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## Early Detection of Type 2 Diabetes among Women with Previous Gestational Diabetes Mellitus

*Development and Pilottest of an Intervention to Aid Women's Decision on Participation in Follow-Up Screening*

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**EARLY DETECTION OF TYPE 2 DIABETES  
AMONG WOMEN WITH PREVIOUS  
GESTATIONAL DIABETES MELLITUS**

DEVELOPMENT AND PILOTTEST OF AN INTERVENTION  
TO AID WOMEN'S DECISION ON PARTICIPATION IN  
FOLLOW-UP SCREENING

BY  
**JANE HYLDGAARD NIELSEN**

DISSERTATION SUBMITTED 2022



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**AALBORG UNIVERSITY**  
DENMARK

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## CV



Jane Hyldgaard Nielsen holds a bachelor's degree in Midwifery from University College of Northern Denmark (2012), and a MSc in Public Health for Aalborg University (2014). After graduation in 2014, she became a lecturer at the Midwifery department at University College of Northern Denmark and have since then worked with in different areas of midwifery students' theoretical education. In 2021 she was appointed as a senior lecturer at the Midwifery department.

During her employment at the Midwifery department, she has had an increasing number of research and development assignments in close collaboration with clinical practices, including e.g., a qualitative study of user's experiences of a new delivery room design based on principles of healing architecture and Snoezelen (published in *BMC Pregnancy and Childbirth*, 2020 (1)).

Her interest within research in the field of women with gestational diabetes mellitus started when she and a fellow student undertook their master thesis in 2011. As part of this she conducted a quantitative register-based study examining the participation, of women with previous gestational diabetes, in the recommended follow-up screening in the Denmark North Region. This showed potentials in early detection of type 2 diabetes, however participation decreased in years after birth (published in *BMC Public Health*, 2014 (2)). Also, a qualitative study examining possible reasons for none-participation were included in the work of her master thesis (published in *Women and Birth*, 2015 (3)).

The PhD- project was conducted alongside other research activities, which included completion of the qualitative study exploring birth environment (1), a study of home monitoring of women with pregnancy complicated by diabetes, two systematic reviews as part of a study group for systematic reviews in the field of in relation to women and children's health (4,5), two projects related to care for women with gestational diabetes (6), as well as co-supervision of a research assistant undertaking a qualitative process evaluation related to this PhD- project. All adding to the experience and research interest in women's health, diabetes and development and implementation of technological interventions to improve care and treatment.

# ENGLISH SUMMARY

## Background

Gestational Diabetes Mellitus (GDM) is a serious clinical, which requires close control and treatment during pregnancy. Furthermore, GDM is associated with high risk of recurrence in subsequent pregnancies and for later development of type 2 diabetes (T2DM). After birth, women are recommended to undergo lifelong follow-up screening for the development of T2DM. Low participations rates among this high-risk group of younger women, however, continue to be a challenge. Follow-up after GDM can be characterized by a multilevel complexity, and even though the effect of reminder systems varies greatly across settings, reminders are found successful in increasing screening rates. Analyses which set out to explore the underlying causes of the working of an intervention, includes focus on contextual factors and take the complexity within different health care system into consideration, are valuable. This can in creating a better understanding of the success and failures of reminder interventions.

## Aim

The PhD thesis consisted of three studies which aimed to:

- 1) To explore for whom and under which circumstances reminder interventions are effective. To explore theoretical underpinnings in reminder intervention design and to explore and analyze context- mechanism- outcome configurations that emerged under experimental conditions and delivery settings of reminder interventions (7)
- 2) To explore the perspectives of GPs and relevant staff members (i.e., registered nurses and midwives) on follow-up screening for T2DM after GDM and to identify barriers to and facilitators of follow-up screening (8)
- 3) To determine the effectiveness of an electronic reminder intervention to women 1-8 years after a pregnancy complicated by GDM in increasing participation in follow-up screening in general practice (9).

## Methods

The overall framework of this PhD thesis is inspired by the British Medical Research Council's (MRC) guidance on *Development and evaluating complex intervention* from 2006 (10). Thus, the three sub-studies of this thesis can be seen in relation to the development and pilot/feasibility phase. To identify the evidence,



theory and under which circumstance electronic reminders work a realist review was performed (Study 1). Moreover, semi-structured interviews were used to explore barriers and facilitators for follow-up screening in general practice in the North Denmark Region (Study 2). A region which in the last study, a randomized controlled trial, served as a setting for the regional pilot test of the developed intervention (Study 3).

## **Results**

In addition to the extensive knowledge derived from the overall development phase, Study 1 contributed to an understanding of how reminders can lead to increased participation in screening, which was related to systems resources, women circumstances, and continuity in care (7). Study 2 revealed both barriers and facilitators for screening in general practice related to the three identified themes: challenges of addressing women's risk, prioritization of early detection of diabetes and the system influence on clinical procedures (8). Based on the first two studies and principles of informed choice, and patient-centred care a program theory for an electronic reminder intervention was developed. The set up for this intervention was tested in Study 3, a randomized controlled trial based on routine data. This showed a 20% increase in women's participation in screening (RR: 1.20; 95% CI 1.03–1.39).

## **Conclusion**

Overall, the findings support a more systematic approach to follow-up screening with long-term use of electronic reminders, when based on the principles of informed choice and patient-centered care. Thus, a support to the recommendation of life-long follow-up screening after pregnancy complicated by GDM. Other advantages of the intervention design were low cost and feasibility of implementation as part of routine health service in a Danish Region. The theoretical underpinnings are considered a strength, as it appears to work as a decision aid and support women's ability to make an informed choice and contribute to increased continuity in their care pathway. Thus supposedly, minimizing potential unintended consequences of reminders related to feelings of stigma and being pressured. Other attempts to further stimulate coverage and increase equity in care are desirable.

# DANSK RESUME

## Baggrund

Gestationel diabetes mellitus (GDM) er en tilstand, som kræver tæt kontrol af mor og barn under graviditet. Endvidere er GDM forbundet med høj risiko for recidiv i efterfølgende graviditeter og for senere udvikling af type 2 diabetes (T2DM). Efter fødslen anbefales kvinderne at deltage i en livslang screening for udvikling af T2DM. Tilslutningen er dog lav blandt denne højrisikogruppe af yngre kvinder. Opfølgning efter GDM kan være kendetegnet ved en kompleksitet på flere niveauer, og selvom effekten af påmindelse om screening varierer meget har det vist sig at være en succesfyldt måde at øge tilslutningen på. Analyser, der sigter mod at udforske de underliggende årsager til, at en intervention fungerer, inkludere fokus på kontekstuelle faktorer, tager kompleksiteten i forskellige sundhedssystemer i betragtning, betragtes som værdifulde. Dette kan skabe en bedre forståelse for succeser og fiaskoer bagved interventioner baseret på en påmindelse.

## Formål

Ph.d.-afhandlingen bestod af tre studier, der havde til formål:

- 1) At undersøge, for hvem og under hvilke omstændigheder interventioner baseret på påmindelse om screening er effektive. At udforske teoretiske fundamenter i designet og udforske og analysere kontekst afhængige mekanismer med betydning for udfaldet, som opstod under eksperimentelle forhold og levering af interventionen (7).
- 2) At udforske perspektiverne hos praktiserende læger og relevante medarbejdere (dvs. registrerede sygeplejersker og jordemødre) på opfølgende screening for T2DM efter GDM og at identificere barrierer for og facilitatorer af opfølgende screening (8).
- 3) At bestemme effektiviteten af en elektronisk påmindelse, til kvinder 1-8 år efter en graviditet kompliceret af GDM, til at øge deltagelsen i screening i almen praksis (9).

## Metode

Den overordnede ramme for Ph.d.-afhandlingen er inspireret af British Medical Research Councils (MRC) vejledning om udvikling og evaluering af kompleks intervention fra 2006 (10). Afhandlingens tre delstudier kan ses i relation til udviklings- og pilotfasen. For at identificere teoretiske forståelser bag- og under hvilke omstændigheder elektroniske påmindelser virker, blev der udført et Review med en realistisk syntese af forskellige fund (Studie 1). Desuden blev semistrukturerede interviews brugt til at udforske barrierer og facilitatorer for den opfølgende screening i almen praksis i Region Nordjylland (Studie 2). En region, som i den sidste undersøgelse, et randomiseret kontrolleret forsøg, fungerede som ramme for den regionale pilottest af den udviklede intervention (Studie 3).

## **Resultater**

Ud over den omfattende viden, fra den overordnede udviklingsfase, bidrog Studie 1 til en forståelse af, hvordan påmindelser kan føre til øget deltagelse i screening. Disse var relateret til ressourcer i systemet, kvinders omstændighed og kontinuitet (7). Studie 2 afslørede både barrierer og facilitatorer for screening i almen praksis, og var relateret til tre overordnet temaer: udfordringer med at adressere kvindernes risiko, prioritering af tidlig opsporing af diabetes og systemets indflydelse på kliniske procedurer (8). Baseret på studie 1 og 2, principper for informeret valg og patient-centreret omsorg blev der udviklet en bagvedlæggende programteori for interventionen. Intervention blev testet i Studie 3, et randomiseret kontrolleret forsøg baseret på rutinedata i danske registre. Dette påviste en stigning på 20 % i kvinders deltagelse i screening (RR: 1,20; 95 % CI 1,03-1,39).

## **Konklusion**

Samlet set understøtter resultaterne en mere systematisk tilgang til den opfølgende screening med brug af elektroniske påmindelser, der er baseret på principperne om informeret valg og patient-centreret omsorg. Dette understøtter således anbefalingen om livslang screening efter graviditet kompliceret af GDM. Andre fordele ved designet af interventionen var de lave omkostninger samt gennemførligheden af implementering i sundhedsvæsen i en dansk region. Det teoretiske grundlag betragtes som en styrke, da det ser ud til at bidrage med beslutnings støtte som øger kvindernes mulighed for at træffe et informeret valg, skabe kontinuitet i deres behandlingsforløb samt minimere potentielle utilsigtede konsekvenser af påmindelser relateret til følelser af stigmatisering og føle sig presset. Yderligere viden om hvorledes tilslutningen og lighed i tilgangen til screening øges er ønskeligt.



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## LIST OF PAPERS

### **Paper I:**

Nielsen JH, Melendez-Torres GJ, Rotevatn TA, Peven K, Fonager K, Overgaard C. How do reminder systems in follow-up screening for women with previous gestational diabetes work? - a realist review. *BMC Health Service Research* 2021; 21: 535. <https://doi.org/10.1186/s12913-021-06569-z>

### **Paper II:**

Nielsen JH, Fonager K, Kristensen JK, Overgaard C. Follow-up after gestational diabetes: a qualitative study of perspectives from general practices. *BJGP Open* 2022; <https://doi.org/10.3399/BJGPO.2021.0241>

### **Paper III:**

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## ABBREVIATIONS

GDM:	Gestationel Diabetes Mellitus
T2DM:	Type 2 Diabetes Mellitus
GP:	General practitioner
IDF:	International Diabetes Federation
WHO:	World Health Organization
EU:	Europa
MRC:	Medical Research Council
CPR:	Civil Registration Number
KMD:	Digitalization Unit for the public sector in Denmark
NPU:	Nomenclature for Properties and Units
OGTT:	Oral Glucose tolerance test

# CHAPTER 1. INTRODUCTION

*This chapter introduces the health issues for women and infants related to Gestational Diabetes Mellitus (GDM) and the background for this project in light of the national and international literature. Based on this the knowledge gap and need for intervention is identified and, subsequently, the summarized rationale and the objectives of the PhD thesis are presented.*

## **1.1 GESTATIONAL DIABETES MELLITUS AND THE RISK OF TYPE 2 DIABETES.**

Gestational Diabetes Mellitus (GDM) is defined as a diabetes which is diagnosed in the second or third trimester of pregnancy and resolves again after birth; thereby not a pre-existing or undiagnosed case of diabetes, prior to gestation (11). It has been estimated that most hyperglycemia cases in pregnancy (75%–90%) are GDM (12).

According to the International Diabetes Federation (IDF) and World Health Organization (WHO), GDM is rising worldwide (12,13). The established risk factors for GDM includes older age in childbearing women, ethnicity, obesity, previous GDM, polycystic ovary syndrome, family history of diabetes (14-16), smoking (17) and a history of stillbirth or giving birth to an infant with a congenital abnormality (12). Previous studies also describe an increasing prevalence within a Danish population (18,19), thus affecting around 3-4% (18-20) or even up to 6% (21). There has been a significant increase in prevalence of GDM in Denmark over the last decade (18).

The rise in GDM is a significant public health problem, as GDM is a serious clinical condition, with risk of complications and health impacts for both mother and child ante, intra and post-partum. Maternal risks include e.g., gestational hypertension and preeclampsia and severe birth complications, whereas fetal complications of GDM pregnancies includes increased risk of e.g., macrosomia, shoulder dystocia, neonatal hypoglycemia, and hyperbilirubinemia. Also, the use of interventions such as cesarean section and instrumental delivery is increased (11,16). GDM requires close control and treatment in a secondary healthcare setting, as it has found to significantly reduce the increased maternal and perinatal risks (16).

Moreover, even though most women return to a normoglycemic state after birth, GDM has a high recurrence rate in subsequent pregnancies and are one of the strongest predictive factors for later development of type 2 diabetes (T2DM). In Denmark, the prevalence of T2DM in women with previous GDM has increased significantly (21).

The risk of later development of T2DM is reported with some variance between studies. Bellamy, Casas, Hingorani, and Williams (2009) found women with previous GDM to be at an approximately 7-fold higher risk of T2DM compared to women with a normoglycemic pregnancy (14). More recent reviews did suggest

that women with previous GDM to be around 8-10 times more likely to develop T2DM (15,22,23). The risk is estimated to be highest before 5-6 years after birth, in some studies (15,22,23), whereas other studies suggest the incidence of T2DM after GDM to increase linearly with duration of follow-up (24). Altogether, it can be concluded that women's increased risk of T2DM remains high 10 and 15 years after GDM (15,23).

Both GDM and T2DM is associated with long-term risks. GDM increases the risk of metabolic syndrome, cardiovascular morbidity, malignancies, ophthalmic, psychiatric, and renal diseases as well as opposes a risk of long-term adverse health outcomes for offspring including T2DM or subsequent obesity (16). T2DM is furthermore associated with diabetic complications such as nephropathy, retinopathy, neuropathy, peripheral artery disease and foot ulceration (12)

## **1.2 RECOMMENDATION OF FOLLOW-UP SCREENING AND EARLY DETECTION OF T2DM**

Standards of Medical Care in Diabetes 2021 should, according to the American Diabetes Association, include women with previous GDM to undergo lifelong follow-up screening for the development of T2DM (or prediabetes) for a minimum of every three years after birth (11). They also state that shorter intervals between screenings could benefit specific high-risk groups, which is in line with Danish guidelines recommending women with previous GDM to participate in follow-up screening, in general practice, twelve weeks after birth and, subsequently, every year (25).

Several studies suggest that women are aware of the importance of screening (3,26,27). Nonetheless, low participation rates have been found, both in Denmark and internationally, among this high-risk group of younger women (2,28). In an earlier, register-based study from the North Region of Denmark a rapid decreasing of participation in the recommended screening was found (approximately 18%, 4-6 years after birth). Women attending at least one screening in general practice, compared to women who did not attend, were more likely to be diagnosed with diabetes (HR 2,7 (95% CI 1,1-5,9) (2). This points to an unutilized potential for disease prevention.

