Self-perceived health was measured through a single-item Likert scale with the values: excellent, very good, good, fair or poor. The lower the score, the better the self-perceived health (EVGFP). EVGFP is said to be a notable predictor of health outcomes and has been used successfully for this purpose since 1972 (131).

The Swedish Problem Areas in Diabetes Scale (SWE-PAID-20)

The Swedish Problem Areas in Diabetes Scale (SWE-PAID-20) provides a score of 0 to 100 measuring diabetes distress. The questionnaire consists of 20 items and the patient rates the degree to which each item is currently a problem for them, ranging from "Not a problem" to "Serious problem". A higher score indicates greater emotional distress and the cut-off score is suggested to be equal to or more than 40. The reported Cronbach's alpha score is 0.94 (132).

The 13-item Sense of Coherence Scale (SOC-13)

The 13-item Sense of Coherence Scale (SOC-13) provides a total score for sense of coherence and three sub-scores: *Meaningfulness*, *Comprehensibility*, and *Manageability*. Each item is scored on a Likert scale from 1 (low) to 7 (high), giving a possible range of 13-91 (133, 134). The scale is recognized as a reliable and valid instrument that can be applied across different cultures and has a range of Cronbach's alpha from 0.70 to 0.92 in 127 studies (134). A cut-off score of 60 or less is considered to be low, 61-75 is considered to be moderate and ≥76 is considered to be high in terms of sense of coherence (135).

The Swedish Hypoglycaemia Fear Survey (SWE-HFS)

The Swedish Hypoglycaemia Fear Survey (SWE-HFS) consists of 20 items rated on a five-point Likert scale ranging from "never" to "always" with a total sum score of 0-80. A high score indicates greater hypoglycaemia fear but no cut-off scores has been presented (136, 137). The reported Cronbach's alpha coefficient is 0.85 (136).

A questionnaire regarding breastfeeding and diabetes management after childbirth

The research group constructed a 13-item questionnaire regarding breastfeeding and diabetes management after childbirth since no validated questionnaire that captured these issues in relation to each other was found. Some of the items are positively scored and some negatively. No total score has been proposed and the validity and reliability of the self-constructed questionnaire has not been tested. The questions were pilot-tested for face validity before data collection started.

A questionnaire for evaluation of the web-based support

A structured questionnaire consisting of 14 items evaluating *Functionality*, *Information and content*, and *Communication* in the web-based support was constructed by the research group. Possible answers were: *disagree*, *neither nor*, *agree* or *did not use this function*. The questionnaire also contains a free text alternative.

An overview of the questionnaires used in Studies I-III is given in Table 3.

Table 3. Overview of the questionnaires used in Studies I-III.

	Study I	Study II	Study III
The Well-Being Questionnaire Short form (W-BQ12)	X	X	X
The Diabetes Empowerment Scale Short version (SWE-DES-10)	X	X	X
Self-perceived health (EVGFP)	X	X	
The Swedish Problem Areas in Diabetes Scale (SWE-PAID-20)	X	X	
The 13-item Sense of Coherence Scale (SOC-13)	X	X	X
The Swedish Hypoglycaemia Fear Survey (SWE-HFS)	X	X	
Questionnaire regarding breastfeeding and diabetes management after childbirth			X
Questionnaire for evaluation of the web-based support		X	

Missing data in the W-BQ12 questionnaire was handled according to the guidelines (129). In all the other psychometrically evaluated questionnaires a half-scale approach was undertaken, meaning that at least half of the items included in the total score needed to be answered in order for the total score

to be calculated. Missing values were imputed with the mean of the valid items in order to calculate a total score (124).

6.3 Data analysis

6.3.1 Statistical methods

All data was inserted into IBM SPSS Statistics version 22.0 and analysed in IBM SPSS Statistics version 16.0 and 22.0 and SAS, version 9.2.

All significance tests were conducted at the 5% significance level, meaning that the null hypothesis was only rejected if the effect of interest was greater.

A correlation coefficient indicates the strength of the correlation as a number between zero to one. It does not show cause and effect. Correlation effect size was categorized according to Cohen (138) and a correlation coefficient of .10 is said to represent a weak or small association, a correlation coefficient of .30 a moderate or medium association, and a coefficient of .50 or higher a large or strong association. According to Polit and Beck (108), psychosocial variables are typically in the 0.20 to 0.40 range.

The respective statistical analysis performed for each study is reported below.

Study I

Descriptive statistics (mean, standard deviation, median, minimum and maximum) for continuous variables and number and percent for categorical variables were presented. For comparison between two groups, the Mann-Whitney's U test was used for continuous variables, the Mantel-Haenszel Chi Square Exact test was used for ordered categorical variables, and Fisher's Exact test was used for dichotomous variables. Associations between variables were calculated with Spearman's correlation coefficient.

Study II

Descriptive statistics (mean, standard deviation, median, minimum and maximum) for continuous variables and number and percent for categorical variables were presented. In addition, the 25^{th} and 75^{th} percentile are presented for continuous variables in the evaluation of the forum for peer support. For comparison between two groups, the Fisher's nonparametric permutation test was used for continuous variables, the Mantel-Haenszel Chi Square Exact test was used for ordered categorical variables, Fisher's Exact

test was used for dichotomous variables, and the Chi square test was used for non-ordered categorical variables. For comparison within groups over time, the Wilcoxon Signed Rank test was used for continuous variables and the Sign test was used for ordered categorical variables. To adjust for significant differences between baseline characteristics (e.g. insulin delivery) a complementary analysis of covariance was performed. A dose-response analysis was conducted using the Jonckheere-Terpstra test. Intention-to-treat analysis was performed using last observation carry forward between the two-month follow up and the six-month follow up in seven cases. The per-protocol criteria were two individual logins to the web-based support and a completed questionnaire at six months after childbirth in the intervention group and a completed questionnaire at six months after childbirth in the control group.

Study III

Descriptive statistics (mean, standard deviation, median, minimum and maximum) for continuous variables and number and percent for categorical variables were presented. For comparison within groups over time, the Wilcoxon Signed Rank test was used for continuous variables; otherwise the sign test was used. Associations between variables were calculated by Spearman's correlation coefficient.

Study IV

Descriptive statistics (mean and standard deviation) were presented for continuous variables and number for categorical variables.

6.3.2 Critical analysis

In Study IV the MODIAB-Web RCT was used as a case that was analysed using the PSD model (113) as a framework for deductive analysis. The model contains a typology for design of technology with the intention to affect peoples' behaviour – the "Persuasive Systems Design". To critically analyse and discuss the challenges of doing an RCT using web-based technology, including devices for social support and with special focus on adherence, four research questions were constructed:

1. What persuasive content and technological elements were used in the design of the web-based support?

2. How was the web-based support used?

3. What was the content of the social peer support and how did the peers support each other?

4. What were the main challenges in relation to adherence to the RCT?

The fourth research question was answered based on the findings from the first three research questions. Adherence was defined as the intended usage in line with the therapeutic regime, in accordance with Kelders et al. (139). An exploratory case study design (112) was used to answer the research questions. Narratives shared in the forum for peer support were analysed by inductive content analysis (140). In this content analysis, the interactions of the study facilitator were included. Initially, the forum posts were read several times to get an overall 'feel' for the data. Then, sections relating to each other were identified and notes were written in the margins as 'headings'. The 'headings' were transferred to a separate coding sheet where they were grouped into categories. The categories were presented under the pre-set topics of Pregnancy, Childbirth and Life as a new mother. The quotations used to illustrate the dialogue in the forum for peer support were professionally translated into English.

7 ETHICAL CONSIDERATIONS

The design and implementation of the studies in this thesis were conducted in accordance with ethical guidelines and principles. To ensure that the basic ethical principles of research involving human subjects were met, the studies complied with the World Medical Association's Declaration of Helsinki (141). The principles state that research should be conducted with *respect* for the individual and their autonomy (including protection of those with diminished autonomy) and aim to *benefit* (minimize the harm) and follow the principle of *justice* (recruitment of participants in a non-discriminatory fashion). Further, all participation should be voluntary and be preceded by informed consent. The patient has the right to decline participation or discontinue their participation at any time without having to specify a reason.

All participants were given oral and written information about the study, including the fact that participation was voluntary and that they could withdraw from the study at any time. Confidentiality was guaranteed in the presentation of the findings. Informed consent was obtained before baseline assessment commenced and ethical approval was given by the Ethics Committee of Gothenburg, Sweden (No. 659-09).

Pre-registration of clinical trials before the start of data collection is recommended. It promotes transparency in the research process and should ideally contain information about predictions, measures, analyses, and how sample size was determined. Pre-registration allows the public and other stakeholders to find publicly and privately supported clinical studies on a wide range of conditions. It also appears to have a positive effect on publishing of null findings from clinical trials (142), an important ethical aspect. The MODIAB-Web study was registered at Clinicaltrials.gov with identification number NCT01565824.

During the study period, some participants found themselves in a vulnerable situation. Those who suffered a miscarriage were offered evidence-based information about their pregnancy loss (143). In total, three participants lost their children: two by intrauterine foetal death and one by neonatal death. These participants were cared for by healthcare professionals according to each participating hospital's routine. No postpartum questionnaires were posted to them for ethical reasons. Participants who provided answers to the questionnaires indicating low well-being or high distress were contacted and offered support. For example, the research team assisted one participant by scheduling an appointment with her ordinary (pre-pregnancy) diabetes team.

8 RESULTS

A summary of the results for each study included in the thesis will be presented in the following section, followed by a summary.