The low participation in the recommended follow-up screening is especially challenging. The duration of a glycemic burden is a strong predictor of adverse outcomes (11,29,30). Young onset of T2DM is, therefore, problematic since this is associated with a long duration of diagnosis and high risk of complications (31,32). Despite an often long presymptomatic phase before T2DM diagnosis (11), undiagnosed patients are at increased risk of developing macrovascular and microvascular complications (12,13). This emphasizes the need for early detection of diabetes among women with previous GDM even further because it captures women within the childbearing age.

The global agreement and recommendation, on routine follow-up screening of women with previous GDM, is also based on early detection of prediabetes, allowing interventions to reduce the diabetes risk, since early detection of T2DM could allow for treatment at the earliest time possible.

Although lifestyle interventions can be difficult to implement, studies suggest that behavioral intervention, focusing on weight loss and increased physical activity, are effective in preventing T2DM (33,34), reducing risk factors and complications related to T2DM (35,36) or even, possibly, increasing the likelihood of remission of T2DM (37). This is similar to findings of a systematic review which showed that postpartum lifestyle interventions for women with previous GDM can contribute to increased postpartum weight loss and improved dietary behaviors; however, sufficient implementation and engagement of women in this type of individual-level intervention remain a significant challenge (38).

The unutilized potential in early detection of T2DM among this high-risk group of younger women remains a significant challenge. As argued by Mortaz, Wessman, Duncan, Gray, and Badawi, the serious health consequences of an undiagnosed diabetes and the lack of early detection by screening is also likely to pose a higher cost to the health care system compared to the cost of screening (39). A focus on how to strengthen women's participation in follow-up screening thus seems warranted. Besides ensuring early detection of T2DM, participation in follow-up care also provide a unique opportunity for women and general practitioner to maintain or initiate lifestyle changes, thus minimizing the risk of developing GDM in subsequent pregnancies or T2DM later in life. An opportunity that, in a Danish context, is in line with the guidelines for general practice (25).

### **1.3 A CHALLENGE WITHIN A COMPLEX HEALTH CARE SYSTEM**

It is well documented in both Danish and international studies, that the care pathway for women with GDM is incoherent and poses significant challenges to women. Several studies have shown that the disruption of care is particularly evident after birth as well as when hospital care is terminated (3,40,41). In addition, it is often unclear who is responsible for the follow-up care after birth (27,42).

Incoherent care is a well-known challenge in Health Care Systems, which in itself is a *Complex System* (43). A complex system can be characterized by a number of subsystems which are a part of a larger system. The extent to which their functioning is shaped by interactions among different actors (44).

Health Care Systems established in 'silos of care' can reduce the attention to patient transitions and communication between them (42). The Danish Health Care System consists of professional, organizational and geographical silos, as it is believed to ensure high productivity and professionalism inside each silo (45). The challenge to create coherence both within hospitals and cross-sectoral are widely acknowledged.

Various improvement activities have been used to strengthen coordination, and more coherent patient care including specific health care coordinators, contact persons, patient's teams, and health communities (45). It is not uncomplicated; thus, management must work across and in collaboration with different hospitals, municipalities, and general practice, all playing a role in the Danish Health Care sector (45). Shared patientcare responsibility has been shown to improve interinstitutional communication and increased efficiency (43).

In Denmark, the recommended follow-up screening for women with a previous GDM is not systematically organized as a national screening program. Women are informed about the recommendation of follow-up screening as part of hospital care (3), as well as national guidelines for general practice in Denmark (25). It does rely on women to book a test or ask their GP, who may also bring up the recommendation of screening during consultations booked with another focus. Screening can thus be described as opportunistic (46).

Seen in a complex system perspective, several factors influence women's participation in follow-up screening. A systematic review from 2019 by Dennison, Chen, Green, Legard, Kotecha, Farmer, Sharp, Ward, Usher-Smith and Griffen (41), synthesized the literature on women's experiences of barriers and facilitators in attending follow-up screening. On an individual level, a range of factors was identified, including women's interactions with health care systems, logistics, as well as family-related practicalities and concerns about diabetes (41). Overall, both national and international qualitative studies consistently report that many women feel left alone with the responsibility for their own follow-up care, a responsibility that most of them found difficult to manage and experienced as a burden (3,41).

Although increased awareness is seen and guidelines for sector transfer and follow-up care have been established in Denmark, it appears that these guidelines do not necessarily get prioritized in busy, every day, general practice clinics with many competing tasks (3), and a GDM diagnosis can easily be overlooked in women's care transitions between health sectors (40). Moreover, clinicians' knowledge, attitudes and beliefs have been reported to play an important role in the suboptimal follow-up care (27,42). Limited time and resources, professional opinions and focus have been identified as barriers for most professionals, in taking responsibility for follow-up care (42). All in all, these barriers lead to an important opportunity for early detection of T2DM after GDM and disease prevention that is being missed. However, little is known about the challenges of follow-up care for women with previous GDM within general practice, in Denmark.

In a complex system perspective, follow-up after GDM is thereby characterized by multilevel complexity. In Denmark, women's care pathway is especially challenged by cross-sectoral transitions in care and an opportunistic screening approach (3), where women have the main responsibility for accessing care, which means that women's resources to participate and prioritization play a significant role.

Addressing the complexity of the health care system in attempts to improve care means increasing awareness of the system properties and how these may play a role in how an intervention affects change, rather than focusing on controlling its



complexity (47). Therefore, when aiming to improve the care pathway and strengthen early detection of T2DM among women with previous GDM, in-depth knowledge on perspectives and contextual factors prevailing in general practice are of great importance.

## **1.4 THE USE OF REMINDER INTERVENTIONS TO SUPPORT UPTAKE**

A systematic review by Jeppesen, Kristensen, Ovesen, and Maindal (2015), problematized the low screening rates across different countries and health care systems, and set out to evaluate whether reminders for women with previous GDM, and their health professionals, could be an efficient intervention to support follow-up screening (40). Reminder systems were found to be successful in increasing postpartum screening rates.

It was concluded that organization, type, and frequency of reminders should be carefully considered, according to the target group (40). Moreover, the review highlighted that evidence for the effect of reminder interventions, past the first follow-up visit after birth, are lacking (40). This is highly relevant as follow-up screening is a lifelong recommendation and participation rates are known to drop over time. In a Danish context, participation in the first screening test is high (>90%) but then decreases dramatically to approximately 18% 4-6 years after birth (2).

This manifests a knowledge gap about the applicability of results, merely focusing on the effect of reminder intervention, to implement in other health care settings. In general, existing evidence is limited regarding explanations to the underlying reason and contextual influence on whether, why, and how reminder interventions might work (48). This applies to the use of reminder intervention when little explanation about the great variations of effects found between different health care settings exists (40). Analyses which set out to explore the underlying causes of a working intervention, includes focus on contextual factors and takes the complexity within different health care systems into consideration. This would be valuable in creating a better understanding of its success and failures (48). Such knowledge would be important to the future development and implementation processes of interventions in health care systems (47).

## **1.5 ETHICAL CONSIDERATIONS IN DISEASE PREVENTION AND SCREENING**

All public health interventions can potentially cause harm to individuals in different ways. This may be direct, psychological, or they can occur in the differentiation of risk groups or if the intervention does not help the ones most in need, as well as in cases of inappropriate use of resources (49). Effective public health intervention may, in fact, increase the social inequalities in health, if those who need it least,

benefit the most (50). This is important since social inequality in diabetes (51) and diabetes patients use of health services is a major and general problem, also in a Danish setting (52). According to Michael Marmot, experiencing a lack of control associated with poor health, stress, and anxiety as well as low commitment to health-promoting behaviors, is another factor (53). In addition, Whitehead, Pennington, Orton, Nayak, Pettigrew, and Sowden (2016) argued that perceptions of control affect people's ability to cope with stress and make important health decisions, which has an impact on individuals stress level, risk behavior, and success in behavior change (54). Reminder interventions, operating on an individual and a health system level, have been found to potentially create opportunity and self-empowerment which includes perceived control, commitment, and predictability as mediators for adherence (55).

Reminder interventions targeting high-risk populations that, in this case, are otherwise healthy women with previous GDM but in high risk of T2DM, should also be of ethical consideration as it can increase the risk of stigmatization. Especially when some women experience stigma from both health care professionals and society during their pregnancy, complicated by GDM (56). Stigma is associated with health consequences for individuals and can also lead to social inequality in health (57). This means, that negative feelings, related to receiving the GDM diagnosis and fear of future health, experienced by some women (58) could be amplified and recurred again when receiving the reminder. Some women even feel guilty in relation to developing GDM (59).

As women with GDM clearly experience the amount of one-way information and written material overwhelming (3), it is important to innovate the current care approach and include dialog, social support and positive experiences. In line with the ethical aspects, outlined by the WHO, as a minimum of considerations in relation to screening:

*“Respect for dignity and autonomy which rely on an informed and uncoerced decision on participation in screening, fair allocation of resources, do good for people, plan possible outcomes and transparent communication”* (60).

These concerns call for reminder interventions that aid women's decision on participation in follow-up screening, taking the ethical aspect mentioned above into consideration. To achieve this, explication and understanding the theoretical underpinnings of reminder interventions are needed.

## **1.6 DISSERTATION RATIONALE**

As described above, GDM is a strong predictive factor for later development of T2DM. While acknowledging the importance of supporting women in lifestyle changes after a pregnancy complicated by GDM, the focus of this PhD is the insufficient uptake of follow-up screening after birth. This focus was taken in order to help support the early detection of diabetes and reduce the serious health consequences associated with undiagnosed diabetes.

Follow-up screening after GDM includes a multilevel complexity with challenges in cross-sectoral care. Moreover, does women's participatory resources and prioritization, and implementation of guidelines on follow-up screening in general practice, affect women's participation.

Reminder systems are found to be successful at increasing postpartum screening rates by supporting a coherent pathway. More knowledge is needed in explaining form whom and under which circumstances the intervention actually works. This includes understanding of the reminder intervention as a part of a larger complex social systems where different subsystems interact and influence each other.

To avoid harms and maximize the probability of effect, a reminder intervention should be based on theoretical understandings and take into account ethical issues in the support of the women's decisions on participation in follow-up screening.

## 1.7 OVERALL OBJECTIVE AND RESEARCH AIM

The overall objective of this thesis is to support early detection of diabetes among women with previous GDM, through the development and testing of an intervention, based on reminders, providing aid to women's decisions on participation, in the recommended follow-up screening.

The overall objective is operationalized into the three following research aims which are addressed and unfolded in the three studies of this thesis:

- 1) *To explore for whom and under which circumstances reminder interventions are effective. To explore theoretical underpinnings in reminder intervention design and to explore and analyze context, mechanism, outcome configurations that emerged under experimental conditions and delivery settings of reminder interventions (7).*
- 2) *To explore the perspectives of GPs and relevant staff members (i.e., registered nurses and midwives) on follow-up screening for T2DM after GDM and to identify barriers to and facilitators of follow-up screening (8).*
- 3) *To determine the effectiveness of an electronic reminder intervention to women 1- 8 years after a pregnancy complicated by GDM in increasing participation in follow-up screening in general practice (9).*

## CHAPTER 2. METHODOLOGY

*This chapter outlines the overall framework, description of the PhD-project, the philosophical and theoretical underpinnings, reflections on the role as a researcher, study setting and ethical research considerations.*

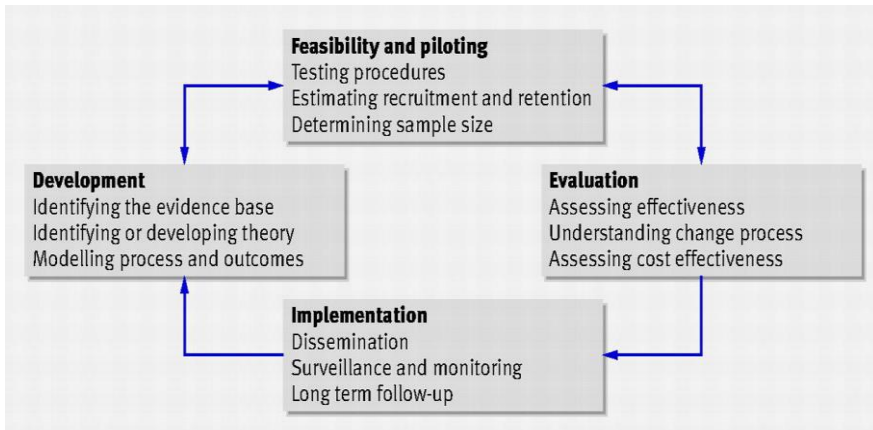
### 2.1 THE OVERALL APPROACH TO INTERVENTION RESEARCH

#### 2.1.1 The British Medical Research Council's (MRC) framework for intervention research

Methodologically, this intervention study was inspired by the British Medical Research Council's (MRC) guidance on *Development and Evaluation of Complex Intervention* from 2006. It is an internationally acknowledged and widely used guidance in the field of public health interventions (10,61).

There is no clear line between simple and complex interventions, however few interventions are truly simple (10). A complex intervention is defined as an intervention that contains several different interacting components, behaviours of those delivering and receiving interventions, different groups and organizational levels, variability of outcomes and flexibility of intervention (10). In this PhD project, many factors, including the transition between sectors, women's own resources as well as the organization and prioritization of the screening in general practice, contribute to complex interactions in the care for women with and after pregnancy complicated by GDM (8).

The MRC-guidance encompasses four different phases of intervention research: development, feasibility/pilot testing, evaluation, and the final implementation of the intervention (Figure 1) (10). The arrows indicate that the development and evaluation of complex intervention is neither a linear nor circular process, but an iterative process which moves back and forth between the different phases, depending on which challenges and knowledge you encounter (10). Also, each phase can guide decisions on whether the research should proceed, go to the next phase, return to a previous phase, repeat a phase, or be aborted (10).



**Figure 1: The four phases of the complex intervention process illustrated in the Medical Research Council's guidance (10)**

The development phase involves identifying the evidence base, identifying or developing theory, and modelling processes and outcomes (10). The identified knowledge, in combination with selected theories, can contribute to insight into how an intervention can create change, challenges and unintended consequences that may be associated with it, as well as suitable designs and methods to evaluate. The guidance rests on the belief that complex interventions may work best if tailored to local circumstances, rather being completely standardized (10).

Evaluations are often undermined by problems of acceptability, compliance, as well as the delivery of the intervention, recruitment and retention, and smaller sample size than expected. Newly developed intervention will therefore benefit from pilot/feasibility studies in order to test how the intervention works within a practice setting before decisions are made to pursue full-scale evaluation and possible implementation (10).

Due to the time frame of this PhD project, the focus will be on the development and pilot/feasibility phase, as greater attention to early phases of development and piloting are recommended (10). Final evaluation and implementation are beyond the scope of this project.

### 2.1.2 Development and pilot test of a reminder intervention

Intervention development is not described in detail in the MRC 2006 guidance. A **Six-Step Guide for Quality in Intervention Development (6SQuID)**, in 2015 (62), was therefore used to inspire the development of the reminder intervention. 6SQuID is a pragmatic guide which can support researchers and practitioners in how best to develop interventions, in a practical, logical and evidence-based way, in order to maximize the effectiveness of interventions (62).

The 6SQuID- guide breaks the process of intervention design down into six essential steps which include:

- 1) *Defining and understanding the problem and its causes*
- 2) *Identifying which causal or contextual factors are modifiable: which have the greatest scope for change and who would benefit most*
- 3) *Deciding on the mechanisms of changes*
- 4) *Clarifying how these will be delivered*
- 5) *Testing and adapting the intervention*
- 6) *Collecting sufficient evidence of effectiveness to proceed to a rigorous evaluation (62).*

The developing process incorporated socio-ecologic thinking, because it supports a better understanding of a specific health problem and possible solutions to it (63,64). This was in line with 6SQuID's recommendations of striving for a deeper understanding of the problem, its causes and contextual factors, and through this essential knowledge on how to design an intervention (10,62).

Use of the socio-ecological model, in the intervention development processes, is consonant with and encompassed by system thinking. This focus on interrelationships between individuals and their environment draws upon an underlying understanding and acknowledgement of human behaviours in complex ecological systems (63). Change in people's health behaviours (including participation in follow-up screening) also involves changing the relevant environmental conditions (63). This is emphasized in Dahlgren and Whitehead's (2007) socio-ecological model of determinants of health, that illustrates how factors at different levels affect the health of the individuals (65). The determinants of health are believed to influence each other, as well as affect and be affected by other levels (65). This means that actions and changes within a level not only affect that level but have an impact on surrounding levels.

Moreover, the 6SQuID guide involves decisions on the mechanism of changes and how these will be delivered. Drawing out a program theory was also incorporated in the process of developing the reminder intervention, tested in Sub-Study 3 (9).

The purpose of the program theory is to map out the assumptions about what happens from the beginning of an intervention (input) until outcome/impact can be identified (64,66). This can be understood as a set of coherent assumptions, principles and assertions that explain or guide a social action (66); a chain or series of factors, which can be described in more or less details (67). The implementation of a program theory is a purposeful and organizational effort to intervene in an already existing social process, in order to solve a problem or provide a service (66).

The program theory developed in this PhD project combined two sub-theories. This is an often-used approach when trying to describe both "what we do" (theory of action) and "how we expect this to work" (theory of change) (64,66). The theory of action should clarify the target group, resources and activities of the program as well as when they take place (64,66). Identification of the factors that influence the

possibility, if any, of realizing this is also important to consider (66). The theory of change should, on the other hand, try to describe assumptions about the relationships between the intervention and the effect. This includes establishment of the outcome chain and what mechanisms are effective in the specific context (66). These two theories are often woven together into one process and its establishment is taking place synchronously (66), which was also the case in this PhD-project. Drawing out the program theory was an ongoing development process wherein I sought to inform by using different sources and methods. This included documentary material, collection of evidence and empirical data, identification of relevant theory as well as seeking vital expertise and experiences among local actors, important to the success of the intervention.

The 6SQuID guide also includes testing and adapting the developed intervention, which emphasizes the iterative process between the development feasibility/piloting phase, outlined in the MRC-guidance. The pilot/feasibility phase sets out to test the actual workings of the developed intervention, within the specific practice setting. Thereby, an evaluation of whether the assumptions and selected theories behind the developed program theory is as effective as initially thought (64,66).

The terminology and conceptual idea of pilot studies varies greatly in literature, whereas some even state pilot and feasibility studies to be the same (68). A narrative review of key literature establishes the common principle that all pilot studies are feasibility studies but not all feasibility studies are pilot studies (68). This implies that when a pilot trial is examining the potential effectiveness of new interventions or interventions in new contexts, the feasibility of trial processes should also be evaluated (68). In this PhD-thesis, the pilot study set out to determine the effectiveness of the developed reminder intervention, but also contributed reflections, processes, and implementations. Thus, adding to important knowledge on the feasibility of the intervention, as recommended for pilot studies (68). The pilot study thereby also encompasses the final step of the 6SQuID guide recommending establishment of sufficient evidence of effectiveness preferable by using control groups to increase the strength of evidence (62).

This is substantiated by the MRC-guidance, suggesting that full-scale evaluations are often undermined by problems on delivery of the intervention, recruitment, and retention, and smaller than expected effect sizes, which could have been predicted by thorough piloting (10).

### **2.1.3 Historical review of the research area with significance for this PhD**

The methodology of complex intervention research, within public health, has been an area of growing interest over the last two decades. The 2006 guidance has been expanded and was published as an updated framework for complex intervention research in 2021 (69), but this occurred after the development and test of the reminder intervention in this PhD thesis. A historical review will be reflected on, as will important consideration, in the discussion section below.

The first MRC-guidance, from 2000, started with a recognition that an increasing number of non-pharmacological interventions emerged and that these also should be rigorously evaluated (70). The research area has been undergoing some theoretical and methodological changes as new knowledge has accumulated over time. New and updated research has continuously been prioritized and has resulted in development, refinement and clarification of the updated guidance and other key concepts. In relation to the MRC-guidance, three different versions have since been published (10,47,70).

Several limitations were found according to the MRC-guidance, from 2000, which, for example, included an insufficient integration of process evaluations and the local context wishing to intervene (10). Furthermore, the recommendation emphasized the need for greater attention to the early phases of development as well as a less linear model. The visual change between the MRC-guidance of 2000 and the one published in 2006 are highly evident in comparison of the phases included.

The MRC-guidance from 2006 was, besides a less linear process, strengthened by greater attention towards the contexts in which interventions take place. This definitively emphasized the need to combine evaluation of outcomes with the process (61,71). However, it did not offer any details on how to conduct a process evaluation (71), causing an increasing focus on this in the following years which resulted in new publications in 2014-15 (71,72). The later publications acknowledged the need to clarify causal mechanisms and identify contextual factors associated with variation in outcomes (71).

In September 2021, the newest MRC-guidance was released (47). Some of most significant changes comply with the approach by this thesis, such as a strong recommendation to include research users, clinicians, patients, and public in research (47).

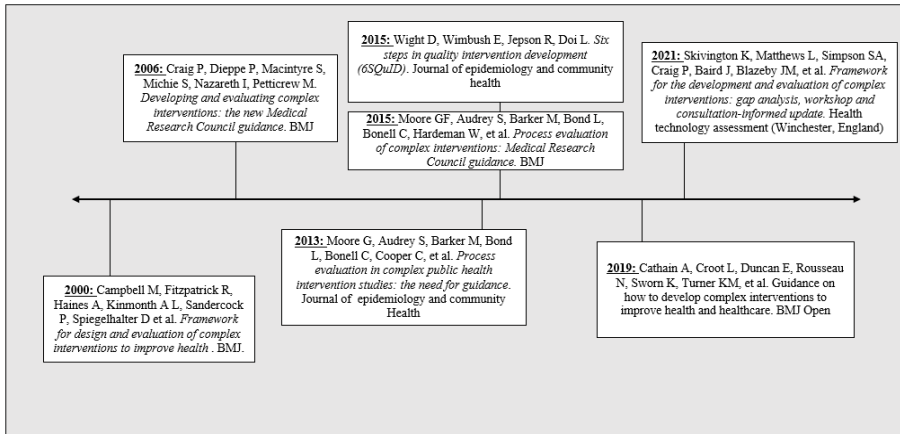
Moreover, the definition of complex interventions has evolved from solely focusing on the various interconnecting parts of an intervention, to include behaviors of those delivering and receiving interventions, and number of organizational levels targeted by the intervention, in the 2006 MRC-guidance (70). In the 2021 MRC-guidance, this definition has been further expanded on as complexity is considered as arising from contextual settings, wherein system thinking can help to understand the interaction between an intervention and the context. Systems can be thought of as 'complex and adaptive', and Interventions can be theorized as 'events in systems'. Intervention outcomes can be conceived as being generated through the interdependence of the intervention and a dynamic system context (47).

This PhD project uses one of the first and widely used and recommended guides for the development of complex interventions (62). A new guidance (the INDEX study) (73) was published in 2019 and identified and assessed different approaches to developing complex interventions, which inspired the new MRC-guidance published in 2021 (61). Many similarities are found between these two guidelines. However, the new guide includes stronger advocacy for early involvement of the



stakeholders and decisions makers and has a more explicit focus on the program theory (62,73). These perspectives are in-line with the updated MRC-guidance (61).

Selected research with significant importance to this PhD project and its timeline are illustrated in Figure 2, below.



**Figure 2: Historical review of literature within the area and -project**

## 2.2 OUTLINE OF THE OVERALL PROJECT

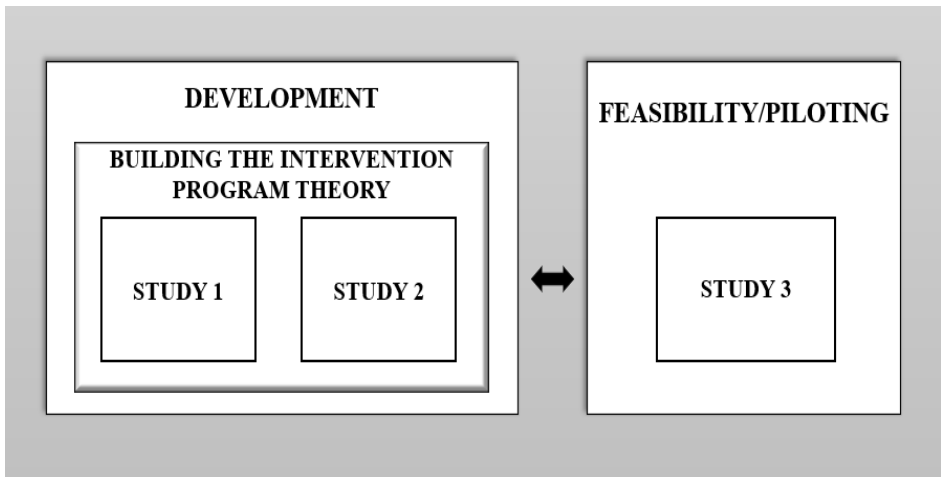
The relations between the before mentioned framework and the three studies of this PhD project are visualized in Figure 3, below. Thus, the three studies can be divided in relation to the development and piloting phase of the MRC-guidance.

It is important to note that the development and piloting phase included more than just Studies 1, 2, and 3. The development phase, according to the MRC-guidance, should identify the evidence base and develop the theory behind the intervention which includes modelling processes and outcomes. This phase was, as mentioned above, guided, in more detail, by the Six-Step Guide for Quality in Intervention Development (6SQuID) and included analysis of the problem and its causes, the greatest scope for changes as well as a developing the program theory. This process relied on results from Study 1 and Study 2 and was undertaken while, between and after these were conducted. These important considerations are included within this PhD thesis, described alongside the findings.

The pilot phase should, according to the MRC-guidance, test procedures and allow for reflections on recruitment, retention and sample size. Study 3 was undertaken as a pilot study, examining the effect and implementation of the reminder-based intervention, in a Danish Region/Regional Health Service (9). This phase was therefore, as mentioned above, also guided by the 6SQuID guide as it both tested the developed intervention and collected sufficient evidence of the effectiveness (62). In this PhD thesis, the findings from the effect evaluation includes reflections

on processes and implementation and provides knowledge on the feasibility of intervention, using the North Denmark Region as a case.

In accordance with the MRC-guidance, the arrow indicates that the development and pilot test of a complex intervention is an iterative process which moves back and forth between the different phases, depending on which challenges and knowledge you encounter. The discussion of this PhD-project will include a revision of the developed reminder-based intervention.



**Figure 3: Outline of the three studies of this PhD-thesis and the phases of the overall project**

Overview of the methods used within the three studies are visualized in Table 1, below, and further elaborated in the remaining part of this chapter.

	Study 1	Study 2	Study 3
<b>Approach</b>	Qualitative	Qualitative	Quantitative
<b>Design</b>	Realist Review	Interview	A two armed, single-blinded randomized controlled trial
<b>Participants</b>	4433 participants	18 general practitioners/ staff members	1463 women with previous GDM
<b>Setting</b>	Australia, Canada, USA, Finland, Chile, and the Philippines	General practices in the North Denmark Region	The North Denmark Region
<b>Method</b>	A systematic, iterative search for interventions studies and additional information related to these	Semi-structured interviews	Randomization included stratification by calendar year for GDM and birth (2012-2018) and allocation to either the intervention (n=731) or control group (n=732)
<b>Data</b>	13 interventions studies, 1 protocol and 2 evaluation of user perspectives	Transcribed interviews	Registry-based data
<b>Analysis</b>	Narrative synthesis of effect. Realist synthesis of middle-range theories and CMO-configurations	Reflexive thematic analysis	Descriptive statistic of baseline characteristics, effect, and stratified sub-group analysis

**Table 1: Overview of the methods used in the three sub-studies of this PhD-thesis**

## 2.3 STUDY 1

*Study 1 was a Realist Review which aimed to theorize, not only if reminder intervention to support early detection of diabetes would work, but also for whom, and in what circumstances (7), a research question which had not previously been asked. In relation to the 6SquID and MRC-guidance, the rationale behind Study 1 was to identify the evidence base behind this type of intervention, including understanding how change can be achieved and gaining important information about the design and evaluation.*

The Realist Review searched for intervention studies which were based on the use of reminders to support the recommended follow-up screening among women with previous GDM. However, the realist synthesis not only relies on the results of primary intervention studies, but all parts of the study (74). Additional information, in relation to these, were also of interest (qualitative or quantitative). The reminder intervention could either target women with previous GDM and/or health care professionals playing a key role in follow-up screening. These could rely on different types of reminders and use both single and multiple strategies, as long as reminders were a significant element of the intervention (7).

The search for eligible literature included an initial search to support development of the search strategy, followed by a systematic search in several relevant databases (7). An example of the search strategy is provided in Appendix A. A search for

unpublished studies, grey literature, as well as a chain search of the reference lists and authors names, in relevant experimental studies, were conducted, because it is recommended in Realist Reviews to gather all available knowledge (75). Selection, appraisal, and data extraction were carried out and crosschecked by a group of three reviewers (7).

A data extraction sheet was used. As recommended by Realist standards, data were extracted not only on the effect of reminders, but also on features of the intervention, setting and delivery context, and the actual “working of the intervention” (75). In addition, data on intermediate, implementation, and unintended outcomes was extracted as well as the experience and satisfaction of women or healthcare professionals (7).

The narrative synthesis of effect of the interventions included exploring prominent patterns in the data, allowing for a better understanding of the variations previously found in the effectiveness of reminders (40). Furthermore, data analysis included identification of the overarching theories underpinning the included interventions, as well as an analytic process inspired by the principles of Realist synthesis, described by Jagosh, Pluye, Macaulay, Salsberg, Henderson, Sirett, Bush, Seller, Wong, Greenhalgh, Cargo, Herbert, Seifer and Green (2011) (76). This synthesis entailed iterative and overlapping steps in: Identification of explanatory middle-range theories and CMO-configurations (CMOc), followed by a discussion of confirmatory and contradictory findings (76).