8.1 Study I

The results for the first study show that women with T1DM in early pregnancy (mean 11.2, SD 4.8 weeks of gestation) report relatively high scores of self-efficacy in diabetes management (SWE-DES-10: 3.91 (0.51)). The majority rated their self-perceived health as high (excellent (6.5%), very good (42.3%), good (38.7%), fair (11.3%) and poor (1.2%)). Further, what can be interpreted as moderate scores were reported in terms of general well-being (W-BQ12: 22.6 (5.7)) and moderate scores for sense of coherence (SOC-13: 68.9 (9.7). Regarding fear of hypoglycemia, relatively low/moderate scores were reported (SWE-HFS 26.6 (11.8)) and the scores of diabetes distress were low (SWE-PAID-20 27.1 (15.9)).

The majority of the participants (72%) had an HbA1c above the recommended limit of ≤ 48 mmol/mol or 6.5% in early pregnancy. A higher capability of self-efficacy in diabetes management showed positive correlations with self-perceived health (r_s = -0.41, p < 0.00) and general well-being (r_s = 0.34, p < 0.00) along with negative correlations with diabetes distress (r_s = -0.51, p < 0.00) and hypoglycemia worries (r_s = -0.27, p = 0.00). A lower HbA1c correlated with a higher score for general well-being in terms of W-BQ12 (r_s = 0.17, p = 0.03) and with the SWE-DES-10 sub-score goal-achievement (r_s = -0.24, p = 0.00). Women with HbA1c levels below the recommended limit (≤ 48 mmol/mol or 6.5%) scored higher in the subscales "goal achievement" in SWE-DES-10 (p = 0.00) and "comprehensibility" in SOC (p = 0.01).

8.2 Study II

The results for the second study show no differences in regards to the primary outcome measure scores, general well-being measured by W-BQ12 [mean difference 1.04 (95% CI, -1.28 to 3.37), p= 0.68] and self-efficacy of diabetes management measured by SWE-DES [mean difference 0.08 (95% CI, -0.12 to 0.28), p= 0.75] after adjustment for baseline differences in the insulin

administration method. No differences between the groups were found in relation to the secondary outcome measures of self-perceived health, diabetes distress, sense of coherence and hypoglycemia fear. Similarly, there were no differences in the results from the per protocol analysis where the W-BQ12 mean score was 23.9 (intervention group) vs 22.7 (control group) [mean difference 1.04 (95% CI, -1.28 to 3.37), p= 0.39] and SWE-DES-10 mean score was 3.92 (intervention group) vs. 3.82 (control group) [mean difference 0.08 (95% CI, -0.12 to 0.28), p= 0.69]. The change in scores between the different times of measurement is presented in Table 4.

Table 4. The change in scores between early and late pregnancy, early pregnancy and 2 months after childbirth, and early pregnancy and 6 months after childbirth (intervention group versus control group).

	Early pregnancy to late pregnancy		Early pregnancy to two months postpartum		Early pregnancy to six months postpartum	
	Mean difference between groups (95% CI)	p/ adj p†	Mean difference between groups (95% CI)	p/ adj p†	Mean difference between groups (95% CI)	p/ adj p†
Primary outcomes						
Well-being 12-item questionnaire (0–36)	2.28 (0.52;4.04)	0.01/ 0.01	2.19 (0.18;4.20)	0.03/ 0.02	1.25 (-0.46;2.95)	0.15/ 0.10
Swedish Diabetes Empowerment Scale, short version (1–5)	-0.00 (-0.16;0.15)	0.95/ 0.90	-0.07 (-0.23;0.09)	0.40/ 0.38	-0.04 (-0.18;0.10)	0.58/ 0.61
Secondary outcomes						
Sense of Coherence 13-item questionnaire (13–91)	0.64 (-2.18;3.46)	0.65/ 0.39	0.13 (-2.85;3.12)	0.93/ 0.83	-1.17 (-4.41;2.06)	0.47/ 0.47
Swedish Problem Areas in Diabetes Scale (0–100)	-0.79 (-5.24;3.67)	0.73/ 0.70	-4.23 (-9.15;0.68)	0.09/ 0.11	-1.70 (-5.90;2.49)	0.42/ 0.48
Swedish Hypoglycemia Fear Survey (0–80)	-0.88 (-3.60;1.83)	0.52/ 0.31	1.09 (-2.28;4.46)	0.52/ 0.56	1.62 (-1.46;4.71)	0.30/ 0.27
Self-perceived Health (Excellent, Very Good, Good, Fair, Poor)		0.33/ 0.29		0.83/ 0.77		0.48/ 0.62

ANCOVA was performed for continuous variables and the Mantel-Haenszel chi square exact test was used for ordered categorical variables.
† p-value adjusted for insulin administration method.

A significant difference between groups in terms of change regarding general well-being (W-BQ12) between early and late pregnancy and early pregnancy and 2 months after childbirth is presented in Table 4. However, this difference did not remain after adjustment for its own baseline value (p=0.08 and p= 0.16).

In an evaluation of the adherence to the web-based support, a wide variation in usage was found. Of the 78 participants who made up the population in the intention-to-treat analysis for the intervention group, 67 were considered active users (meeting the criteria of two individual logins) – see Figure 5. At six months postpartum, a consistent pattern appeared, showing a descriptive difference in the psychosocial measures and favouring a higher use of the intervention (Figure 5).

Intervention adherence All participants (*N*=78)	Median (min.; max.)	25th/75th percentile
Total logins to the system (*n*=67)*	91 (2; 6413)	19.75/214.25
Visits to facts page	8 (0; 508)	3/26
Number of entries to the self-care diary	1 (0; 5850)	0/25.25
Visits to the forum	54 (0.0; 703)	7/125

Outcome variables divided by level of intervention use 6 months after childbirth

Participants (*N*=78)	No/low usage† *n*=17	Medium usage‡ *n*=42	High usage§ *n*=19	*P*
W-BQ12 (score range 0–36)	*n*=14	*n*=38	*n*=17	0.28
Mean (SD)	21.5 (5.4)	23.3 (6.4)	24.7 (5.2)	
Median (min.; max.)	22.5 (15; 31)	24 (10; 35)	25 (13; 34)	
SWE-DES-10 (score range 1–5)	*n*=14	*n*=38	*n*=17	0.37
Mean (SD)	3.7 (0.7)	3.9 (0.5)	4.0 (0.5)	
Median (min.; max.)	3.9 (2; 5)	4 (3; 5)	4 (3; 5)	
SOC-13 (score range 13–91)	*n*=14	*n*=38	*n*=17	0.37
Mean (SD)	67.8 (11.5)	67.0 (11.8)	71.3 (8.9)	
Median (min.; max.)	65 (48; 84)	68 (47; 89)	72 (51; 85)	
SWE-PAID-20 (score range 0–100)	*n*=14	*n*=38	*n*=17	0.15
Mean (SD)	32.1 (20.5)	29.2 (20.2)	22.5 (16.0)	
Median (min.; max.)	30 (4; 86)	26 (0; 70)	17.5 (5; 58)	
SWE-HFS (score range 0–80)	*n*=14	*n*=38	*n*=17	0.14
Mean (SD)	27.8 (10.2)	26.7 (13.6)	21.9 (10.2)	
Median (min.; max.)	27.5 (11; 43)	28.5 (2; 66)	23 (4; 40)	

SOC-13, 13-item Sense of Coherence questionnaire; SWE-DES-10, Swedish Diabetes Empowerment Scale, short version; SWE-HFS, Swedish Hypoglycaemia Fear Survey; SWE-PAID-20, Swedish Problem Areas in Diabetes Scale; W-BQ12, 12-item well-being questionnaire.
For comparison between groups the Jonckheere–Terpstra test was used.
*Eleven participants did not meet the criteria of two individual logins to the system.
Groups for the dose–response analysis were calculated using percentiles as cut-offs in the following way: †Below the 25th percentile; <9. ‡25th to 75th percentile; 9–191.75. §Above the 75th percentile; ≥ 192.

Figure 5. Intervention adherence and psychosocial outcome measures divided by intervention use. Re-printed under a Creative Commons Attribution-NonCommercial License. Originally published in Diabetic Medicine 2017 (144).

The questionnaire for evaluation of the web-based support was answered by 65 participants. Technical difficulties were infrequent but some functional

problems were reported. In the written comments to the questionnaire, the high demands of daily life in caring for the new born child and simultaneously managing diabetes were given as explanations for low use.

8.3 Study III

The results for the third study show that the majority of the participants had fairly high levels of general well-being and diabetes management at both two and six months postpartum. Moderate scores for sense of coherence were reported. However, a sense of coherence categorized as low was found in around a quarter of the participants (24.4% at two months and 27.0% at six months) after childbirth. Almost all had a positive or fairly positive experience of breastfeeding and the breastfeeding rate was 78.6% (74.0% exclusively) at two months and 53.0% (28.6% exclusively) at six months postpartum. Despite this, about half of the participants stated that breastfeeding had a negative impact on daily diabetes routines to a high degree or to some extent (46.8% at two months and 46.9% at six months). Around one-third of the women stated that they had received too little support or that they needed more support from health care professionals in order to manage their diabetes (33.6% at two and 38.0% at six months).

A higher degree of general well-being (W-BQ12) (r_s 0.30, $p<0.01$), sense of coherence (SOC-13) (r_s 0.25, $p<0.01$) and sense of self-efficacy of diabetes management (SWE-DES-10) (r_s 0.23, $p<0.05$) correlated with less negative impact of breastfeeding on daily diabetes routines at two months postpartum. Participants with a higher score of general well-being, sense of coherence and sense of self-efficacy of diabetes management received the needed support from health care professionals in order to manage their diabetes during the breastfeeding period to a higher degree at both two months (W-BQ12: r_s -0.26, $p<0.01$; SOC-13: r_s -0.26, $p<0.01$; SWE-DES-10: r_s -0.30, $p<0.01$) and six months (W-BQ12: r_s -0.22, $p<0.05$; SOC-13: r_s -0.37, $p<0.01$; SWE-DES-10: r_s -0.44, $p<0.01$) postpartum. Further, a higher score of general well-being (r_s 0.28, $p<0.01$), sense of coherence (r_s 0.23, $p<0.05$) and self-efficacy of diabetes management (r_s 0.24, $p<0.01$) correlated with less need for support from family members to manage their diabetes.