## 2.4 STUDY 2

*Study 2 aimed to explore the perspectives of GPs and relevant staff members on follow-up screening for T2DM after GDM and to identify barriers to and facilitators of follow-up screening (8). In relation to the 6SquID and MRC-guidance, the rationale of Study 2 was that those perspectives were highly important given the knowledge possessed in their overall role in the health care system, their contact to women and their families, and responsibilities in relation to the recommended screening could give input to intervention design and create an understanding of the actual context which the intervention should be tailored for.*

In this study, a purposeful sampling strategy enabled recruitment of 18 informants (12 GPs and 6 staff members). A mixed sample attempted to represent solo and group practices, practices in urban and rural areas, and participants of different ages, genders, and years of experience in general practice (8). The strategy embraces diversity to ensure all key groups with important knowledge to the research question are selected (77). This was acknowledged when some GPs wished to be represented by a staff member with delegated responsibility for pregnant women and/or follow-up care for patients with diabetes or other chronic diseases (8). The different perspectives offered more nuanced and in-depth data, which accumulated a high level of information power (78). All general practices in the

region received an open invitation to participate in a newsletter from the regional General Practice Research Unit (Appendix B). This elicited no response, and general practices were then contacted directly by phone or in person (8). Approximately 50 general practices throughout the region were contacted and the most common reason for not participating was lack of time.

Semi-structured interviews were conducted and audio-recorded by the first author, and transcribed verbatim by an assistant, afterwards. The semi-structured interview guide was divided into three theoretical areas, identified in the previously published research, to influence on follow-up screening. Interviews attempted to extract practitioners' cultural understandings of the early detection of diabetes, technical opportunities in general practice, and political and organizational implications on practice. In order to explore individual experiences, understandings and attitudes, open-ended questions were primarily used (79). Pilot tests of the interview guide was recommended (79) and prioritized. Only minor changes and refinements were needed, therefore, these interviews were included in the final study material. Flexibility, in relation to time and location, were offered to promote the participant to feel at ease (79), however, all participants choose to be interviewed during working hours at their own clinics/workplaces. Face to face interviews were preferred, because it enables direct observation of emotion and visual cues, which can be important to dynamics, interpretations, and depth in interviews (79). Nonetheless, three participants preferred to be interview by telephone which was accommodated, as a previous study only found face to face interviews to be marginally superior and the difference was negligible (80).

A Reflexive Thematic Analysis following the procedures outlined by Braun and Clarke were pursued (81). Reflexive notes, made when first reading the verbatim transcribed interviews, were discussed to gain a greater initial insight of data. This followed by inductively coding of both semantic and latent meanings throughout the dataset, while using NVIVO qualitative data analysis software (QSR International Pty Ltd. Version 12, 2012) (8). To help reflexivity in coding, three transcripts were compared and discussed, among two researchers, as recommended (81). Based on the smaller, meaningful units, which codes constitute, the construction of themes (81) was possible. The process of revising and defining themes was pursued by discussing the essence, structure, and limits of themes (79). Several researchers contributed to this process to ensure and promote reflexivity.

## 2.5 STUDY 3

*Study 3 was designed as a two-armed, single-blinded, randomized, controlled trail which aimed to determine the effectiveness of an electronic reminder intervention to women within 1-8 years after birth (9). In relation to the 6SquID and MRC-guidance this study was a pilot study that contributed with an effect evaluation at health system level as well as reflections on processes and implementation. Thereby also contributing with some important knowledge on the feasibility of the developed intervention, using the North Denmark Region as a case.*

Women who gave birth between 2012-2018 and were diagnosed with GDM during pregnancy were found eligible for inclusion. Women who were suspected of being misdiagnosed with GDM, had died, developed a diabetes diagnosis during/after pregnancy, or no longer lived within the North Denmark Region, were excluded from this study. For women who registered with several births with GDM, only the GDM-pregnancy of the youngest live-born child was included.

As no prior study has examined the effect of reminders beyond the first year after birth (7), the study population was stratified on the calendar year for the GDM pregnancy, based on the birth year of their child. Hereafter, randomization to either the intervention group or the control group was performed within each stratum. A sample size calculation estimated that 388 women, per arm, would be required.

Study 3 relied on registry data from the National Patient Register, containing individual information on personal conditions and all hospital admissions in Denmark, based on WHO's "International Statistical Classification of Diseases and Related Health Problems (ICD-10)". The Danish Employment's database was also used to contribute to characterization of the participating women (9).

The primary outcome was a performed blood test for diabetes (OGTT, fasting P-glucose and HbA1c), as it suggested participation in the recommended follow-up screening. Two different data sources were used to assess the primary outcome; the registry of National Health Insurance Statistics, containing information on health insurance services, made up general practice and regional data from biochemical departments using NPU terminology (Nomenclature for Properties and Units terminology). The secondary outcome was a diagnosis of T2DM which was also identified through the NPU or ICD10- coding. Outcome data was retrieved approximately 6 months after sending out reminders.

Baseline characteristics of all the included women were expressly reported. The effect of the intervention was estimated as Risk Ratios (RR) and Risk Difference (RD) for both primary and secondary outcomes (95% confidence intervals). A forest plot was made to graphically display the estimated results, accordingly to the stratified groups, represented by years after birth. Also, stratification for age, ethnicity, employment status, municipality, parity and BMI, to estimate the effect of the intervention for different subgroups were made. All statistical analyses were performed using Stata 16.1 for Windows® (StataCorp, College Station, TX, USA).

## 2.6 PHILOSOPHICAL AND TEORETICAL UNDERPINNINGS

At a philosophical level, this PhD project is inspired by *Critical Realism*. This philosophical approach for social science emerged in the 1970-80's through the work of Roy Bhaskar (82). The primary goal of Critical Realism is to gain knowledge, in terms of theories, which help us identify the causal mechanism driving social events (82). Prominent realistic evaluators, such as Pawson and Tilley (*Realistic Evaluation*, 1997), have a theory-driven approach to evaluate interventions which are associated with Critical Realism (61,83). The scientific

theoretical starting point of realistic evaluation, like Critical Realism, does not reduce ontology (the nature of reality) to epistemology (knowledge of reality) but applies a stratified generative ontology where parts of the existing reality are found at deeper levels, which cannot be directly observed by the researcher (82). However, it is not denied that there is a real social world, which we can attempt to understand and access (82). The assumption is that underlying mechanisms generate change in both interventions and in society, but they will only be triggered in certain contextually circumstances. Some contextual factors will be supportive to a specific program theory, some will not, wherefore it is crucial for realists to sort these from each other (84). In attempts to do so, realist evaluations try to pinpoint the patterns between context, mechanisms, and outcomes (CMOCs) (84).

Nonetheless, even though Study 1, as well as the developed program theory and the exploration of contextually factors in Study 2, acknowledge Realist principles. In addition, the MRC-guidance from 2006 urged randomised, controlled trails to be considered as the most robust method to assesses effectiveness (10).

This type of effect evaluation is, much like Critical Realism, based on an ontology wherein an objective reality exists independent of the observer (85). However, an epistemology effect evaluation perceives social reality to be composed of measurable, objective, facts which can be precisely measured by the researcher (86). Thus, experimental research is believed to provide an opportunity for researchers to examine the effect under stringent and controlled conditions (86). The randomized controlled, recognized and recommended by the MRC-guidance from 2006, to assess the effectiveness of intervention (10) thereby draws upon the theoretical approaches of positivism and falsificationism (87).

Realistic evaluators often criticize the randomized, controlled trial for becoming a "black box" wherein one does not know what it is about the intervention that creates effects (84). Pawson and Tilley believe that these different understandings of causality are contradictory and incompatible. In contrast, newer generations of realistic evaluators believe that these could be considered complementary rather than competitive (85).

Pursuing this approach, the effect evaluation can be carried out first, to establish whether and to what extent the intervention has worked (85). This could then be followed by the application of realist principles in examining explanations for why the effort has worked (or not worked) (85). Thus, the two approaches are carried out separately, on their own terms, and insights are used to complement each other (85).

## **2.7 RESEARCHERS ROLE DURING DATA COLLECTION**

The use of qualitative and quantitative methods affects the researcher's role differently, during data collection.

Relying on synthesis of the data available to the public, in Study 1, transparency and reproducibility were important (88). Therefore, the role of researcher was to ensure transparency and make thorough descriptions of the most critical methodological processes which can influence the final quality of the review (88). This includes the search process, selection and appraisal of documents, data extraction and synthesis processes (88).

Data collection of the perspectives from general practice, in Study 2, were related to the qualitative paradigm, the purpose of which was to understand and explore meanings. All research activities were influenced and positively valued by the researcher subjectively and reflexively (79). In this study, the interviewer's (the PhD student) presuppositions and understandings of the phenomenon were colored by a theoretical insight into the topic of care and treatment for women with previous GDM, as well as a background in a midwifery and public health profession. This study is based upon the belief that General Practitioners play a key role in the recommended follow-up screening, as well as in the overall care of women and family's health. This allowed me to be open to perspectives within general practice and pursue a special position. Researchers, without the same professional background, can approach interviews with a certain naivety, encouraging details, while simultaneously avoid informants to feel cautious in conversations, due to fear of judgment from a fellow professional (89). Being an "outsider" can also generate reticence or suspicion (89). This was not believed to be the case in Study 2, as it was possible to draw on prior understanding of the topic and cultures overall, within the health care system. Methodological literature suggested that this type of shared knowledge and interest of the topic may increase the interviewer's credibility, and enable issues to be pursued more thoroughly, without having to seek explanations of basic terminology and concepts (89). The special position could also have been a strength during analysis, hence the familiarity of a true "insider", may dominate the process of data analysis and prevent novel insights (89).

On the other hand, according to Study 3, the randomized controlled trials are a design which helps to prevent selection bias and controls potential confounding (90). The process of random assignments to the intervention or control group eliminates any human influence on allocation (90). Furthermore, the single-blinded design and the anonymized registry-based data ensured that I could assess outcome without any knowledge of which group the participants belonged to. Moreover, participants within the control group were unaware of the intervention being tested. This was believed to prevent bias in the estimated effect of an intervention (90), and required statistic competencies of the researcher.

## **2.8 STUDY SETTING**

The setting of interest was the North Denmark Region, which is one of five regions in Denmark. This region covers an area of 7,933,32 km<sup>2</sup> and contains 578,839 citizens. It is the smallest region in Denmark, in relation to population size (91). Over 90% of the budget within this region goes to the Health Care Sector (91). In



the secondary Health Care Sector, Aalborg University Hospital, as a tertiary level hospital, is of great importance to the region (91). This also applies to women diagnosed with GDM. All women with GDM in this region are referred to ‘specialized care’ during pregnancy and birth, at Aalborg University Hospital (92).

Because of the Danish welfare model aims to promote society-wide health and social equity through tax-financed services, all Danish residents have a right to be registered to a locally placed general practice and receive free-of-charge care (93). This encompasses GPs who play the key role in early detection of diabetes and the recommended follow-up screening after birth for this specific group of women. The region has approximately 285 GPs serving on average, 1779 patients, whereas most GPs are private solo or group practices, and few are managed by the region (8). The payment is a mixture of per capita payment and fees for services, and there is no requirement for recertification (94).

This cross-sectional care for women with GDM, imposes a quality gap for women within this region (3,94), as well as a decrease in participation in follow-up screening in years after birth (2). In this PhD project, the administration of the North Denmark Region and the Center for General Medicine at Aalborg University gave important support and input to the developed program theory and participants from Study 2 and in the pilot test of the developed intervention were recruited from this region.

## 2.9 ETHICAL RESEARCH CONSIDERATIONS AND APPROVALS

Prior to beginning each study, specific ethical research considerations were made.

Study 1 aimed to provide secondary research of published articles with data already available to the public, in order that no prior approval was needed (95,96). Observing the Danish legislation on scientific dishonesty (97), and the three basic principles of *Honesty*, *Transparency* and *Accountability* which, according to the Code of Research Conduct, should permeate all phases of research (98,99). These considerations were also highly important while disseminating the analysis and findings of Study 1. This includes ensuring clarity in how the findings emerged, as well as how and when primary studies contributed as a source. Furthermore, the Realist Review was prospectively registered and published in the PROSPERO database of systematic reviews (ID: CRD42019123769).

The Danish legislation stipulates that such qualitative studies are to be based solely on the individual participants informed and written consent. The National Ethical Committee does not approve nor deal with qualitative studies, unless they are part of a trial which includes human biological material. Neither do the North Denmark health authorities nor the institutions involved (Aalborg University, University college North Denmark and Aalborg University Hospital) have ethical committees (95,96). Obtainment of individual informed consent, as a minimum, requires the participants to receive information about the identity of the person responsible for

data, the purpose of the study, what information is processed and that the participant can withdraw his/her consent at any time (96). For all participants of the qualitative Study 2, written information as well as oral information was provided and written informed consent was obtained before each interview. The informed consent sheet is included in Appendix C. In addition, Study 2 followed the ethical principles stated within Declaration of Helsinki on *Privacy* and *Confidentiality* (100), and anonymization of personal information was respected.

The project was registered and the qualitative data for Study 2 was handled and stored on an institution-approved and encrypted file drive, at University College of Northern Denmark (Article 30). This complies with the legal requirements for storage, journaling, and IT security requirements of research data (101).

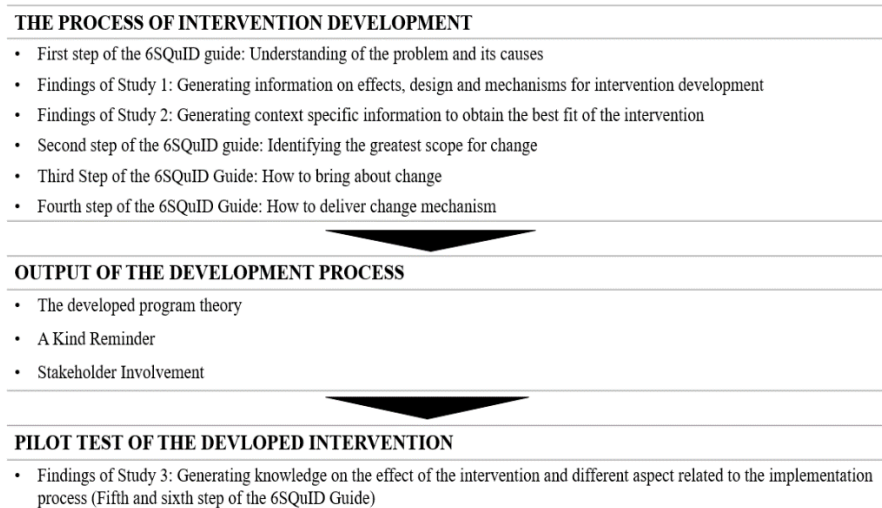
For Study 3, the North Denmark Region played a key role in the delivery of the intervention and collection of data for the identification of women and outcome measurement. A collaboration agreement between University College of Northern Denmark and the North Denmark Region was drafted, in agreement with the General Data Protection Regulation legislations (101), with the North Denmark Region as the party responsible for data. The Project was listed at the North Denmark Region (Project id-number 2020-006). The quantitative data was also handled and stored on an institution-approved and encrypted file drive at the North Denmark Region.

The Scientific Ethics Committee for the North Denmark Region was consulted, in relation to determination of the application for approval of Study 3. However, the Science Ethics Committee of the Region decided, with reference to Danish legislation (102), that the project could begin without further approval. None of the women who participated in the intervention study of this thesis were deprived of the opportunity to participate in follow-up screening study. Documentation is provided in Appendix D. Finally, the randomized, controlled trial was retrospectively registered in the clinical trial registry, recognized by the World Health Organization and International Committee of Medical Journal Editors (ID: ISRCTN23558707).