8.4 Study IV

Study IV aims to critically examine the MODIAB-Web study, with special focus on technology for increased adherence and social support, as well as conducting web-based interventions in the form of RCTs. The PSD model

was used as a framework for the analysis. Implemented design principles in the web-based support in the categories *Primary Task Support*, *Dialogue Support*, *System Credibility Support* and *Social Support* were identified.

Due to inclusion pace and randomization effects, a maximum of 36 participants could have access to the web-based support at any given time. The forum for peer support was visited by 62 participants and one study facilitator, a mother with T1DM, who was appointed by the research group in the first year of the intervention. Almost all activity in the forum for peer support occurred in the first three years (2011-2014). Although only 23 participants and the study facilitator actively posted in the forum for peer support, there was a rich exchange in their interactions. Some improvements in relation to social support could have been implemented, however. Considering the low number of participants with simultaneous access to the web-based support, the study facilitator should have been used for the whole study period, as the activity level in the forum dropped when she left. However, we argue that there is a potential for social support by using web-based technologies in RCTs, even in cases of limited participation in quantitative terms. The majority of the participants were active readers and therefore in this sense received social support.

A critical mass of simultaneous active users was not achieved and therefore undermined the extent of interactions in the forum for peer support. One shortfall in the study design was that the study facilitator was not engaged beyond the initial year. A threat to adherence and a methodological weakness in studies evaluating web-based social support is that it is almost impossible to control if participants choose to communicate in alternative ways outside of the study platform.

8.5 Summary

Studies I, II and III all report on patient-reported outcome measures at different time points. A summary of these outcome measures is presented in Table 5. Approximately a quarter of the participants experienced a low sense of coherence (19-27%) and high diabetes distress (22-25%) during the study period.

Table 5. Summary of patient-reported outcome measures in early and late pregnancy and at two and six months after childbirth.

	Early pregnancy	Late pregnancy	2 months postpartum	6 months postpartum
General Well-being W-BQ12 (0-36)	n=168 22.6 (5.7) 23.5 (5; 33)	n=131 22.4 (5.7) 23 (6; 36)	n=127 22.6 (6.3) 24 (7; 35)	n=137 23.1 (6.3) 25 (5; 35)
Self-efficacy of diabetes management SWE-DES-10 (1-5)	n=167 3.9 (0.5) 4 (2.2; 5)	n=130 4.0 (0.5) 4 (3; 5)	n=128 3.9 (0.6) 3.9 (2; 5)	n=137 3.8 (0.6) 3.9 (2; 5)
Sense of Coherence SOC-13 (13-91)	n=168 68.9 (9.7) 71 (38; 88)	n=131 68.6 (10.6) 70 (36; 88)	n=127 68.5 (12.0) 71 (39; 86)	n=137 67.1 (13.0) 69 (23; 89)
Low SOC ≤60	32 (19.0%)	30 (23.1%)	31 (24.4%)	37 (27.0%)
Medium SOC 61-75	88 (52.4%)	61 (46.9%)	54 (42.5%)	56 (40.9%)
High SOC ≥76	48 (28.6%)	39 (30.0%)	42 (33.1%)	44 (32.1%)
Diabetes distress SWE-PAID-20 (0-100)	n=148 27.1 (15.9) 23.8 (0; 71.3)	n=128 26.7 (18.0) 23.8 (0; 83)	n=125 26.4 (19.0) 21.3 (0; 80)	n=137 27.9 (19.3) 25 (0; 86)
High diabetes distress ≥40	36 (24.3%)	32 (25.0%)	27 (21.6%)	34 (24.8%)
Hypoglycemia fear SWE-HFS(0-80)	n=144 26.6 (11.8) 25 (4; 61)	n=128 24.6 (10.4) 24.5 (2; 50)	n=126 27.7 (13.1) 27 (2; 72)	n=137 27.0 (12.8) 27 (2; 66)
Self-perceived health	n=168	n=130	n=128	n=137
Excellent	11 (6.5%)	12 (9.2%)	17 (13.3%)	14 (10.2%)
Very good	71 (42.3%)	56 (43.1%)	50 (39.1%)	52 (38.0%)
Good	65 (38.7%)	39 (30.0%)	38 (29.7%)	44 (32.1%)
Fair	19 (11.3%)	16 (12.3%)	18 (14.1%)	19 (13.9%)
Poor	2 (1.2%)	7 (5.4%)	5 (3.9%)	8 (5.8%)

Mean (Standard deviation), Median (Min; Max) or number (percent)

Regarding Study IV, the MODIAB-Web RCT was well planned but lacked theoretical basis in the form of a model for the technological design or the use of design principles of a more general kind. One advantage of using such a model is insights into a greater repertoire of design options based on practical and theoretical knowledge outside of the local project group. The use of design theory in the form of the PSD model in the analysis of the MODIAB-Web intervention enabled a discussion of the rationale behind the use of the categories of the PSD model and unutilized potential in its design principles.

9 DISCUSSION

The findings from the studies confirm that well-being and diabetes management are indeed closely related during pregnancy and postpartum for women with T1DM. The findings indicate that the majority of the women scored fairly high in terms of well-being and diabetes management, not only during pregnancy but also postpartum (Studies I, II and III). This is encouraging and somewhat contradicts previous findings that indicated a slight deterioration in well-being postpartum (42, 53). Nevertheless, about a quarter of the women experienced a low sense of coherence and high diabetes distress and around a third of the participants needed more professional support in order to manage their diabetes postpartum.

It would therefore be a mistake to interpret these findings as a suggestion that postpartum care for women with T1DM is sufficient in its current form. The Saint Vincent declaration (1) established that pregnancy outcomes should be comparable to those without diabetes. The declaration referred to medical outcomes but there is no reason why person-reported outcomes of psychosocial parameters could not be included in this aim. It is unclear how well-being is experienced by women in general during the childbearing period and the MODIAB-Web study lacks a control group of women without diabetes. However, previous studies have shown that women with T1DM experienced lower vitality (55) and were more worried about their health postpartum (56) compared to women without diabetes.

Although the majority of the participants had acceptable scores, the lack of cut-off scores for most questionnaires means that the results are difficult to interpret. It is difficult to determine ‘how low’ the scores in the lower range are. Self-perceived health is measured in the Swedish Pregnancy Register; however, the offered response options differ slightly between the register and the MODIAB-Web study. During late pregnancy, 82.3% of the participating women in our study stated that they perceived their health as excellent, very good or good (Table 5) and in the general maternal population, 78.0% perceived their health as very good or good (excellent was not a response option). Postpartum the numbers were reversed and 82.1% of the women with T1DM answered that their health was excellent, very good or good (Table 5) while 91.5% of the women in the general maternal population stated that their health was very good or good (145). These findings are strengthened by the previously mentioned studies (55, 56) that also found a difference compared with a population of women without T1DM. This discrepancy between women with T1DM and women in the general

maternity population postpartum is a cause for concern. Regarding sense of coherence, previous research has identified an association between low sense of coherence during pregnancy and higher parental stress postpartum (146). Pregnant women with a low sense of coherence appear to be more vulnerable compared to those with moderate and high levels of sense of coherence. The proportion of participants with a low sense of coherence increased from 19% in early pregnancy (Study I) to 27% at six months after childbirth (Study III), see Table 5. This could be an indication of insufficient support after childbirth. Women with a low sense of coherence appear to be more exposed postpartum and it is worrisome that more women are experiencing this vulnerability after childbirth when the professional support that surrounded them during pregnancy has ceased. This, together with the fact that one-third (Study III) requested more professional support to manage their diabetes, suggests that there is a group of more vulnerable women with T1DM whose needs are currently not being met by the health care system.

The web-based intervention provided in the MODIAB-Web study did not prove successful in increasing general well-being and self-efficacy of diabetes management in users at six months postpartum (Study II). The reasons for this may be multiple. The difficulties of designing and implementing web-based interventions are discussed in detail in Study IV. The adherence to the intervention after childbirth did not take off as anticipated (Studies II and IV). Whether this was due to unsatisfactory content in the support, poor response in the forum for peer support or stressors of motherhood and managing diabetes at the same time, or a combination of numerous factors, is difficult to determine. It is possible that the web-based support had some effect that was not captured with the outcome measures, although they were multiple. A consistent descriptive difference in psychosocial measures appeared, favouring a higher degree of use at 6 months after childbirth (Study II). Although not statistically significant and therefore not demonstrable, this trend might be an indication of some effect of the web-based support. Also, no changes were analysed on an individual level and effects might have occurred on such a basis. Regardless of the intervention study's lack of effect (Study II), new knowledge about well-being and diabetes management in women with T1DM during pregnancy and postpartum was generated (Studies I, II and III).

Well-being can be defined as a balance between a person's psychological, social and physical resources and challenges (93). Social support provided to women with T1DM during the childbearing period has the potential to influence all of these factors (79-83). House (86) states that social support entails the offering of empathy and taking a genuine interest in a person,

offering aid or direct assistance and advice or helpful suggestions, as well as information and constructive feedback. It is possible to make use of specific technological elements when designing web-based interventions to facilitate social support (Study IV). Health care professionals have a unique position to mobilize and offer social support to women with T1DM during the childbearing period. Berg (147) has constructed a model of care for women of high risk pregnancies: Genuine Caring in Caring for the Genuine, in which she describes ideal midwifery support. A *dignity-protective* action takes place if a caring relationship based on mutuality, trust, ongoing dialogue, enduring presence and shared responsibility is formed. To achieve this, the midwife uses her *embodied knowledge.* This knowledge is gained by the midwife being genuine towards herself and having sound theoretical and practical knowledge, as well as an intuitive and reflective practice. The midwife may safeguard the woman's capacity to give birth in a natural manner by *balancing the natural and medical perspectives*. This does not mean ignoring the risks involved; rather it means remaining sensitive to pregnancy and birth as a genuine, normal process. This model was developed for midwifery support, although aspects of it may be applied to caring situations with different types of health care professionals and to other settings such as web-based support.

The balancing act between pregnancy and birth as a normal process and the risks involved with T1DM was apparent in the MODIAB-Web intervention. The users of the forum for peer support discussed how healthcare professionals sometimes focused too much on the condition of diabetes and medical risks during visits and that this overshadowed the joyful parts of maternity care (Study IV). To safeguard a smooth transition to motherhood in women with T1DM, special care ought to be taken in balancing healthy and normal processes with medical risks and complications. This also relates to the web-based support in the MODIAB-Web study. For example, the evidenced-based information was an important part of the web-based support (Study II), the idea being to complement other available maternity information with specific content relevant to the users. Despite being developed with women with T1DM (122), it is possible that the support lacked balance in this aspect. Even though the authors who developed the information took a holistic approach, the fact that all the information was adapted to diabetes might have meant focus shifted towards risk-awareness rather than the normality of pregnancy. One way around this could have been to incorporate more general information texts focusing on positive aspects of childbearing and perhaps to be more selective of images portraying a normal healthy process.

Different approaches may be taken to ensure that the social support offered by health care professionals truly protects the dignity of the woman. As described by Lorig and Holman (105), self-management of chronic conditions involves managing both emotional and medical issues while navigating the role of adapting certain aspects of life according to the demands of the condition. It is common for relationships between a professional and a person needing help to be unbalanced in terms of power (148). This asymmetrical power balance between a patient and a health care professional can be described as threefold. A person is disadvantaged by the institutional, existential and cognitive aspects of being a patient (149). Person-centred care offers an alternative to the paternalistic model of traditional medicine, as does an empowering patient-provider relationship. The concepts may appear idealistic but as research progresses they become more tangible, useful and easier to apply.

The self-management skills identified by Lorig and Holman (105) could likely be fortified by social support from both peers and health care professionals. Even though no effects on well-being and diabetes management could be demonstrated in Study II, there is potential in person-centred web-based social support interventions. If they offer a contact area for the user and the health care provider, they may bridge communication between clinical settings and the woman's home environment and foster a reciprocal partnership in care (150). A study examining needs of web-based support in childbearing women with T1DM identified that it was seen as desirable to be able to initiate contact with health care providers through web-based support (71). We were unable to provide such communication when the study commenced, as the technological solutions were not yet in place. Today, the use of secure servers and e-ID would make this possible. A scoping review of person-centred web-based communication in persons with chronic conditions concludes that the provision of person-centred care through web-based platforms is possible but that it needs to be further explored in terms of how to improve self-management (151). A web-based intervention for women with T1DM that offers person-centred care through contact with health care professionals during pregnancy but also postpartum may well prove successful in improving diabetes management.

As previously discussed, an indication of slight improvement in the psychosocial measures following a higher use of the intervention at six months postpartum was seen descriptively but was not statistically demonstrated (Figure 5). This is interesting and strengthens the idea that web-based support could be beneficial to women with T1DM after childbirth. Supposing such an effect did exist, its direction is nevertheless unclear. Was

it the web-based support that improved the psychosocial outcome measures or is it high-functioning women who have the energy to use the web-based support to a high degree? This is an important aspect of any research. If an intervention is provided, does it really benefit those who are in need of it most? The findings from this thesis do not provide an answer. The question is also an important one in terms of adherence to web-based interventions. Who adheres to the intended usage and who does not? Beyond the critical analysis in Study IV, are there any strategies to improve adherence in groups of more vulnerable users who potentially could have a greater benefit from participation?

One aspect arising during the study period was the explosion of technological advances in general and specifically in relation to diabetes. This had implications for the study (Studies II and IV) but likely also represents a new era in diabetes management which has implications for women with T1DM during pregnancy as well as postpartum. When data collection was initiated, continuous glucose monitoring was available but not commonly used. Flash glucose monitoring was introduced in Sweden during the study period.

A Cochrane review from 2017 examining techniques of monitoring blood glucose during pregnancy did not find evidence supporting superiority of any blood glucose monitoring technique but also concluded there was a lack of well-designed studies (152). However, the results of an RCT study examining the effects of continuous glucose monitoring in women with T1DM during pregnancy (published after the Cochrane review) *did* find improved neonatal outcomes in the group using continuous glucose monitoring (153). These findings, if replicated, may potentially have a big impact on both well-being and diabetes management since the main focus of the women is having healthy children and many of the challenges are related to striving for normoglycemia (38, 40, 41). Technical advances might assist diabetes management. If some of this pressure was eased, both the psychological and physical challenges to well-being would be less difficult to overcome, thus having a potentially stabilizing effect on well-being during pregnancy. Recent qualitative research on women with T1DM in early motherhood describes new technology in regards to blood glucose monitoring as being of utmost importance to the women. Further, it was found that continuous glucose monitoring and related technology increased women's freedom and freed up time to care for the child (154). Unfortunately, the mode of glucose monitoring was not always documented in the pregnancy medical records at the start of the study, rendering any type of retrospective analysis in this regard potentially unreliable.

The use of modern technology for glucose monitoring represents ‘a new playing field’, especially during pregnancy. The use of continuous or intermittent glucose monitoring has great potential to improve diabetes management – and by extension, well-being – but there are potential pitfalls in its use. Further research is needed on the psychological impact of stress that may occur by receiving continuous information and the potentially frequent urge to act on this information. This might be particularly important to the group of more vulnerable women (around 25-30%) who experience poor well-being and/or struggle with diabetes management and need extensive professional support during pregnancy and postpartum. A possible way to promote a positive transition to motherhood in women with T1DM is to find a means of identifying this vulnerable group during pregnancy and to extend professional support after childbirth.

10 METHODOLOGICAL CONSIDERATIONS

The main study in this thesis (MODIAB-Web) had an experimental, multi-centre design, was pre-registered and the statistical analysis plan was set before locking the database and commencing data analysis. Moreover, the study was conducted in accordance with the CONSORT statements (111). Nevertheless, there are some methodological weaknesses that need to be addressed.

Validity is the main criteria for quality in research conducted with quantitative methodology (108). The following section will address the different aspects of validity that are applicable to Studies I, II and III.

Internal validity refers to how likely it is that an independent variable and not any other factor truly causes the effect in the dependent variable (108). In the MODIAB-Web RCT (Study II), 288 pregnant women with T1DM were assessed for eligibility and 95 declined participation. Since there was no analysis of non-responders, one must consider the possibility of selection bias. Considering the amount of pressure that pregnant women with T1DM face, it is possible that the women who agreed to participate in the study were those who experienced better health and had greater control over their diabetes in early pregnancy.

Internal validity was also threatened by, the long inclusion time. When the study was initiated in 2011, personal use of smartphones was limited, as was the utility of digital resources in diabetes care. Technology to improve care for pregnant women and mothers with T1DM developed rapidly (155) during the study duration and became available to all of the participants, including those in the control group. However, the group allocation of the experimental design meant this particular threat was subdued, as changes were likely to affect each study group in an equal manner, but it still risked partially undermining the intervention's effectiveness.

Outcome measures were analysed on an intention-to-treat basis to strengthen the internal validity. We also conducted a per-protocol analysis. Here we acknowledge that there are problematic aspects to such an approach, mainly because self-selection affects the comparison between groups.

In Studies I and III the relatively weak correlations need to be taken into account when interpreting the findings. A correlational design in itself is susceptible to threats in terms of internal validity (108). The associations

found should be interpreted as exploratory and hypotheses-generating and need to be confirmed in other studies with a different research methodology.

External validity refers to whether the relationships found in a study also hold true in other settings outside of the strictly controlled research setting (108). In terms of the representativeness of the study sample, the multi-centre approach increased the generalizability of the findings. In terms of replication, the multi-site design is also said to be beneficial because the intervention has already been duplicated in multiple locations.

Statistical conclusion validity refers to whether the research design and the chosen statistical measures can detect a true relationship (and protect against false statistical conclusions) (108). In the RCT study (Study II) the calculated sample size might have been too small to detect a difference between the groups if such a difference existed, despite the fact that a power analysis was conducted. This is because the participants in the intervention group did not use the intervention as much as anticipated, meaning there was a threat to treatment adherence. Eysenbach (156) states that one way to address the issue of non-use in web-based intervention studies is to conduct a dose-response analysis. Considering the slight trend in the dose-response analysis presented in Study II, it is reasonable to believe that a difference might have been detected with a larger group of participants using the web-based support as intended.

Regarding the reliability and validity of the questionnaires, five of the questionnaires (W-BQ12; SWE-DES-10; SWE-PAID; SOC-13; SWE-HFS) have undergone psychometric evaluation, as reported in the methods section in this thesis. The single-item Likert scale measuring self-perceived health has been successfully used for this purpose for a long period of time (131). Nevertheless, there are methodological shortcomings to discuss.

The main argument for choosing the W-BQ12 questionnaire (used in Studies I, II and III) was that although it is generic, it was developed for persons with T1DM and only consists of 12 questions. It was validated for use in women with high-risk pregnancies (127) after the initiation of our study. W-BQ12 has been criticized for being too focused on negative aspects of well-being (157). Pregnancy-specific instruments that measure well-being exist (158) and might have been a better choice, although not validated in pregnant women with a chronic condition. The notion that well-being is difficult to define (94) and fairly stable over time (93) raises questions about the use of well-being as a primary outcome measure in the MODIAB-Web intervention all together.