## CHAPTER 3. FINDINGS

*The structure/elements included in the findings section is inspired by both the MRC-guidance and the six steps included in the 6SQuID guide (10,62), thus findings from the three studies are reported in combination with the important considerations about the development work and pilot test and the results thereof.*

To summarize the impact of the 6SQuID and MRC-guidance on the project and findings sections, an overview of the overall structure of the findings section is visualized in figure 4 below.



**Figure 4: Overview of the findings section, inspired by the MRC-guidance and the Six-Step Guide for Quality in Intervention Development (6SQuID) (10,62)**

### 3.1 THE PROCESS OF INTERVENTION DEVELOPMENT

#### 3.1.1 First step of the 6SQuID guide: Understanding of the problem and its causes

As documented in the introduction of this thesis, low participation rates in the recommended follow-up screening among women with previous GDM, constitutes a multilevel challenge with an untapped potential in early detection of type 2 diabetes and is characterized by multilevel complexity.

Nonetheless, a deep understanding of the problem and its causes are important, even if a public health problem has already been identified as requiring intervention (62). A systematic search of previously published literature, on reasons for the low participation in follow-up screening experienced by women, and the clinicians'

provided screenings, was therefore conducted. The identified causes found in literature, were then organized, following a socio-ecological perspective, to create an overview of the underlying causes. This is an essential step in the 6SQuID guide in regard to development, as it is believed to enhance the understanding of how the problem unfolds itself and makes it easier to identify where to intervene (62). Figure 5 below, visualizes how the underlying causes move according to different socio-ecological levels and ensures a perspective on the problem which acknowledged the interrelationships between individuals and their environment.

<b>Policy Level:</b>	Insurance policies for health care coverage	Political prioritization of early detection of type 2 diabetes	Labor parties ensuring the opportunity for time for health care follow-up	
<b>Community Level:</b>	Transportation opportunities	Distances to screening facilities	Care pathway between health care sectors	
<b>Institutional Level:</b>	GP unaware of risk and recommendation	GP do not initiate leadership for screening	Support from GP in decision on screening	
	Baby friendly setting in clinics	Time and resources in general practice	Time consuming and uncomfortable test (OGTT)	
<b>Individual Level:</b>	Social impact on women's concern of diabetes	Balance between work and family	Support at home	No observable symptoms
	Attention towards screening	Personalized information	Prioritization of baby needs	Relying on results from discharge
	Feeling alone with the burden	Health beliefs: Fear of diagnosis or feeling healthy	Beliefs about own capabilities	

**Figure 5: Underlying causes for the low participation in screening (41,103-105)**

The causes of the problem are distributed on different levels with both proximal and distal factors influencing the problem. These factors can influence and act as an underlying cause for factors on other levels. They can therefore help shape and perpetuate the problem (causal pathways) (62). Lack of available transport opportunities can, for instance, act on a community level as an underlying cause for women's individual experience of having difficulty balancing time between work and family, a well-documented reason for non-participation among women (41). The pathways of the problem can, in this way, be seen as complex, diverse and strongly interwoven within each other (62).

The diagrammatic overview shows that a significant number of causes move on an individual or institutional level. Fewer, though not less important factors, move on policy and community levels. Possible ways to intervene seem to include changes at both institutional and individual levels, whereas reminder systems have previously been found successful at increasing participation.

Alongside the analysis of problems, Study 1 and 2 contributed with important in-depth knowledge. This information included the specific intervention settings regarding which underlying causes were important, to the actual workings of the intervention, as well as knowledge on any barriers and facilitators to follow-up screening, in general practice. This could give input as to which factors are malleable and have the greatest scope for change.

### **3.1.2 Findings of Study 1: Generating information on effects, design and mechanisms for intervention development**

The systematic, Realist Review included 16 studies in the synthesis, 13 of which were intervention studies and 3 were considered important additional information, in relation to these intervention studies (1 Protocol and 2 Evaluation of User Perspectives). Most of the studied reminder intervention had been delivered in America and Canada, as well as one in Australia, Finland, Chile, and the Philippines (7). Three studies had a serious risk of bias, however, no studies were excluded according to quality, since Realist also considers these to contribute to possible determination of the success or failure of a program (74). Studies were not excluded due to the content of reminders. Only studies in English were identified (7).

The narrative synthesis of the effect added to the growing body of evidence suggesting that reminders may effectively increase participation in follow-up screening after birth. However, the effect sizes varied greatly across the included studies. An important explanatory finding was, that when participation in follow-up screening was associated with an extra cost for women, the reminder was not effective at increasing participation. Simple strategies and multiple strategies where the reminder intervention was combined with other components was identified. The narrative synthesis was not able to produce the basis for a clear conclusion on which strategy and type of reminder (email, phone call, short message service (SMS) etc.) was the most successful, nor was it clear whom the reminder should target (women or clinicians) to optimize its effect. The majority of the studies reporting positive effects targeted, solely, women. Finally, the Oral Glucose Tolerance-Test (OGTT), Fasting Blood Glucose, and HbA1c were found to be the dominant choices of outcome measures (7).

Nonetheless, findings from Study 1 did elucidate that the included reminder interventions were built upon an overall understanding in the potentials of early detection of diabetes, as well as this type of interventions being able to create an important behavior change, leading to an increased participation in follow-up screening (7). These understandings were underpinned by theories within psychology, such as social cognition models wherein humans are rational beings where change in behavior happens through a change in their cognitive processes (106). Thereby, implicitly relying on overarching theories, like Reasoned Action Models wherein humans are likely to do what they intend to do and can rationally, systematically, and logically use information (106) provided by the reminder intervention. Finally, the reminder intervention drew upon the researchers

understanding of the importance of the continuity of care. A reminder could support continuity in women's care across health care sectors, as well as reminders, possibly, contributing to the decision-making processes. Therefore, the intervention system is also underpinned by overarching theories about communication and continuity of care (107,108).

The operationalization of the CMOc's, describe resources and reasoning as mutually constitutive of a mechanism (109). This is unfolded in Table 1 in Study 1 where Dalkin, Greenhalgh, Jones, Cunningham and Lhussier (2015), defines the CMO-configurations (CMOc) formula as when intervention resources are introduced in a context in a way that enhances a change in reasoning (7) Through a cross-case comparison and thematic grouping of the most essential and strongest substantiated CMOc identified in Study 1, were consolidated into 7 CMOc's under 3 thematic headings. These related to system resources, women's circumstances, and continuity of care (7).

These CMOc's, as well as the result of the narrative synthesis, and a socio-ecological perspective, was discussed, which helped us to support and refine what Justin Jagosh and other scholars in the field of Critical Realism have termed Middle-Range Theories (74,76). Jagosh et al. 2011, defines Middle-Range Theories as:

*“Middle-Range Theory (MRT) is an implicit or explicit explanatory theory that can be used to explain specific elements of programs or how program logic manifests in implementation. “Middle-range” means that it can be tested with the observable data and is not abstract to the point of being disconnected from the on-the-ground workings of programs, yet not so specific to pertain to one program.” (74,76)*

These findings are explained and illustrated in table 2 below. This table thereby, inspired by figure 3 in study 1 (7), combines and summarize findings from the narrative synthesis, the identified CMO-configurations, and the discussions of Middle-Range Theories according to different socio ecological systems.

<p><b>Thematic grouped CMO-configurations related to:</b></p> <ul style="list-style-type: none"> <li>• System resources</li> <li>• Women circumstances</li> <li>• Continuity of care</li> </ul> <p><b>Narrative synthesis:</b></p> <ul style="list-style-type: none"> <li>• Reminders can support screening, but effects vary across settings</li> <li>• When screening was associated with an extra cost for women the reminder was not effective in increasing participation</li> <li>• No clear conclusion on strategy, type and whom the intervention should target</li> <li>• No knowledge on effect of reminders beyond the first year after birth</li> <li>• OGTT, Fasting blood glucose and HbA1c were the dominant choices of outcome measures</li> </ul>	<p><b>Policy Level:</b></p>	<p><i>Women supported by social, policy and financial incentives were better able to respond to reminders prioritize screening</i> Insurance policies as well as work obligations and time used on appointments and transport influence participation in screening</p>
	<p><b>Community Level:</b></p>	<p><i>Collaboration across health care sectors and continuity in care supported the effect of reminders</i> Collaboration and clear pathways of knowledge among health care sectors could support clinicians in providing timeliness and continuity in care</p>
	<p><b>Institutional Level:</b></p>	<p><i>Systematic identification of women with GDM supported the effect of reminders</i> Tracking completion rates provides an opportunity to repeat reminders and/or actively minimize practical barriers for women to participate</p> <p><i>Standardization of care in general practice supported the effect of reminders</i> Providing clinicians with knowledge of screening can lead to increased uptake in screening, however reminder solely to clinicians did not bridge the communication gap between health care sectors</p> <p><i>Relational continuity seemed to increase participation in screening</i> Personalized health care person in charge, can lead women to overcome barriers related to uncertainty of their own risk and effects of screening</p>
	<p><b>Individual Level:</b></p>	<p><i>Women who do not experienced fear of diagnosis seemed to be more likely to engage in screening</i> Overweight and socially disadvantaged women seem to be less likely to engage with screening, which may be related to fear of being diagnosed</p> <p><i>Continuity in information seemed to support the effect of reminders</i> Information on risk of diabetes and the importance of screening should preferably build on the same type of information provided during pregnancy</p>

**Table 2: Overall findings, which could help explain the success or failure of reminder interventions across differing circumstances and for whom (7)**

### 3.1.3 Findings of Study 2: Generating context specific information to obtain the best fit of the intervention

Eighteen participants, comprised of 12 GPs and 6 staff members, were interviewed in Study 2. The majority of which came from general practices in rural areas of the North Denmark region (Urban 6/Rural 12). The majority were female (Female 16/ Male 2), most were under 50 years of age (<50 years: 11/ >50 years: 7) and most had less than 10 years of work experience in general practice (<10 years' experience: 12/>15 years' experience: 6) (8).

The analysis led to the three main themes (8):

- 1) Challenges of addressing women's risk
- 2) Prioritization of early detection of diabetes
- 3) System influence on clinical procedures

The essence of these main themes and the 5 subthemes will be unfolded below, while quotes from participants, supporting these findings, are thoroughly described in the published paper (8).

#### Theme 1: Challenges of addressing women's risk

##### *Insufficient knowledge*

Many of the included participants had little knowledge of women's increased risk of T2DM, making them less attentive towards screening. In cases where GPs were aware of women's increased risk, they had insufficient knowledge of screening procedures which often resulted in a hesitant or unconcerned approach to screening. GPs also tended to underestimate women's risk, due to the young age of the women. The included participants also emphasized that screening was compromised by the insufficient knowledge. The GPs found it challenging to keep updated through the available discharge summaries from the secondary health care sector (8).

##### *Balancing contradicting risk perceptions*

Differences in understandings on health, risk and disease influenced the participants approach to the recommendation of screening. None of the included participants directly rejected or were opposed to the idea of early detection of T2DM. However, some were concerned about medicalization of this group of young, supposedly healthy, women (8). Others had a more biomedical perception of risk, favoring screening, but expected women to take responsibility for their own health and for accessing screening (8). Overall, many participants were highly ambivalent about screening and risks when communicating with women who have previously found GDM challenging (8).

#### Theme 2: Prioritization of early detection of diabetes

This theme elucidated that early detection of diabetes was generally supported, in general practice. Many GPs found disease prevention essential to their professional role, however, all participants felt that they were often forced to weaken this focus in clinical practice due to lack of available resources(8). This also applied to follow-up screening, after GDM, when an urgent need to prioritize the most pressing problems in general practice was more often present. In some cases, barriers to screening stemmed from the lack of resources with testing and an overload of tasks related to early detection(8). Some participants took an organizational perspective to this by arguing that the overall healthcare system was already at a tipping point.



With this fear of overburdening the system they refrained from such activities (8).

### Theme 3: System influence on clinical procedures

#### *Systematizing clinical procedures to improve quality of care*

Many GPs were open to increased systematization and standardization of procedures in their own clinics. They saw this as an important means to improve clinical judgements and facilitate follow-up screenings of women with previous GDM (8). This was especially evident within the larger group practices that appeared to be particularly responsive to the healthcare authorities' recommendations (8).

Some clinics made their own, internal guidelines to support clinical work and ensure that important patient information was retained and acted on, over time (8). Such guidelines seemed to benefit from local adjustments and relied, in the most successful cases, on interdisciplinary/peer discussion and pragmatic compromising (8). Moreover, potentials were found within the few general practices. Record systems were programmed to provide the GP/staff with pop-up reminders, which had strongly improved follow-up screening among women with previous GDM (8). This feature also enabled them to track women who cancelled or failed to make the expected appointment but was challenged by insufficient information transferred on the women's GDM diagnosis from the secondary healthcare sector (8).

All participants shared a positive attitude to the use of screening reminders, if they were handled on a system level outside of the general practice. Finally, delegating the responsibility of screening to the practices staff seems to facilitate screening; however, not all general practices have this organizational option or wish to delegate responsibility (8).

#### *Trusting own clinical skills without system interference*

This subtheme indicated that some GPs showed a less overt resistance to systematization and standardization of procedures in the practice (8). This was grounded in an unwavering professional pride and a desire to preserve their independence and integrity, while making their own clinical judgements in each individual situation (8). Some GPs preferred to rely on knowledge accumulated through years on the job and were less inclined to update their knowledge. This did, therefore, sometimes result in barriers to follow-up screening (8).

#### *Influence of recommended test*

This subtheme found that participants generally agreed that the recommended test for screening had increased uptake. They found the HBA1c test convenient for women and perceived it as an improvement that eradicated previous barriers, such as the discomfort of the OGTT or fasting (8). They also expressed appreciation that hospital laboratory test results arrived on the same day, however some GPs argued that the process could be further improved as in-house analysis could improve

communication with women about their health (8).

### **3.1.4 Second step of the 6SQuID guide: Identifying the greatest scope for change**

The next step was to find out which of the proximal or distal factors are malleable and had the greatest scope for change (62). Knowledge from the literature (summarized in section 3.1.1) and Studies 1 and 2, were analyzed in order to determine how and on what level(s) to intervene. This included a deeper reflection of the context of the North Denmark Region, were local websites, guidelines and other documents were used in the process. Furthermore, discussions with important stakeholders in the Administration of the North Denmark Region, Center for General Practice at Aalborg University and Aalborg University Hospital helped gain necessary knowledge of what was malleable within a Danish practice.

The institutional and/or individual levels had been identified as the most relevant and likely levels to intervene on. It was important to gain full understanding of what was sensitive to the interruption of an intervention, based on reminders, within the North Denmark Region. Considerations made to each level, accordingly, are explained in the following section.

#### Institutional level:

The identified causes for low uptake in follow-up screening, of women with previous GDM, on this level, included the GP's unawareness of the risk and recommendations, as well as the GPs being hesitant to initiate leadership on screening and their lack of support to women in decision making. This was also evident in the findings of Study 2 (8).