Diabetes management was measured by SWE-DES-10. However, SWE-DES is intended to measure diabetes empowerment (128). Empowerment is closely related to self-efficacy, which is an important component of diabetes management. The score from SWE-DES-10 was thereby interpreted as being a measure of self-efficacy of diabetes management. This approach is somewhat controversial in terms of validity, which needs to be acknowledged. The sub-scales for SWE-DES-10 were used in Study I. The sub-scale 'stress management' was not associated with any of the other used instruments, raising concerns about its validity in pregnant women with T1DM.

None of the questionnaires were commonly used during pregnancy or postpartum apart from SOC-13. Sense of coherence measured by SOC-13 has, as far as I know, not been validated for use in a Swedish pregnant population. However, it has been used in a national cohort of Swedish-speaking pregnant women and new mothers (146), allowing for comparison. In an Australian study examining the reliability and validity of SOC-13 in pregnant women it was difficult to establish construct validity (159). It is unclear whether this would transfer to a similar Swedish population.

The self-constructed questionnaires examining breastfeeding and diabetes management after childbirth (Study III) and evaluating the web-based support (Study II) had not undergone any psychometric testing at all. This needs to be considered when interpreting the results. The use of such self-constructed questionnaires can be defended, however. Sometimes, there is a need to tailor questions to a specific context for which no validated questionnaires are suitable. In these instances, a more pragmatic approach is needed: useful data may come out of simple tools (160).

Overall, the research design of the MODIAB-Web study appears to be acceptable in terms of validity. The MODIAB-Web RCT can be classified as a complex intervention (161, 162). Developing evidence for complex activities and interventions can nevertheless be viewed as a considerable challenge (163). In such complex interventions, RCTs are the 'gold standard' but processes and mechanisms should also be illuminated, especially in the case of null-findings (161). Study IV used a case study design (112), the purpose of which was to create in-depth understanding and insights, but examples should be viewed as illustrative rather than definitive. These aspects are important as the sample is small and results may be transferred but not generalized (164).

Finally, the web-based intervention was developed using a participatory design (120) and was based on principles for person-centred care (74, 118). There are methodological problems with measuring person-centred care in intervention studies (165) and perhaps even more so in web-based interventions. However, person-centeredness was not measured at all in the MODIAB-Web study. Doing so could have provided further insight and perspective to the findings.

11 CONCLUSIONS

The findings from this thesis confirm that well-being and diabetes management are closely linked during the childbearing period in women with T1DM. The findings from this thesis suggest that:

- It is reasonable to extend the implication of the Saint Vincent declaration to involve patient-reported outcomes such as well-being.

- To safeguard a smooth transition to motherhood in women with T1DM, medical risks need to be balanced with the natural, joyful process of pregnancy and motherhood. Such a balance needs to be taken into account, both during clinical consultations and when designing and implementing intervention studies.

- Web-based support comprising social support from peers and evidence-based information might not be enough to improve well-being and diabetes management during pregnancy and postpartum.

- To achieve a more person-centred web-based intervention, a dynamic interaction with health care professionals within the web-based support needs to be offered.

- A more vulnerable group of women with T1DM has been identified which is in need of extended professional support post-partum.

- Careful planning of study design and factors related to adherence is needed when conducting web-based interventions, especially when providing social support in the context of randomized controlled trials.

12 FUTURE RESEARCH

The findings from Study I prompt exploration of the idea that it would be beneficial to design an educational intervention which starts even before conception. From Study III, evidence of a lack of professional support postpartum points to the need to identify and cater to a more vulnerable group of women with T1DM during pregnancy. A person-centred approach would seem to be the way forward but further evaluation is required, especially postpartum. One solution could be a form of web-based support but then it would be essential for active communication between users and health care professionals to be offered within the platform.

The rapid development of technology in regards to blood glucose monitoring opens up a new era of diabetes management during pregnancy and postpartum, and its effect on well-being during all aspects of childbearing needs to be explored. It would also be interesting to find out if it could help women stabilize glycaemia during breastfeeding. Ideally, in order to promote transition to motherhood, women with recent experience of T1DM and childbearing should be highly involved during planning, implementation and evaluation of future interventions.

ACKNOWLEDGEMENTS

Firstly, I would like to express my gratitude to **the Institute of Health and Care Sciences** at the Sahlgrenska Academy, University of Gothenburg for funding me and providing me with a workplace. I am also very thankful to the **women who participated** in the study and to all the **health care professionals** who partnered with us in conducting the study**.**

Many people have contributed to making this doctoral thesis possible. I will not be able to thank you all by name but I am ever so grateful to each and every one of you.

My main supervisor **Carina Sparud Lundin**: Thank you for believing in me, the challenges you have set me, the time you have spent with me and the knowledge you have poured into me over the years. I am truly grateful and I have learned so much from you. You set a great example and I will try to follow it to the best of my ability.

My co-supervisor **Marie Berg**: Thank you for giving so generously of your expertise and your time. As PI for the project you have led the way. Your genuine commitment to improving care for pregnant women and mothers is inspiring. Also, I will never look at the background to an article in the same way again.

My co-supervisor **Annsofie Adolfsson**: I have benefited so much from your statistical skills, your presentation techniques and your general scientific know-how. My sincerest thanks for all the time you have spent discussing, trouble-shooting and teaching me hands on. I really appreciate your having taken your valuable time to travel to Gothenburg on so many occasions.

My co-supervisor **Agneta Ranerup**: Your ability to identify, capture and break down research problems is admirable. You have truly broadened my research perceptions. I am particularly thankful for all the insights you provided me with when we wrote the critical analysis in article IV.

Sofie Dencker, thank you for filling in for me on such short notice. Your careful work and accurate entry of data made all the difference.

Thank you to **Anna Dencker**, **Lilas Ali** and **Lotta Selin** for reviewing my thesis and providing helpful critique at my pre-disputation and to **Ingela Henoch**, **Pia Alsén** and **Janeth Leksell** for reviewing my work and helping me move forward at my half-time seminar.

Thank you to the **administrative staff** at the institute. Especially to **Karin Mossberg**, for your organizing and to my long-time friend **Yen-Leng To** for brightening my days (I wish you were still at the office).

The staff at the **Biomedical library**: thank you for providing superb service and invaluable support.

To all members of the **Childbirth Research Group** and my co-workers in the **Midwifery program**, thank you for providing me with an environment of belonging.

I am thankful for the encouragement I have received from my clinical colleagues at **Närhälsan Torslanda barnmorskemottagning** and **Eriksberg barnmorskemottagning** and I am particularly grateful to **Siv Andersson** who made it possible for me to start my PhD at such short notice.

My doctorial colleagues: you are many and I only have space to mention 'the originals' but trust me when I say that you have all helped brighten this time in my life. In no particular order: **Jonna Norman**, **Jeanette Melin**, **Sara Wallström**, **Malin Edqvist**, **Ida Lyckestam Thelin**, **Hilda Svensson**. And a special thank you to my dear friend **Anna Wessberg** for always being there for me.

Spädbarnsfonden Västra Götaland. When we lost Max I could not breathe. Thank you for teaching me not only to in- and exhale but to live again. I am so relieved that there is a place where both my children are seen and talked about. You make such a difference in my life.

My family: **mamma**, **pappa**, **Johanna** and **Jenni**. This has been a long process and you have been there, supporting me from the beginning. Thank you. **Melker**, *jag är så glad över att vara din moster, du är fantastisk.*

Farmor, **farfar**, **mormor**, **morfar** and **Suzy**, I miss you dearly and wish that you could have been here to share this experience with me.

Max, *du gjorde mig till mamma och visade mig vad föräldrakärlek är. Jag är så oerhört stolt och det finns inte en dag som jag inte tänker på dig. Min älskade skruttis!*

Albert, *lillebror som stannade kvar, vår regnbåge. Med dig kom glädjen och lyckan tillbaka. Du lyser upp ett rum och min kärlek till dig och till din bror är oändlig. Tänk att jag får vara din mamma!*

Daniel, I am at a loss for words to describe how much you have helped and supported me during this time. My life is better because of you.

REFERENCES

1. The Saint Vincent Declaration. Acta Ophthalmol Scand. 1997;75(S223):63-.
2. Colstrup M, Mathiesen ER, Damm P, Jensen DM, Ringholm L. Pregnancy in women with type 1 diabetes: have the goals of St. Vincent declaration been met concerning foetal and neonatal complications? J Matern Fetal Neonatal Med. 2013 Nov;26(17):1682-6.
3. Stevenson. Oxford Dictionary of English. 3rd ed: Oxford University Press; 2010.
4. International Confederation of Midwives. Ethics and Philosophy for Midwives. 2017 [cited 2017 September 20th]; Available from: http://internationalmidwives.org/who-we-are/policy-and-practice/code-of-ethics-philosophy-model-midwifery-care/.
5. Alberti KG, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus provisional report of a WHO consultation. Diabet Med. 1998 Jul;15(7):539-53.
6. Skog O, Korsgren S, Melhus A, Korsgren O. Revisiting the notion of type 1 diabetes being a T-cell-mediated autoimmune disease. Curr Opin Endocrinol Diabetes Obes. 2013 Apr;20(2):118-23.
7. Ajanki T. Historien om diabetes och insulinets upptäckt. Sundbyberg: Lund: Svenska diabetesförbundet, Historiska media; 1999.
8. Patterson C, Guariguata L, Dahlquist G, Soltesz G, Ogle G, Silink M. Diabetes in the young - a global view and worldwide estimates of numbers of children with type 1 diabetes. Diabetes Res Clin Pract. 2014 Feb;103(2):161-75.
9. Patterson CC, Dahlquist GG, Gyurus E, Green A, Soltesz G, Group ES. Incidence trends for childhood type 1 diabetes in Europe during 1989-2003 and predicted new cases 2005-20: a multicentre prospective registration study. Lancet. 2009 Jun 13;373(9680):2027-33.
10. The Swedish National Diabetes Register. Annual Report. 2015 [cited 2017 October 9]; Available from: https://www.ndr.nu/pdfs/Arsrapport_NDR_2015.pdf.
11. Heinemann L, Freckmann G. CGM Versus FGM; or, Continuous Glucose Monitoring Is Not Flash Glucose Monitoring. J Diabetes Sci Technol. 2015 Sep;9(5):947-50.
12. Petersson A. Kost vid diabetes - en vägledning till hälso- och sjukvården. Socialstyrelsen; 2011.
13. Colberg SR, Laan R, Dassau E, Kerr D. Physical Activity and Type 1 Diabetes. J Diabetes Sci Technol. 2015;9(3):609-18.

14. Nathan DM. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: overview. Diabetes Care. 2014 Jan;37(1):9-16.
15. Lewallen LP, Cote-Arsenault DY. Implications for nurses and researchers of Internet use by childbearing women. Nurs Womens Health. 2014 Oct-Nov;18(5):392-400.
16. Sakala C, Newburn M. Meeting needs of childbearing women and newborn infants through strengthened midwifery. Lancet. 2014 Sep 20;384(9948):e39-40.
17. Hertfelt Wahn E. Teenage childbearing in Sweden: support from social network and midwife. Stockholm: Karolinska institutet; 2007.
18. The National Board of Health and Welfare. The Swedish Medical Birth Register. Stockholm 2014.
19. Berg M, Berntorp K, Wennerholm U. Diabetes och graviditet - Den komplicerade graviditeten. In: Lindgren H, Christensson K, Dykes A, editors. Reproduktiv hälsa Studentlitteratur AB, Lund; 2016.
20. Casson IF. Pregnancy in women with diabetes--after the CEMACH report, what now? Diabet Med. 2006 May;23(5):481-4.
21. Temple R. Preconception care for women with diabetes: Is it effective and who should provide it? Best Practice and Research: Clinical Obstetrics and Gynaecology. 2011;25(1):3-14.
22. Chaudry R, Gilby P, Carroll PV. Pre-existing (type 1 and type 2) diabetes in pregnancy. Obstetrics, Gynaecology & Reproductive Medicine. 2007;17(12):339-44.
23. Kinsley B. Achieving better outcomes in pregnancies complicated by type 1 and type 2 diabetes mellitus. Clin Ther. 2007;29 Suppl D:S153-60.
24. Roskjaer AB, Andersen JR, Ronneby H, Damm P, Mathiesen ER. Dietary advices on carbohydrate intake for pregnant women with type 1 diabetes. J Matern Fetal Neonatal Med. 2015 Jan;28(2):229-33.
25. Brown J, Ceysens G, Boulvain M. Exercise for pregnant women with pre-existing diabetes for improving maternal and fetal outcomes. Cochrane Database Syst Rev. 2017 Dec 21;12:Cd012696.
26. Azar M, Lyons TJ. Management of pregnancy in women with type 1 diabetes. Minerva Endocrinol. 2013 Dec;38(4):339-49.
27. Ringholm L, Pedersen-Bjergaard U, Thorsteinsson B, Damm P, Mathiesen ER. Hypoglycaemia during pregnancy in women with Type 1 diabetes. Diabetic medicine : a journal of the British Diabetic Association. 2012 May;29(5):558-66.
28. Evers IM, ter Braak EW, de Valk HW, van Der Schoot B, Janssen N, Visser GH. Risk indicators predictive for severe hypoglycemia during the first trimester of type 1 diabetic pregnancy. Diabetes Care. 2002 Mar;25(3):554-9.

29. Nielsen L, Pedersen-Bjergaard U, Thorsteinsson B, Johansen M, Damm P, Mathiesen E. Hypoglycemia in pregnant women with type 1diabetes: predictors and role of metabolic control. Diabetes Care. 2008;31:9 - 15.
30. Feig DS, Hwee J, Shah BR, Booth GL, Bierman AS, Lipscombe LL. Trends in incidence of diabetes in pregnancy and serious perinatal outcomes: a large, population-based study in Ontario, Canada, 1996-2010. Diabetes Care. 2014 Jun;37(6):1590-6.
31. Inkster ME, Fahey TP, Donnan PT, Leese GP, Mires GJ, Murphy DJ. Poor glycated haemoglobin control and adverse pregnancy outcomes in type 1 and type 2 diabetes mellitus: systematic review of observational studies. BMC Pregnancy Childbirth. 2006;6:30.
32. Evers IM, De Valk HW, Visser GHA. Risk of complications of pregnancy in women with type 1 diabetes: Nationwide prospective study in the Netherlands. Br Med J. 2004;328(7445):915-8.
33. Macintosh MCM, Fleming KM, Bailey JA, Doyle P, Modder J, Acolet D, et al. Perinatal mortality and congenital anomalies in babies of women with type 1 or type 2 diabetes in England, Wales, and Northern Ireland: Population based study. Br Med J. 2006;333(7560):177-80.
34. Bell R, Glinianaia SV, Tennant PW, Bilous RW, Rankin J. Peri-conception hyperglycaemia and nephropathy are associated with risk of congenital anomaly in women with pre-existing diabetes: a population-based cohort study. Diabetologia. 2012 Feb 8:1-12.
35. Persson M, Norman M, Hanson U. Obstetric and Perinatal Outcomes in Type 1 Diabetic Pregnancies: A large, population-based study. Diabetes Care. 2009;32(11):2005-9.
36. Yu L, Zeng XL, Cheng ML, Yang GZ, Wang B, Xiao ZW, et al. Quantitative assessment of the effect of pre-gestational diabetes and risk of adverse maternal, perinatal and neonatal outcomes. Oncotarget. 2017 Sep 22;8(37):61048-56.
37. The National Board of Health and Welfare The National Guidelines for Diabetes Care. 2017
38. Berg M, Sparud-Lundin C. Experiences of professional support during pregnancy and childbirth - a qualitative study of women with type 1 diabetes. BMC Pregnancy Childbirth. 2009 Jul 3;9:27.
39. Socialstyrelsen. Kunskapsstöd för mödrahälsovården 2014.
40. Berg M. Pregnancy and diabetes: how women handle the challenges. J Perinat Educ. 2005;14(3):23-32.
41. Berg M, Honkasalo ML. Pregnancy and diabetes - A hermeneutic phenomenological study of women's experiences. J Psychosom Obstet Gynaecol. 2000;21(1):39-48.
42. Edwards H, Speight J, Bridgman H, Skinner TC. The pregnancy journey for women with type 1 diabetes: a qualitative model from

contemplation to motherhood. Practical Diabetes. 2016 Jul-Aug;33(6):194-9.
43. Rasmussen B, Dunning T, Hendrieckx C, Botti M, Speight J. Transition to motherhood in type 1 diabetes: design of the pregnancy and postnatal well-being in transition questionnaires. BMC Pregnancy Childbirth. 2013;13:54.
44. Stenhouse E, Letherby G, Stephen N. Women with pre-existing diabetes and their experiences of maternity care services. Midwifery. 2013 Feb;29(2):148-53.
45. Rasmussen B, Hendrieckx C, Clarke B, Botti M, Dunning T, Jenkins A, et al. Psychosocial issues of women with type 1 diabetes transitioning to motherhood: a structured literature review. BMC Pregnancy Childbirth. 2013;13(1):218-28.
46. Lavender T, Platt MJ, Tsekiri E, Casson I, Byrom S, Baker L, et al. Women's perceptions of being pregnant and having pregestational diabetes. Midwifery. 2010;26(6):589-95.
47. Do NC, Secher AL, Cramon P, Ringholm L, Watt T, Damm P, et al. Quality of life, anxiety and depression symptoms in early and late pregnancy in women with pregestational diabetes. Acta Obstet Gynecol Scand. 2017 Feb;96(2):190-7.
48. Dalfra MG, Nicolucci A, Bisson T, Bonsembiante B, Lapolla A, Qlisg. Quality of life in pregnancy and post-partum: a study in diabetic patients. Qual Life Res. 2012 Mar;21(2):291-8.
49. Dalfra MG, Nicolucci A, Lapolla A. The effect of telemedicine on outcome and quality of life in pregnant women with diabetes. J Telemed Telecare. 2009;15(5):238-42.
50. Illias I, Papageorgiou C, Katsadoros K, Zapanti E, Anastasiou E. Preliminary report: psychological assessment of Greek women with diabetes during pregnancy. Percept Motor Skill. 2005;101:628-30.
51. Langer N, Langer O. Pre-existing diabetics: Relationship between glycemic control and emotional status in pregnancy. Journal of Maternal-Fetal and Neonatal Medicine. 1998;7(6):257-63.
52. Levy-Shiff R, Lerman M, Har-Even D, Hod M. Maternal adjustment and infant outcome in medically defined high-risk pregnancy. Dev Psychol. 2002;38(1):93-103.
53. Debono M, Cachia E. The impact of diabetes on psychological well being and quality of life. The role of patient education. Psychol Health Med. 2007 Oct;12(5):545-55.
54. Sparud-Lundin C, Berg M. Extraordinary exposed in early motherhood - a qualitative study exploring experiences of mothers with type 1 diabetes. BMC Womens Health. 2011 Apr 7;11:10.
55. Berg M, Erlandsson LK, Sparud-Lundin C. Breastfeeding and its impact on daily life in women with type 1 diabetes during the first six months after childbirth: a prospective cohort study. Int Breastfeed J. 2012;7(1):20.