As shown in a previous study, from the North Denmark Region in 2015, most women felt left alone with the decision regarding participation but also unsure about the risk (3). In contrast, women who were met by a general practitioner/staff felt safer and found that recommendations were well adapted to their situation (3). Study 1 findings agreed with this since women who did not experience fear were more likely to engage in screening (7). In addition to this, findings from Study 1 illuminated that relational continuity or a personal contact is a mechanism that is important to the success of reminders (7). In the North Denmark Region, general practice clinics are often located in small communities or towns, thus GPs are working as a well-known family physician. However, due to lack of doctors and a growing number of larger clinics, it is not always possible to support relational continuity. Nonetheless, being a family physician led us to believe that previously found barriers to screening, related to lack of baby-friendly settings, is of minor importance, in a Danish context.

Previously, literature has shown that providing knowledge, in forms of reminders to support clinicians in general practice, could strengthen women's participation in screening (41). However, findings from Study 1 suggested that reminders, solely provided to clinicians, were hard to implement and, most likely, not enough to

bridge the communication gap between health care sectors (7). Moreover, findings from Study 2 and stakeholder discussions from general practice in the North Denmark Region show that they share a positive attitude to the use of reminders, to support screening, if it was handled outside general practice (8). Findings from both Studies 1 and 2 show that standardization of care, in practice, increases participation in screening (7,8), and that a reminder may support this process (7). Standardization of care and making their own clinical guidelines adapted to their own clinic seemed to be the most popular concern among younger GPs. This could possibly minimize barriers for screening in general practice, related to lack of time and resources, as well as increased job satisfaction (8).

Few participants in Study 2 felt they were able, or desired, to standardize the process of follow-up screening, for women with prior GDM. The focus on the risk of T2DM after GDM has increased in practice over the last 5-7 years. This became evident in Study 2, as well as in discussions with stakeholders and review of local and national guidelines and documents. Furthermore, Study 2, revealed that many GP's saw themselves as playing an important role in preventive initiatives (8).

Systematic tracking of women with previous GDM, in practice, is an important mechanism to strengthen the effectiveness of reminders as it offers the GPs the opportunity to actively help minimize barriers for women (7). In the context of the North Denmark Region, Study 2 showed that features to remind GPs and systematic tracking of women, with previous GDM, already exist in general practice, in the North Denmark Region. Only few clinics seemed to use it. It depends on the electronic systems, used in the specific clinics, and requires a sufficient knowledge transfer on women's diagnoses along with a recommendation to screen, from the secondary health care sector to general practice (8).

Discussions with important stakeholders, in the secondary health care system, identified an ongoing quality improvement project in the North Denmark Region which aimed to improve information strategies across sectors, including how to share diagnoses and passing responsibilities onto general practice, in a clear and timely manner. This also includes women with previous GDM, which could make GPs more aware of risk and recommendations for screening and thereby support the barriers found in Study 2 (8). Discussion with stakeholders, in general practice, revealed that the use of reminders and other features, in the already existing electronic system, in general practice. This is one of many topics for future quality improvement initiatives that have been suggested by the GPs organizations.

#### Individual level:

In Section 3.1.1 lack of awareness on the risk and recommendation on screening as time passes after birth was found to be a barrier to women's participation. In a previous study, from the North Denmark Region of Denmark in 2015, most women seemed aware of their own risk even years after birth, and perceived follow-up screenings as very important to their future health. However, as time passed, the recommendation seemed less important and difficult to remember, as their lives

grew to have several competing interests, and no one helped them maintain motivation to participate in screening (3). Providing women with recurring information about the purpose of screening and procedures can increase motivation to participation (41).

In Study 1, it was found that a reminder to women was effective in increasing women's participation in screening, however, no knowledge on the effect of reminders beyond the first year after birth are available (7). The information given, should, according to findings from Study 1, be in line with information given in specialized care units, in order to avoid the experience of lack of continuity between health care sectors (7). In the North Denmark Region, women suggest that getting a reminder can be a motivator for future participation in screening (3), suggesting an eagerness towards reminders in this specific setting. Women found that reminders could be helpful in remembering the importance and time of screening, when balancing the many tasks of family life (3). This is also an opportunity to, directly or indirectly, meet women's need to share the burden of being solely responsible for participation and their need for information (3). This is in line with other studies that suggest recurring information about the purpose of screening could minimize fear and apathy related to incorrect information and long-term screening (41). GPs, in the context of the North Denmark region, can be hesitant in discussing risks and recommendations with women, which is especially important (8).

Altogether, findings from Studies 1 and 2 suggest that reminders should be carefully designed to facilitate risk management and avoid doing harm (7). Preservation of women's autonomy, and right to choose whether to participate in follow up screening should be respected (8). A previous study has found that promotion of patient-centered approaches to improve the experience of care, and facilitate participation in screening, either directly or indirectly (41).

Final evaluation of the greatest scope for change:

Based on the reflections made above, the individual level seem most sensitive to the interruptions of an intervention based on reminders, within the North Denmark Region. System-based reminders in general practice appear difficult to implement without simultaneous targeting the individual level. Moreover, general practices within the North Denmark Region were found to be in a process, which strengthens the quality of care for women with previous GDM. If a reminder were sought to be implemented in general practice clinics, in the context of the North Denmark Region, it would primarily attempt to support those who already considered national guidelines as interference on the part of healthcare authorities. Even if implemented, it would, most likely, not have the intended effect. Therefore, even though Study 1 suggests that reminders, targeting both women and practitioners, are effective in increasing women's participation in screening this could potential be a waste of resources.

The system could be at its tipping point ready to engage with intervention targeting women, which is of significance when developing and implementing public health interventions (10). Women within the same context will likely find the use of reminders to be a reasonable solution to support future participation in screening (3), and GPs will further support such an initiative to women (8).

Table 3, below, shows the assessment factors on the individual level, which are able to be modified for change, when providing a reminder.

<b>Modifiable individual factors</b>	
<b>Factor</b>	<b>Evidence Modifiable</b>
Lack of continuous awareness of screening	Knowledge provided by reminders can support women's memory, attention and decision-making process and support participation in screening
Lack of personalized information	Patient centered care and improved experience of care may support participation in screening
Feeling alone and burden by the sole responsibility	Health care providers can ease transitions in care between health care sectors and thereby reduce stress for women which support participation in screening
Health beliefs (Fear of diagnosis or feeling healthy)	Awareness of the rationale for screening, and the consequences of a diabetes diagnosis influence on women's beliefs and participation in screening
No observable symptoms	Education that this is not sufficient could increase participation in screening
Relying on results from discharge after birth	Education that this is not sufficient could increase participation in screening

**Table 3: Modifiable individual factors, shaping the problem of non-participation in the recommended follow-up screening after birth (7,103,104,106,110,111)**

### 3.1.5 Third Step of the 6SQuID Guide: How to bring about change

Having identified the most promising, modifiable, causal factors in the individual level, the next step was to think through how to achieve change (62). More precisely, the specific identification of the mechanism that trigger the necessary changes to lead to the intended outcome. The mechanisms of change on the individual level are visualized in Table 4, below.

Modifiable factors	Changes mechanism	
	Resources	Reasoning
Lack of continuous awareness of screening	Knowledge of risk and recommendations	Memory, attention, resonance and perceived relevance
Lack of personalized information	Patient centered care and considerations of proper risk communication	Confidence in own decision making
Feeling alone and burden by the sole responsibility	Providing a personal contact	Ease stress
Health beliefs (Fear of diagnosis or feeling healthy)	Awareness of the rationale for screening, and the consequences of a diabetes diagnosis	Motivation and encouragement
No observable symptoms	Information	Motivation
Relying on results from discharge after birth	Information	Motivation

**Table 4: Changes mechanisms for the reminder intervention on the individual level (7,41,104,106,108,111,112)**

Interventions which take place within a system such as a health care setting, can influence and create changes in relationships as well as redistribute and transform resources within in the whole system (62). The causal pathways were found to be strongly interwoven with each other. Reminders, targeting women on the individual level, could therefore also influence important mechanisms within the institutional level. This could include strengthening the focus on the follow-up screening and minimize GPs ambivalence towards communications with women. The mechanism of change on the institutional level are visualized in Table 5, below.

Modifiable factors	Changes mechanism	
	Resources	Reasoning
Lack of support from GP in decision on screening	Input to facilitate decision making process	Encouragement/motivation
GP's hesitant to initiate leadership for screening	Shared understanding and leadership	Ease stress
GP's unaware of risk and recommendation	Strengthen focus on guidelines	Awareness

**Table 5: Changes mechanisms for the reminder intervention on the institutional level, believed to be influenced by a reminder targeting the individual level (8,108)**

### 3.1.6 Fourth step of the 6SQuID Guide: How to deliver change mechanism

This step required understanding how to deliver the identified change mechanism. Again, this included a reflection on our own context as well as discussions with important stakeholders in the North Denmark Region administration and general practice organizations, to gain the relevant practical expertise and develop the implementation plan. This planning required clarifying resources and activities, to ensure a successful implementation, including considerations of possible restraints in delivery (62).

This process identified three significant factors, creating an opportunity to ensure a successful implementation and delivery of the reminder to women with previous GDM in Denmark. This included:

- 1) The Danish civil registration system holding a permanent and unique number (CPR number) for all residents in Denmark
- 2) Linking individual data across multiple nation-wide registers
- 3) Sending information to women using of a secure nation-wide email system accessed by almost all citizens in Denmark for information from public authorities

This enabled identification of women with previous GDM and gave access to a personal mailbox, which was believed to entail few possible restraints and ensures a low-cost intervention. Study 1 did not produce a clear conclusion on which type of reminder was the most effective (7). The HBA1c-test found to be facilitator to screening in Study 2 are also believed to support successful implementation and delivery of the reminder, as the OGTT are found to be a significant barrier for screening in other studies (113)

Implementation and delivery of the reminder relied on resources and activities from the North Denmark Region, the digitalization unit for the public sector (KMD) and me, as a PhD-student, are visualized in Table 6, below.

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## Delivering change mechanisms for a reminder intervention to women with previous GDM

### Resources/activities for successful implementation

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#### The North Denmark Region:

- A well-known health authority in which women trust
- Knowhow, prioritization and approval of the project  
(1 Department Manager, time financed by the region)
- Regional data on patients and practice  
(1 data manager, time financed by the region)

The North Denmark Region identifies women with previous GDM between January 2012- December 2018 and sends individual data (CPR) to the digitalization unit for the public sector of Denmark (KMD)

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#### Digitalization unit for the public sector of Denmark (KMD):

- Capacity to send mails to all citizens in Denmark
- Technology and technical assistance  
(1 Support manager, time financed with Ph.D. funds)

KMD support manager helps prepare final draft of the reminder and arrange linkage between women's CPR and their individual E-Boks and sends out an Email reminder to women

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#### The Ph.D-student:

- Key responsible for development and implementation process  
(Time used was financed with Ph.D funds)
- Primary contact for women if any questions  
(Time used was financed with Ph.D funds)

The Ph.D -student were responsible for contacts and management between the North Denmark Region and KMD, as well as respond to women's inquiries

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**Table 6: How to deliver change mechanisms for a reminder intervention to women with previous GDM**

Moderators that influence the implementation of an intervention, includes characteristics of those who receive the intervention, the interventionist as well as the setting of implementation (90). In the North Denmark region, exemption from use of this secured email system (e.g., due to mental or physical illness) was estimated to have been granted to approximately 7% of the overall population within the region. To what extent this applies to women with previous GDM were unknown. Further moderators, related to women and the North Denmark region, were related to women's general understanding, prioritizing and response to health recommendations as well as availability and political prioritizing of screening. The PhD student's role in the delivery of resources and activities (Table 6), personal qualifications within communication and knowledge of the topic could possibly interfere with implementation (90) of the reminder.

The reminder was not believed to have any direct harms; however, reminder interventions can entail other potential harms, as discussed in the background



section of this thesis. Drawing on theoretical approaches to communicating risk and how to support women's decision on participation in follow-up screening were also part of the phase, determining how to deliver the reminder.

### **3.2 OUTPUT OF THE DEVELOPMENT PROCESS**

*This section describes the output of the development process which includes the program theory and the reminder sent to women. This also includes important knowledge from stakeholders' experience with the developed intervention.*

#### **3.2.1 The developed program theory**

The developed program theory of this PhD-project is visualized in Figure 6, below. This includes a description of action taken (theory of action) which was the planned resources and activities going into the intervention.

as Also included is how the intervention is expected to work (theory of change), which is the change mechanism leading to the intended outcomes.

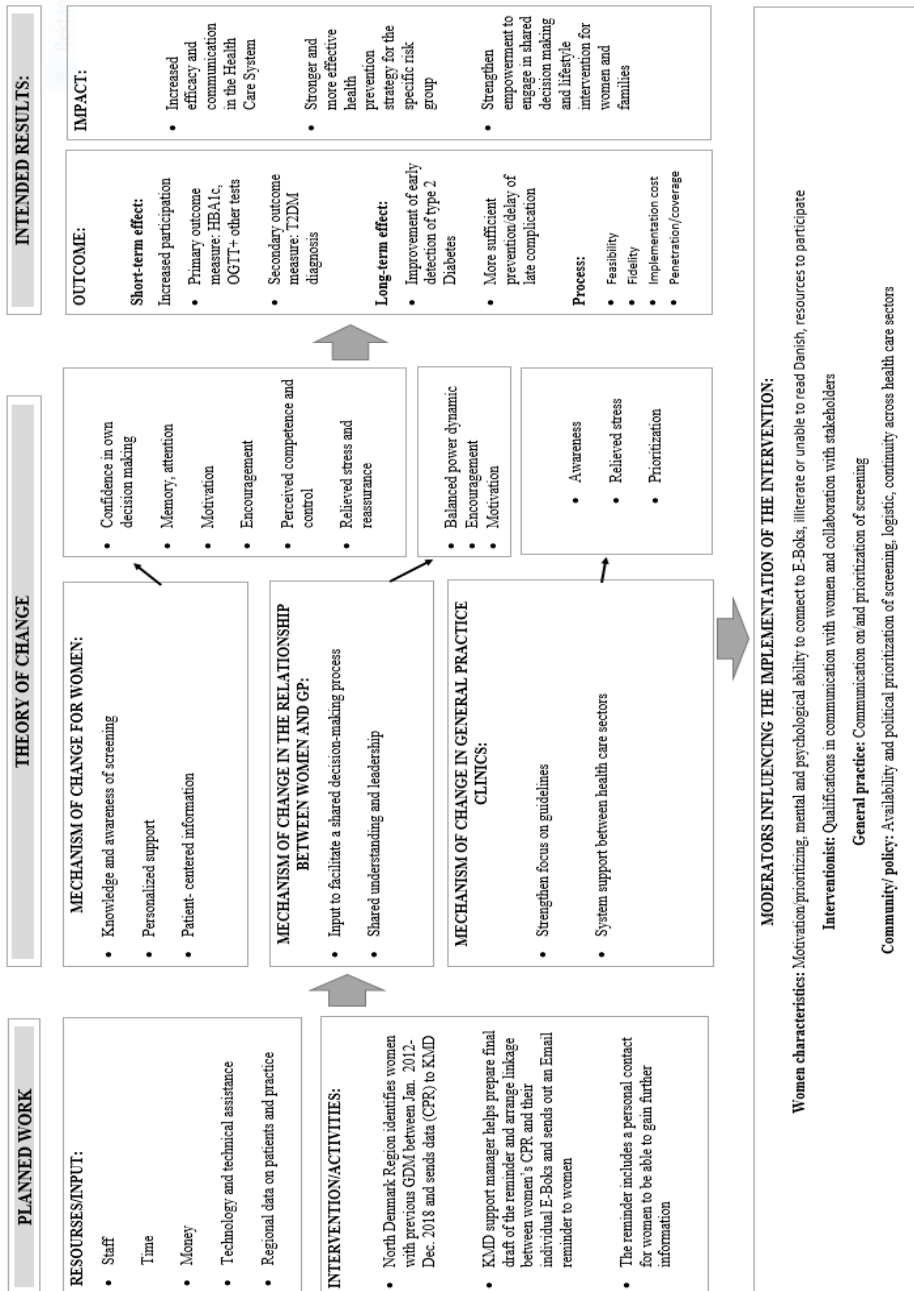


Figure 6: The developed program theory of the reminder intervention

### 3.2.2 A Kind Reminder

In patient-centered care, respect for patient autonomy, dignity and needs are essential. Involvement in decision making and information to facilitate autonomy, selfcare and health promotion are important (112).

Decision aids (reminders) are successful in supporting patients in the shared decision processes (114). It was important to plan the information content within the reminder, according to the premises of the patient, as recommended in communication literature (115). This meant closely considering the purpose of the information, to whom it is addressed, the situation around this communication, how it is wished to be perceived, what they must know, and how it is going to be provided to them (115). These considerations were discussed within the research team and with relevant stakeholders as needed. This process had direct influence on how the reminder was designed. Nonetheless, communication literature also finds great barriers if the person who receives the written information is not fluent in the language used or illiterate (116).

In discussion with stakeholders from the North Denmark Region Administration it became evident that all citizens within the region, who find it difficult to read mails received in the nationally secured mailbox, are provided with help to read. It was decided to proceed with a test of the reminder, while including contact information for those needing further information or explanation of the reminder. In the project period of this PhD thesis, six women used this contact information. Four women were not completely fluent in the Danish language, one needed to be assured about her understanding of the reminder and one found that she was misdiagnosed with GDM.

The developed reminder, in Danish, is provided as Appendix E.

### 3.2.3 Stakeholder Involvement

Evaluating the readability of written patient information before it is provided to the patient has been recommended for years. As evidence suggests, the design of health information is often poorly executed (117). Various methods have been used, which also include qualitative interviews with those who are to receive the information (117). Qualitative perspectives can contribute to knowledge about understandings, relevance and meaningfulness (118) of the reminder.

Approximately 5-10 interviews are recommended (118), thus seven qualitative interviews were conducted. As recommended, an interview guide was prepared, with primarily exploratory questions beginning with e.g., *how, what, and which* (118) (Appendix F). The only inclusion criteria were that the women had a previous pregnancy complicated by GDM, making them eligible to participate in follow-up screening. Women were recruited using a snowball sampling technique, thus already included participants help identify other potential participants (79).

The qualitative interviews with stakeholders followed the earlier described Danish legislation for qualitative research. Informed written consent was obtained after

women had received information about who was responsible for data, the purpose of the study, what information would be processed, and that the participant could withdraw her consent at any time (96). The audio recorded qualitative data was handled and stored on an encrypted file drive.

After the interviews were completed, the thematic analysis did (81), as recommended, consist of identifying of any need for changes or adjustments as well as important perspectives of those who received the written information (118).

The key points identified within the interviews are described in the following and are supported by quotes from women.

#### How did women experience the intention behind the reminder?

All women found that it was clear that it was a reminder, which one woman explained:

*"It's so clear for me that this is not something I HAVE to do, but a reminder that I should prioritize this ... for my own sake...there is a clear difference." (Stakeholder 1)*

Overall, women did not experience that they were being pressured into something, but that they were being taking care of, and that they were free to decide whether to participate or not. Another woman expressed how she felt this was explained to her in the title of the reminder:

*"It's just like that ... you just lower your parades. There is no one who wants to hit me on the head. I do not feel there is anyone who is angry with me, but more that they believe that I am able to make an independent decision... I feel kept an eye on... in the good way." (Stakeholder 4)*

The tone used in the reminder did not seem to overshadow the importance of the message of screening for anyone. Several pointed to the PhD student's profession within health care and the logo of the North Denmark Region as important contributors to their increased confidence in the recommendation.

The picture of the PhD student and the personal contact were found to be relevant. Not equally important for everyone, but all seemed to agree that it helped support the feeling of a personalized and kind or supportive approach to the women. This was described by one of the participants:

*"It's different ... it personalizes it all somehow ... it's cool and it helps to support the good tone used in the reminder...it feels nice." (Stakeholder 7)*

#### How did women experience layout and readability of the reminder?

Women contributed with various constructive comments including certain words or sentences that hindered a good text flow, but, in general, the reminder was found to be easy to read. Furthermore, the length of the reminder was found to be

manageable and reasonable, according to the purpose of the reminder. The presentation of the research team behind the reminder, based on the women's feedback, should be displayed as a footnote instead of being a part of the central text.

Two women found that the risk and consequences of diabetes could be elaborated further and stated that increased worries and concerns would motivate them to participate even more. However, most women appreciated that the reminder was not filled with technical and professional explanations or suggestions for lifestyle changes. One woman described it as:

*"It is written in such a humble and respectful way. Not some admonitions that I should go on a diet and exercise more, but just to be nice to me." (Stakeholder 2)*

These women also suggested that they would rather address the issue of lifestyle changes themselves or with their general practitioner, but that the reminder indirectly could support these processes. One woman expressed:

*"That information I can find myself, but this [the reminder] can help maintain my focus on this [lifestyle changes] ...in a more positive way." (Stakeholder 1)*

Finally, more than half of the women emphasized that the reminder fulfilled two main purposes for them: to remind them of screening and to give them support, communicating about screening with their general practitioner. One woman said:

*"It's just cool because my doctor doesn't really want to talk about it, so it's nice that someone is thinking of me and now I can say to my doctor ... well I KNOW I have to [be screened]." (Stakeholder 3)*

The interviews with women gave rise to small changes within the text and confirmed that the intention and that theory of a patient-centered approach was applicable to the development of a reminder. This also illuminated possible mechanisms triggered by the reminder, creating change.

### **3.3 PILOT TEST OF THE DEVELOPED INTERVENTION**

*This section describes the findings of the pilot test of the developed reminder intervention within the North Denmark region, in accordance with the MRC-guidance and the two last steps of the 6SQuID guide: testing the intervention and collecting sufficient evidence on effectiveness to warrant future investments.*

#### **3.3.1 Findings of Study 3: Generating knowledge on the effect of the intervention and different aspect related to the implementation process (Fifth and sixth step of the 6SQuID Guide)**

The reminder was effective in increasing women's participation in screening. According to the primary outcome, a total of 471 women were screened (32%). Of these, 257 women (35%) belonged to the intervention group and 214 women (29%) to the control group. This showed a 20% increased chance of participation in screening, among women in the intervention group (RR: 1.20; 95% CI 1.03–1.39) and a 5% increase in absolute risk (RD: 0.05; 95% CI 0.01–0.10) (9).

In relation to the secondary outcome, 56 (3.8%) of the women who participated in screening were diagnosed with T2DM. The secondary outcome was slightly more prevalent in the intervention group (32 women in intervention group, 24 in control group), although no significant differences were found (P-value: 0.27) (9).

In the analysis risk difference, which describes the difference in the probability of being screened, found that the effect of the reminder seemed to increase with women's age as well as with those of non-western origin, urban dwelling, multiparity, and underweight women (9).

Besides these findings, Study 3 also provided explanatory knowledge about different aspects important to the implementation processes. This explanatory knowledge emerged during discussion of our findings and implementation of the intervention. In line with core concerns, relating to implementation science, which include the importance of describing how an intervention works. This should include its implementation processes, to understand and interpret the interventions success or failure (119). This is determined from the service outcome regarding effectiveness, as it includes feasibility, fidelity, implementation cost, penetration/coverage, and sustainability of interventions (119).

Feasibility is a notorious challenging within clinical research (119,120). Reflections on recruitment and retention processes attempt to understand how and why the developed intervention succeeded in creating a change. The simple design of the reminder and the unique possibility to use the civil registration number to link the individual's data across multiple nation-wide registers and a nationally secured mailbox, made it possible to identify, recruit, send out the reminders and make outcome assessments without adding any significant difficulties to current practices.

Fidelity of the intervention should include retrospective interpretations on such things as whether it was delivered in real life systems as intended (119). Contextually, factors seem to assure high adherence to study protocol. There were no local changes or modifications that altered the content of the intervention during implementation and delivery, which otherwise is a challenge to the fidelity of interventions with a more complex design (120). Only 1.37% of the study population within the intervention group did not receive a reminder.

Penetration/coverage gives an idea of the integration of the intervention within a service setting (119,120). In this study, 35% of the women receiving a reminder intervention participated in follow-up screening in general practice.

Implementation cost of the intervention was believed to be low, since the surrounding system enabled suitable resources to carry out the planned activities.

Therefore, limited staffing, maintenance, and performance cost, ended in an approximate total cost of less than 1000 Euros. However, no cost- effectiveness studies have been made (9).

## CHAPTER 4. DISCUSSION

*This chapter includes a discussion of key findings from the three studies as well as a discussion and revision of the developed and tested intervention, the underlying program theory and thereby indirectly the different steps of the 6Squid guide.*

### 4.1 DISCUSSION OF FINDINGS

The overall objective of the PhD project was to support early detection of diabetes among women with previous GDM by development and pilot test of an intervention based on an electronic reminder system, providing aid to women's decision-making regarding participation in the recommended follow-up screening after birth.

Overall, this PhD study indicated that the developed reminder intervention was effective in increased women's chance of participation in follow-up screening by 20%. No direct harms were identified.

A range of factors that drives and/or could influence the intended effect of the developed program theory were identified through the systematic, realist review undertaking in Study 1. In Study 2, the qualitative exploration of facilitators and barriers for follow-up screening in general practice clinics in the North Denmark Region, contributed to an understanding of the contextually circumstances. In combination with other sources used to inform the development process, the program theory was qualified.

In the discussion of the study findings below, first part will focus on selected, important mechanisms of the developed intervention – support of women's decision-making, continuity of care – and aspects of the implementation process. This in order to refine the intervention and optimize implementation as this is an important step after having undertaken a pilot study (68).

#### 4.1.1 The ability of the reminder to support change in decision-making processes

Based on findings from study 1, a key mechanism of the underlying program theory for the developed and tested intervention, is the electronic reminders' ability to support women's decision making through changes in the interaction between women and her GP.

The pilot RCT study was designed to evaluate the overall effectiveness of the intervention, not the specific underlying mechanisms or to what extent the success of the reminder reflects its success in supporting women and increasing their confidence in decision-making. Obtainment of such knowledge would require process evaluation or realist evaluation (71). Stakeholder involvement of women in the intervention design prior to dispatch of the reminder, did however indicate that



the reminder contributed to a feeling of power or confidence to engage in communication with their GP. The ability of reminders to cause these effects is substantiated in a review by Williams, Elwyn and Edwards (2013) concluding that decision aids, such as reminders, are successful at supporting patients in shared decision-making (114). Additional, also significantly improve outcomes for disadvantaged patient (121) Other literature however also suggests that knowledge provision and encouragement will not alone be enough to enable shared decision-making for many people (114,116).

An important barrier for this, is the power imbalance of the doctor–patient relationship and the perceived ability of patients to engage in shared decision-making (114). Although the role of and expectation to patients have changed over time, patients often still adopt traditional patient roles characterized by passivity and compliance.

To promote feelings of self-efficacy or confidence in decision-making processes, it is important to explicitly describe and make it noticeable to patients that they can engage in decision-making (114). When reminders (as intended this PhD study) communicate this to women, it is believed to help redress the perceived or real, power imbalances found to be a barrier to involvement (114). In this way a simple reminder letter communicate room for shared decision making and can act as a catalyst to help make shared decision-making a reality in busy clinics (108).

Clinicians has been found to play an important role in the ability of women with previous GDM to understand their own, subsequent risk of T2DM and thus their motivation for attending follow-up screening (7,41). This supported by literature on patient communication suggested that patients need to be supported in acquiring and understanding knowledge about the available options in the decision-making processes (114).

Findings from Study 2 showed, that also in the Danish setting of this PhD project, GPs were often reluctant to discuss women’s risk of T2DM after GDM or hesitant to communicate and participate in decision-making processes with women (8). This is a challenge also identified in other health care settings (41), that could inhibit this important change mechanism and thus the effectiveness of the intervention. Also, study 2 illustrated that women’s long-term risk of T2DM after GDM was unfamiliar and underestimated by many GPs (8). Over time, routine use of reminders could potentially help build a shared understanding of screening and balance the power dynamics between women and their GP. An understanding, that could possibly be supported by the general recognized potential in early detection of diabetes that was found to be increasing in general practice clinics in the North Denmark Region (8).

In general, initiatives to support shared decision-making processes with women should be prioritized, as it is viewed as fundamental to safe and effective healthcare (114). Overweight and socially disadvantaged women were less likely to participate in screening, possibly due to fear of being diagnosed, as reported in study 1. This finding emphasizes the importance of avoiding stigmatization and supporting

shared decision-making processes and through this promotion of self-empowerment (108) and social equality in health for women with prior GDM.

#### **4.1.2 The role of continuity of care as a mechanism of change**

Continuity of care was found in study 1 to be essential to women's participation in screening after birth (7). Key mechanism of the underlying program theory for the developed and tested intervention, is the electronic reminders' ability to support continuity in care – relational, information and management across health care sectors.

Study 2 found that implementation of guidelines on the recommended follow-up screening of women with previous GDM are increasingly prioritized in some general practice clinics. Thus, promoting continuity of care for some women (8). Same conclusions are found in a similar study from a Danish setting, as it supports GPs communication on the long-term risks associated with prior GDM to women after delivery (122).

This implementation of guidelines, in general practice, did however seems to depend upon interdisciplinary peer discussions and knowledge-sharing, as this provided a possibility for them to identify resources and make the necessary local adjustments (8). This is supported by findings in the systematic review of Chauhan, Jeyaraman, Man, Skidmore, Sibley, Ahmed and Zarachanski (2017), where behavior interventions such as education, training, and team-based approaches, are effective in changing practices among primary healthcare professionals (123). Much like the successful results from a quality improvement study for diabetes prevention after gestational diabetes (GooD4Mum), finding implementation of guidelines for screening increasing in general practice when using audit feedback (124,125).

Nonetheless, knowledge about reminders to women, or women increasingly requesting screening, could strengthen the focus on follow-up screening among GPs. However, information must be interpreted and actively used by health care providers to create continuity of care (107), wherefore lack of initiatives to support this could inhibit this important change mechanism and thus the effectiveness of the intervention.

Factors of importance for the continuity in follow-up screening, were in Study 1, also found to be related to the ability to share knowledge about recommendations and women's diagnosis across health sectors (7). In study 2, lack of continuity in care appeared to be partly explained by loss of information on the GDM diagnoses in the transition between the health sectors (8). A challenge which is also found to be influencing follow-up screenings of women with previous GDM in other health care settings (103). Initiative to improve information's strategies across sectors to support change in general practice is currently ongoing in the North Denmark Region. Therefore, mechanism of the underlying program theory includes system support between health care sectors- by the simple targeting women. Nonetheless,

improvement of discharge summaries from hospital sector to general practices improve continuity of care for women with previous GDM (26,103).