56. Berg M. Well-Being, Diabetes Management, and Breastfeeding in Women with Type 1 Diabetes Two and Six Months after Childbirth. Journal of Women's Health Care. 2012;01(03).
57. Sparud-Lundin C, Wennergren M, Elfvin A, Berg M. Breastfeeding in Women With Type 1 Diabetes: Exploration of predictive factors. Diabetes Care. 2011;34(2):296-301.
58. Schoen S, Sichert-Hellert W, Hummel S, Ziegler AG, Kersting M. Breastfeeding duration in families with type 1 diabetes compared to non-affected families: results from BABYDIAB and DONALD studies in Germany. Breastfeed Med. 2008 Sep;3(3):171-5.
59. Finkelstein SA, Keely E, Feig DS, Tu X, Yasseen AS, 3rd, Walker M. Breastfeeding in women with diabetes: lower rates despite greater rewards. A population-based study. Diabet Med. 2013 Sep;30(9):1094-101.
60. Hummel S, Vehik K, Uusitalo U, McLeod W, Aronsson CA, Frank N, et al. Infant feeding patterns in families with a diabetes history - observations from The Environmental Determinants of Diabetes in the Young (TEDDY) birth cohort study. Public Health Nutr. 2014 Dec;17(12):2853-62.
61. Nucci AM, Virtanen SM, Sorkio S, Barlund S, Cuthbertson D, Uusitalo U, et al. Regional differences in milk and complementary feeding patterns in infants participating in an international nutritional type 1 diabetes prevention trial. Matern Child Nutr. 2017 Jul;13(3).
62. Achong N, Duncan EL, McIntyre HD, Callaway L. The physiological and glycaemic changes in breastfeeding women with type 1 diabetes mellitus. Diabetes Res Clin Pract. 2017 Nov 14;135:93-101.
63. Sorkio S, Cuthbertson D, Barlund S, Reunanen A, Nucci AM, Berseth CL, et al. Breastfeeding patterns of mothers with type 1 diabetes: results from an infant feeding trial. Diabetes Metab Res Rev. 2010 Mar;26(3):206-11.
64. Stage E, Norgard H, Damm P, Mathiesen E. Long-term breast-feeding in women with type 1 diabetes. Diabetes Care. 2006 Apr;29(4):771-4.
65. Fallon A, Dunne F. Breastfeeding practices that support women with diabetes to breastfeed. Diabetes Res Clin Pract. 2015 Oct;110(1):10-7.
66. Lagan BM, Sinclair M, Kernohan WG. What Is the Impact of the Internet on Decision-Making in Pregnancy? A Global Study. Birth: Issues in Perinatal Care. 2011;38(4):336-45.
67. Larsson M. A descriptive study of the use of the Internet by women seeking pregnancy-related information. Midwifery. 2009;25(1):14-20.
68. Walker LO, Mackert MS, Ahn J, Vaughan MW, Sterling BS, Guy S, et al. e-Health and new moms: Contextual factors associated with

sources of health information. Public Health Nurs. 2017 Nov;34(6):561-8.
69. Prescott J, Mackie L. "You Sort of Go Down a Rabbit Hole...You're Just Going to Keep on Searching": A Qualitative Study of Searching Online for Pregnancy-Related Information During Pregnancy. J Med Internet Res. 2017 Jun 5;19(6):e194.
70. Rasmussen B, Dunning P, O'Connell B. Young women with diabetes: using Internet communication to create stability during life transitions. J Clin Nurs. 2007 Mar;16(3A):17-24.
71. Sparud-Lundin C, Ranerup A, Berg M. Internet use, needs and expectations of web-based information and communication in childbearing women with type 1 diabetes. BMC Med Inform Decis Mak. 2011 Jul 7;11(1).
72. Eysenbach G. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res. 2011;13(4):e126.
73. Eysenbach G. What is e-health? J Med Internet Res. 2001 Apr-Jun;3(2):E20.
74. Morgan S, Yoder LH. A concept analysis of person-centered care. J Holist Nurs. 2012 Mar;30(1):6-15.
75. Murray E, Burns J, See TS, Lai R, Nazareth I. Interactive Health Communication Applications for people with chronic disease. The Cochrane database of systematic reviews. 2005(4):CD004274.
76. Vorderstrasse A, Lewinski A, Melkus GD, Johnson C. Social Support for Diabetes Self-Management via eHealth Interventions. Curr Diab Rep. 2016 Jul;16(7):56.
77. Nwolise CH, Carey N, Shawe J. Preconception Care Education for Women With Diabetes: A Systematic Review of Conventional and Digital Health Interventions. J Med Internet Res. 2016 Nov 08;18(11):e291.
78. Shorey S, Chan SW, Chong YS, He HG. A randomized controlled trial of the effectiveness of a postnatal psychoeducation programme on self-efficacy, social support and postnatal depression among primiparas. J Adv Nurs. 2015 Jun;71(6):1260-73.
79. Gjerdingen DK, Froberg DG, Fontaine P. The effects of social support on women's health during pregnancy, labor and delivery, and the postpartum period. Fam Med. 1991;23(5):370.
80. Diener E, Seligman MEP. Very Happy People. Psychol Sci. 2002;13(1):81-4.
81. Turner R. Social Support as a Contingency in Psychological Well-Being. J Health Soc Behav. 1981;22(4):357.
82. Bloom JR. The relationship of social support and health. Soc Sci Med. 1990;30(5):635-7.
83. Cohen S, Wills TA. Stress, Social Support, and the Buffering Hypothesis. Psychol Bull. 1985;98(2):310-57.

84. Cobb S. Social Support as a Moderator of Life Stress. Psychosom Med. 1976;38(5):300-14.
85. Heaney CA, Israel BA. Social networks and social support. In: Rimer BK, Viswanath K, Glanz K, Ebooks C, editors. Health behavior and health education theory, research, and practice. 4. ed: Hoboken : John Wiley & Sons, Inc.; 2008.
86. House JS. Work stress and social support. Reading, Mass.: Addison-Wesley; 1981.
87. Swedish Research Council. Health Care Sciences. 2016 [cited 2017 November 14th]; Available from: https://www.vr.se/inenglish/researchfunding/applyforgrants/specialareas/healthcaresciences.4.5adac704126af4b4be280008166.html.
88. University of Gothenburg the Board of Sahlgrenska Academy. General Study Syllabus for Third-Cycle Studies in Health Care Sciences. 2015.
89. Meleis AI, Sawyer LM, Im E-O, Hilfinger Messias DK, Schumacher K. Experiencing Transitions: An Emerging Middle-Range Theory. Advances in Nursing Science. 2000;23(1):12-28.
90. Nelson AM. Transition to Motherhood. J Obstet Gynecol Neonatal Nurs. 2003;32(4):465-77.
91. Ryff CD. Happiness is everything, or is it? Explorations on the meaning of psychological well-being. J Pers Soc Psychol. 1989;57(6):1069-81.
92. Constitution of the World Health Organization, Signed on July 22, 1946, in New York City. International Organization. 1947;1(1):225-39.
93. Dodge R, Daly AP, Huyton J, Sanders LD. The challenge of defining wellbeing. International Journal of Wellbeing. 2012;2(3):222-35.
94. Thomas J. Working Paper: Current Measures and the Challenges of Measuring Children's Wellbeing. Household, Labour Market and Social Wellbeing: Office for National Statistics United Kingdom; 2009.
95. Nic M, Hetan S. A well-being manifesto for a flourishing society. Journal of Public Mental Health. 2004;3(4):9-15.
96. Bradley C, Gamsu DS. Guidelines for encouraging psychological well-being: report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. Diabet Med. 1994 Jun;11(5):510-6.
97. Schilling LS, Grey M, Knafl KA. The concept of self-management of type 1 diabetes in children and adolescents: an evolutionary concept analysis. J Adv Nurs. 2002;37(1):87-99.
98. Ruggiero L, Glasgow R, Dryfoos JM, Rossi JS, Prochaska JO, Orleans CT, et al. Diabetes self-management. Self-reported

recommendations and patterns in a large population. Diabetes Care. 1997 Apr;20(4):568-76.
99. Haas L, Maryniuk M, Beck J, Cox CE, Duker P, Edwards L, et al. National standards for diabetes self-management education and support. Diabetes Care. 2014 Jan;37 Suppl 1:S144-53.
100. Beverly EA, Ganda OP, Ritholz MD, Lee Y, Brooks KM, Lewis-Schroeder NF, et al. Look who's (not) talking: diabetic patients' willingness to discuss self-care with physicians. Diabetes Care. 2012 Jul;35(7):1466-72.
101. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns. 2002 Oct -Nov;48(2):177-87.
102. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. Am J Public Health. 2014 Aug;104(8):e25-31.
103. Aujoulat I, d'Hoore W, Deccache A. Patient empowerment in theory and practice: polysemy or cacophony? Patient Educ Couns. 2007 Apr;66(1):13-20.
104. Audulv A, Asplund K, Norbergh KG. The integration of chronic illness self-management. Qual Health Res. 2012 Mar;22(3):332-45.
105. Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. Ann Behav Med. 2003;26(1):1-7.
106. Corbin JM, Strauss A. Unending work and care: Managing chronic illness at home. San Francisco, CA, US: Jossey-Bass; 1988.
107. Bandura A. Self-efficacy: Toward a unifying theory of behavioral change. Psychol Rev. 1977;84(2):191-215.
108. Polit DF, Beck CT. Nursing research: generating and assessing evidence for nursing practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2012.
109. Meadows KA. Patient-reported outcome measures: an overview. Br J Community Nurs. 2011 Mar;16(3):146-51.
110. McClimans L. A theoretical framework for patient-reported outcome measures. Theor Med Bioeth. 2010 Jun;31(3):225-40.
111. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Med. 2010 Mar 24;8:18.
112. Baxter P, Jack S. Qualitative case study methodology: study design and implementation for novice researchers. The Qualitative Report. 2008;13(4):544-59.
113. Oinas-Kukkonen H, Harjumaa M. Persuasive Systems Design: Key Issues, Process Model, and System Features. Communications of the Association for Information Systems. 2009;24(1):485-500.
114. Soltani H, Dickinson F, Kalk J, Payne K. Breast feeding practices and views among diabetic women: a retrospective cohort study. Midwifery. 2008;2:471 - 9.

115. Soltani H, Arden M. Factors associated with breastfeeding up to 6 months postpartum in mothers with diabetes. J Obstet Gynecol Neonatal Nurs. 2009 Sep-Oct;38(5):586-94.
116. King R, Wellard S. Juggling type 1 diabetes and pregnancy in rural Australia. Midwifery. 2009;25(2):126-33.
117. Hummel S, Winkler C, Schoen S, Knopff A, Marienfeld S, Bonifacio E, et al. Breastfeeding habits in families with Type 1 diabetes. Diabet Med. 2007 Jun;24(6):671-6.
118. Ekman I, Swedberg K, Taft C, Lindseth A, Norberg A, Brink E, et al. Person-centered care--ready for prime time. Eur J Cardiovasc Nurs. 2011 Dec;10(4):248-51.
119. Berg M, Adolfsson A, Ranerup A, Sparud-Lundin C. Person-centered Web support to women with type 1 diabetes in pregnancy and early motherhood--the development process. Diabetes Technol Ther. 2013 Jan;15(1):20-5.
120. Spinuzzi C. The methodology of participatory design. Technical Communication. 2005;52(2):163-74.
121. Adolfsson A, Linden K, Sparud-Lundin C, Larsson PG, Berg M. A web-based support for pregnant women and new mothers with type 1 diabetes mellitus in Sweden (MODIAB-Web): study protocol for a randomized controlled trial. Trials. 2014 Dec 29;15(1):513.
122. Linden K, Berg M, Sparud-Lundin C. Web-based information for pregnant women and new mothers with type 1 diabetes--a description of the development process. BMC Med Inform Decis Mak. 2012 Nov 20;12:134.
123. Adolfsson A, Jansson M. Prototype for Internet support of pregnant women and mothers with type 1 diabetes: focus group testing. Psychol Res Behav Manag. 2012;5:97-103.
124. Streiner DL, Norman GR, Cairney J. Health measurement scales : a practical guide to their development and use. 5. ed: Oxford: Oxford University Press; 2015.
125. Bradley C. WB-Q User Guidelines. Health Psychology Research Royal Holloway, University of London, 2003.
126. Pouwer F, van der Ploeg HM, Ader HJ, Heine RJ, Snoek FJ. The 12-item well-being questionnaire. An evaluation of its validity and reliability in Dutch people with diabetes. Diabetes Care. 1999 Dec;22(12):2004-10.
127. Watrowski R, Rohde A. Psychological well-being of gynecologic and obstetric patients: a validation of the 12-item Well-Being Questionnaire (W-BQ12). Wien Klin Wochenschr. 2014 Sep;126(17-18):524-31.
128. Leksell J, Funnell M, Sandberg G, Smide B, Wiklund G, Wikblad K. Psychometric properties of the Swedish Diabetes Empowerment Scale. Scand J Caring Sci. 2007 Jun;21(2):247-52.

129. Wikblad K. The Swedish version of the Diabetes Empowerment Scale (SWE-DES) - MANUAL 2005.
130. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The Diabetes Empowerment Scale-Short Form (DES-SF). Diabetes Care. 2003 May;26(5):1641-2.
131. Smith T. The Impact of Alternative Response Scales on Measuring Self-ratings of Health. 2008 [cited 2015 June 7th]; Available from: http://www.surveypractice.org/index.php/SurveyPractice/rt/printerFriendly/213/html.
132. Amsberg S, Wredling R, Lins PE, Adamson U, Johansson UB. The psychometric properties of the Swedish version of the Problem Areas in Diabetes Scale (Swe-PAID-20): scale development. Int J Nurs Stud. 2008 Sep;45(9):1319-28.
133. Antonovsky A. The structure and properties of the sense of coherence scale. Soc Sci Med. 1993 Mar;36(6):725-33.
134. Eriksson M, Lindström B. Validity of Antonovsky's sense of coherence scale: a systematic review. J Epidemiol Community Health. 2005 June 1, 2005;59(6):460-6.
135. Langius A, Björvell H. The salutogenic model and the use of the sense of coherence scale in nursing research - a methodological report. Vard Nord Utveckl Forsk. 1996;16(1):28-32.
136. Anderbro T, Amsberg S, Wredling R, Lins PE, Adamson U, Lisspers J, et al. Psychometric evaluation of the Swedish version of the Hypoglycaemia Fear Survey. Patient Educ Couns. 2008 Oct;73(1):127-31.
137. Gonder-Frederick LA, Schmidt KM, Vajda KA, Greear ML, Singh H, Shepard JA, et al. Psychometric properties of the hypoglycemia fear survey-ii for adults with type 1 diabetes. Diabetes Care. 2011 Apr;34(4):801-6.
138. Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale: L. Erlbaum Associates; 1988.
139. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JE. Persuasive system design does matter: a systematic review of adherence to web-based interventions. J Med Internet Res. 2012 Nov 14;14(6):e152.
140. Elo S, Kyngäs H. The qualitative content analysis process. J Adv Nurs. 2008;62(1):107-15.
141. World Medical Association. World medical association declaration of Helsinki ethical principles for medical research involving human subjects. JAMA. 2013;310:2191 - 4.
142. Kaplan RM, Irvin VL. Likelihood of Null Effects of Large NHLBI Clinical Trials Has Increased over Time. PLoS One. 2015;10(8):e0132382.
143. Adolfsson A, Arbhede E, Marklund E, Larsson P-G, Berg M. Miscarriage: Evidence Based Information for the Web and Its

Development Procedure. Advances In Sexual Medicine. 2015;5(4):89-110.
144. Linden K, Berg M, Adolfsson A, Sparud-Lundin C. Person-centred, web-based support in pregnancy and early motherhood for women with Type 1 diabetes mellitus: a randomized controlled trial. Diabet Med. 2018;35:234-43.
145. The Swedish Pregnancy Register. The Swedish Pregnancy Register Yearly Report 2015. 2015 [cited 2017 December 11th]; Available from: https://www.medscinet.com/gr/dokumentarkiv.aspx.
146. Hildingsson I. Sense of coherence in pregnant and new mothers - A longitudinal study of a national cohort of Swedish speaking women. Sex Reprod Healthc. 2017 Mar;11:91-6.
147. Berg M. A midwifery model of care for childbearing women at high risk: genuine caring in caring for the genuine. J Perinat Educ. 2005 2005 Winter;14(1):9-21.
148. Tengland P-A. Empowerment: A Conceptual Discussion. An International Journal of Health Care Philosophy and Policy. 2008;16(2):77-96.
149. Kristensson-Uggla B. Personfilosofi - filosofiska utgångspunkter för personcentrering inom hälso- och sjukvård. In: Ekman I, editor. Personcentrering inom hälso- och sjukvård från filosofi till praktik: Liber, Stockholm; 2014.
150. Ventura F. Person-centred e-support. Foundations for the development of nursing interventions in outpatient cancer care. 2016.
151. Wildevuur SE, Simonse LW. Information and communication technology-enabled person-centered care for the "big five" chronic conditions: scoping review. J Med Internet Res. 2015 Mar 27;17(3):e77.
152. Moy FM, Ray A, Buckley BS, West HM. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. Cochrane Database Syst Rev. 2017 Jun 11;6(6):CD009613.
153. Feig DS, Donovan LE, Corcoy R, Murphy KE, Amiel SA, Hunt KF, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet. 2017 Nov 25;390(10110):2347-59.
154. Carlsson IM, Berg M, Adolfsson A, Sparud-Lundin C. Reprioritizing life: a conceptual model of how women with type 1 diabetes deal with main concerns in early motherhood. International journal of qualitative studies on health and well-being. 2017;12(sup2):1394147.
155. Polsky S, Giordano D, Voelmle MK, Garcetti R, Garg SK. Using technology to advance type 1 diabetes care among women during the reproductive years and in pregnancy. Postgrad Med. 2016 May;128(4):418-26.

156. Eysenbach G. Issues in evaluating health websites in an Internet-based randomized controlled trial. J Med Internet Res. 2002 Dec;4(3):E17.
157. DiPietro JA, Ghera MM, Costigan K, Hawkins M. Measuring the ups and downs of pregnancy stress. J Psychosom Obstet Gynaecol. 2004 Sep-Dec;25(3-4):189-201.
158. Morrell CJ, Cantrell A, Evans K, Carrick-Sen DM. A review of instruments to measure health-related quality of life and well-being among pregnant women. J Reprod Infant Psychol. 2013;31(5):512-30.
159. Ferguson S, Davis D, Browne J, Taylor J. Examining the Validity and Reliability of Antonovsky's Sense of Coherence Scale in a Population of Pregnant Australian Women. Eval Health Prof. 2015 Jun;38(2):280-9.
160. Flyvbjerg B. Five Misunderstandings About Case-Study Research. Qualitative Inquiry. 2006;12(2):219-45.
161. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ. 2007 Mar 3;334(7591):455-9.
162. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.
163. Richards DA, Borglin G. Complex interventions and nursing: looking through a new lens at nursing research. Int J Nurs Stud. 2011 May;48(5):531-3.
164. Patton MQ. Qualitative research & evaluation methods. 3. ed: London: SAGE; 2002.
165. Olsson LE, Jakobsson Ung E, Swedberg K, Ekman I. Efficacy of person-centred care as an intervention in controlled trials - a systematic review. J Clin Nurs. 2013 Feb;22(3-4):456-65.