Study 1 found that different types of relational continuity (e.g., a well-known health care team or a person to contact if needed) facilitated participation in follow-up screening (7). An important mechanism of the underlying program theory for the developed and tested intervention, thereby include contact information for those who needed further information or explanation adapted to their individual needs. In accordance with findings from Study 1, a personal contact could help reduce stress for women and ease transition between health care sectors (7). It encompasses possibility to support several aspects of patient-centered care, thus with consideration of the patient's beliefs, values and expressed needs, emotional support, involving patients in decision-making and ensuring transition and continuity of patient care (112). Stakeholders' involvement of women prior to dispatch of the reminder, indicated that women found it to support the feeling of a personalized and kind approach. An annual personalized reminder is also among one of the recommendations of how to support future participation in follow-up screening after GDM (126). However, only few women used the contact information provided in the developed reminder (six women). Women's response and reasoning towards this mechanism are yet to be fully understood.

#### **4.1.3 Important implementation processes to consider in the future**

In this PhD-thesis, the successful recruitment of women with previous GDM and no loss to follow-up in our study population could help explain the observed effect of reminders. This aligns with recommendations that interventions should be as simple and unobtrusive as possible, in comparison to current practices, as it will help make recruitment and retention easier and support the effectiveness in everyday practice (120). Possible recruitment problems could have created a delay and, consequently, extra costs to trial evaluations. This can often be caused by personal barriers for both participants and/or health care professional and can be pursued and improved through intervention design (120). The simple design of our intervention must, therefore, be considered feasible without any significant barriers related to recruitment and retention.

Design and contextual factors can be a challenge to the fidelity of interventions of more complex designs (116). These however seemed to assure high adherence to the study protocol and underlying program theory of this PhD project, where no changes/adjustments were made. It was delivered in real life systems as intended.

Moderators influencing the implementation of the intervention and underlying program theory includes women's characteristics and the ability to be connected to the national secured mailbox. Only 1.37% of the study population within the intervention group did not receive a reminder, which was lower than expected. If this is reasonable and reflects the North Denmark Region or other regions within Denmark is unknown. Quality of the delivery will, most likely, not be affected by

the timing of the intervention, since the delivery system is standardized and based on the link to national registers which are considered valid (127). The surrounding system also enables suitable resources to carry out the planned activities. Limited staffing, maintenance, and performance costs were needed, which resulted in a low-cost intervention. Important features which could support a routinely dispatch of reminders to women with previous GDM. Higher coverage could however contribute to long-term sustainability (119), as it reflects the integration of an intervention within a service setting (115, 116). 35% of women received a reminder intervention and participated in follow-up screening in general practice. This is considered low in comparison to previous effectiveness studies (128-131), but is considerably higher than previous screening rates within the North Denmark Region (approximately 17% 4–6 years after birth) (2).

Uncertainties and the possibility for refinement must also include the systems through which the reminder is sent out to women. Study 1 was not able to conclude the best type of reminder, and no knowledge on women's acceptance of the type of reminder used was explored. However, email reminders have been suggested as one of the preferred methods for receiving a reminder, among this specific group of women in high risk (132). When reflecting on the Danish setting, the type of reminder used in this PhD-thesis, can possibly provide the same flexibility as a short message service on mobile phones. E-Boks has an available app for mobile phones, which many women are believed to use. Apps are previously found to satisfactorily support screening practices for women with previous GDM (133).

Uncertainties and possibility for refinement should also be considered, according to the content of the reminder. Evidence-based recommendations to promote uptake in screening among women with previous GDM, suggest that women would benefit from information on T2DM often being asymptomatic (104). This is not included in the content of the reminder of this PhD-thesis, as more knowledge on women's perspectives is needed.

Finally, even though the sub-group analysis in Study 3 should be interpreted with caution. It suggests that the reminder could be especially supportive to multiparas and women of non-western origin (9), for whom barriers to participation have been identified in previous studies (41). More knowledge on the experience of different sub-groups responds to mechanism of the underlying program theory are needed.

## **4.2 STRENGTH AND LIMITATIONS**

### **4.2.1 The overall framework of this thesis**

Overall, the intervention design and test were strengthened by the use of the MRC-guidance and use of the six step guide for quality in intervention development (6SQuID) for development. Even though the developed intervention ended up as a simple low cost intervention targeting behavioral change at the individual level, both supported a profound awareness of the importance of a good theoretical

understanding of how an intervention can bring about change and the need for knowledge on processes and the local context.

Although the PhD project was designed and the intervention developed and tested before the updated 2021 MRC framework was published, some of the key elements of this updated framework was in fact included in this thesis due to the projects affiliation to the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPH'er). This collaboration has inspired inclusion of some of the new or enhanced elements of the updated framework such as strong focus on program theory and inclusion of system thinking. Along with the six step guide for quality in intervention development (6SQuID) and socioecological thinking, this contributed to a deep understanding of the problem and its causes as well as helped identify where and how best to intervene while approaching the complexity described within the introduction of this thesis.

The updated 2021 MRC framework moreover urge early involvement of users, clinicians and patients in research. In this PhD thesis the perspectives of different stakeholders were included; GP's organization, the North Denmark Region administration and women with previous GDM. This however without integration of methodological principles based on e.g., patient public involvement in research that could possibly have qualified this process.

Although this is typically not the primary focus of pilot studies, it is considered a strength of this overall PhD project, that it was possible to assess the effect of the intervention due to the sample size (inclusion of all women with prior GDM in the test setting - a whole regional health service) and its randomized controlled design. This design is recommended by the MRC-guidance as it is the most robust method of preventing selection bias (10). The pilot test could have been strengthened by inclusion of a nested, qualitative process evaluation to examine in depth the fidelity, implementation, causal mechanisms, and contextual factors even more, helping to better understand why the intervention work and how it can be optimized (10). A qualitative study of women's' perspectives on the intervention was conducted as an adjunct study to this PhD but is not included in the PhD thesis due to time constraints (134).

#### **4.2.2 Study 1**

The Realist Review was guided by the RAMESES standards by Wong, Greenhalgh, Westhorp, Buckingham and Pawson (2013), which encompasses the principles of good practice in realist synthesis (75). As transparency and reproducibility are important (88), the reporting guideline follows the format of abstract, introduction, methods, result and discussion (75). Four critical methodological processes can have strengths and limitations which influence the final quality of a review (88). This includes the search process, selection and appraisal of documents, data extraction and synthesis processes.

The search process was strengthened by the clear selection criteria and the thoroughly developed search strategy, which consisted of assistance from a librarian, several relevant databases, grey literature, contact with authors and a

chain search. The included cases were restricted to experimental studies and supplement knowledge related to these, which resulted in sparse knowledge focusing directly on the implementation processes, intervention deliverers, or recipient experiences (7). This is a well-known challenge in Realist Reviews, as primary studies mostly report on outcomes, rather than the processes which explain how outcomes came about (74). The search was based on a comprehensive strategy and the low amount of supplementary information can reflect a few attempts to theorize programs (7).

The process of selection and appraisal of documents was especially strengthened by the use of a review team (88), which ensured that at least two reviewers considered each record, and any disagreements were resolved through discussion with the third reviewer, if needed (7). The included studies were appraised according to international guidelines (135,136). Studies in serious risk of bias were also included, as the Realist Review also extracts important knowledge of context and mechanism from these studies as well (75).

Data extraction was strengthened by the developed comprehensive sheet which was carried out and crosschecked by a group of three reviewers (7). These and synthesis results were regularly shared and discussed within the review team to ensure validity and consistency in the inferences made, as recommended in Realist Reviews (75). Inevitably, a large amount of data was extracted to support the premise of the Realistic Review, which may have caused missed connections in data. Finally, the data extraction and synthesis processes were further strengthened by a senior researcher who supported the ongoing application of the realist philosophical ‘lens’, thus qualifying the analysis of data using realist concepts, which is recommended in Realist Reviews (75).

#### **4.2.3 Study 2**

The purpose of study 2 was to understand and explore meanings in general practice, a qualitative approach was required. This influenced by the researcher’s subjectivity and reflexivity (79). The PhD students’ presuppositions and understandings of the phenomenon was colored by a theoretical insight into the topic, a background in midwifery and public health profession, as well as a recognition of the key role played by general practice in follow-up screening of women with previous GDM. This seemed to constitute a strength in this study, as it became possible to pursue a middle position as neither a fellow general practitioner nor a social scientist but had another profession within health care. This middle position, according to literature, is found to promote a certain naivety and encouragement of details without informants feeling cautious in conversations due to fear of judgment from a fellow professional (89). Being an “outsider” could generate reticence or suspicion (89), but this was not a limitation in this study, as it was possible to draw on prior understandings of the topic and cultures within the overall health care system. This can contribute to the interviewer’s credibility and strengthen analysis. The familiarity of a true “insider” could have dominated the process and prevented novel insights (89).

Collaboration with senior researchers who have extensive experience within qualitative research and general practice strengthened dialogues and ensured ongoing reflection of the project's validity. Guidance of an experienced researcher are considered to contribute to the credibility in qualitative research (77,137). In addition, discussions with stakeholders within general practice organization increased the opportunity to test different perspectives, adding strength to the qualitative research (77,137).

Settings and characteristics of the included participants needed to be thoroughly described in order to clarify the contextual dependence related to the descriptions and interpretations made (137). This supported the transferability and applicability of the study results (77,137). In addition, the purposeful sampling strategy of this study ensured a mixed sample which reflected the diversity of general practice clinics in Denmark. Postpartum consultations and screening increasingly were delegated to nurse or midwife staff (8). Important methodological considerations as participants contributed to relevant experiences (137). A limitation could be related to the lack of perspectives of younger GPs with more recent qualifications, or GPs with higher seniority in general practice, however a high level of information power were accomplished (8).

According to the Reflexive Thematic Analysis Strategy, efforts were made in order to ensure the methodological depth. Findings were not only analyzed and described, as descriptive presentations of the participants experiences, but explained the identification and interpretation of general patterns across data (79). Consideration of the contextual scope and meaning of the findings all strengthened the dependability of the results (77,137) and consistency between research questions, methods, analysis, findings, and conclusions was valued (137).

#### 4.2.4 Study 3

Selection of outcomes was thoroughly analyzed, according to its relevance for women's participation in screening and if measurement could be biased (systematic error). This was deemed important to the internal validity (90) and resulted in the inclusion of three possible tests which could be performed in the general practice clinics and measured by several data sources. This seemed to help prevent detection bias, as the effect of the reminder could have been overlooked if it only relied on OGTT and pay-per-performance principles. Limitations could be found in relation to the secondary outcome, as ICD-10 coding fails to identify those who are diagnosed and treated for T2DM solely in the primary health care sector. On the other hand, identification of T2DM through NPU coding seemed to ensure satisfactory identification, as HbA1c test was found to be the most frequently used test for screening, in general practice clinics. Diagnosis can also be retrieved through this.

In addition, the fidelity of the intervention was strengthened by the validity of the Danish National Patient Register database, enabling identification of women with a GDM diagnosis and linking them to a national secured mailbox (9). This

strengthened the internal validity, as no variability in the actual delivery of the intervention happens across patients (90).

The internal validity also refers to other possibilities for systematic errors such as confounding and selecting bias. A randomized controlled trial, in general, is considered a strong design to help prevent these (90). Our baseline information confirmed successful randomization based on the women's characteristics, which is essential, as incomparable demographic factors can cause selection bias and confounding outcomes attributed solely to the intervention (90).

It is also a strength, of study 3 as a pilot study, that a sample size or power calculation was made, and that the estimated number of women per arm was exceeded in the final study population (9). Evidence indicates an inverse relationship between sample size and the magnitude of the intervention effects (90).

Retention rates were considered high and the application of intention-to-treat principles ensured that the, approximately, 1% of women within the intervention group who did not receive the reminder, remained in our analysis. This reflected real-life practice and minimized the chance of overestimating effects and results being affected by attrition bias (90).

The single-blinded design also prevented performance bias of the estimated effect of the intervention. It ensured that the outcome assessor and the control group were blinded to treatment allocation. However, due to the nature of the intervention, women within the intervention group were not blinded, which could have an impact on the outcome, beyond that of the intervention itself (90). A possible limitation could be related to the information provided to GPs, prior to despatching the reminder. This could have increased uptake of screening within the control group, a random error which may have resulted in underestimating the effect (90). However, this is not expected to have had a great influence, as GPs are inundated by information, and the reminder was addressed to women.

Subgroup analysis could potentially contribute to a discussion about the design of future reminder systems. However, these results should be interpreted with caution as the numbers were small and randomization may not have been maintained in the developed subgroups.

Finally, as the study relied on national registries and no future consent from participants (Section 2.9), it was possible to include all women considered eligible for inclusion. This ensured no non-consent bias prior to inclusion, and high enrollment rates were ensured. When generalization to other populations and contexts are analyzed, this must be considered a strength (90).



# CHAPTER 5. STUDY IMPLICATIONS

*This chapter will discuss the implications of the overall PhD study for clinical practice, policy and give suggestions for future research.*

The use electronic reminders have been reported to be efficient in earlier studies. The implications discussed below will be based on the main contribution to the existing literature of this PhD study. These includes: 1) Identification of the mechanisms of change in reminder interventions as well potential unintended consequences (7), 2) New insights on barriers and facilitators of screening in general practice (8), 3) Development of an program theory for an reminder intervention and a written reminder that is based on the principles of informed choice and patient-centered care, and 4) Demonstration of the ability of this type of reminder to effectively support the recommendation of life-long participation in follow-up screening among women who experienced a pregnancy with GDM up to nine years earlier (9).

## 5.1 CLINICAL IMPLICATIONS

The findings of this PhD project support routine and long-term use of electronic reminders, based on the principles of informed choice and patient-centered care, to increase participation in follow up screening for women with previous GDM and through this early detection of T2DM.

The use of reminders based on the principles of informed choice and patient-centered care is recommended, as it seems to work as a decision aid, supporting women's ability to make an informed choice on participation in screening. This also contributes to increased continuity in women's care pathway, while potential unintended consequences of reminders caused by feelings of stigma and being pressured are sought to be minimized. This recommendation is in line with the general guiding principles for care of patients in the Danish health care system.

Patient-centered care involves patients in all aspects of their care and ensures open communication if patients are to experience empowerment (112). A change towards informed choice and patient-centered care should therefore start already during pregnancy. This with involvement and increased focus on empowerment and avoidance of feelings of stigmatization and fear of diagnosis among women with GDM, from obstetricians, midwives and nurses involved in care and treatment in the secondary health care sector. This approach to women's care is believed to help minimize several of the identified barriers for women's participation e.g., lack of personalized knowledge and beliefs in own capability (as illustrated in Figure 5).

Furthermore, clinical, and organizational efforts to support knowledge transfer, of women's diagnosis, risk and recommendations for screening, between the secondary and primary health care sector should continue to be a priority. In this thesis, possible

barriers were related to system and clinical procedures as well as challenges in addressing women's risk in general practice clinics (8). At the same time, were collaboration and clear pathways of knowledge among health care sectors found to support clinicians in providing timeless and continuity in care.

Based on the findings of the thesis, facilitation and expansions of the ongoing quality improvements, in care for women with previous GDM, found in several clinics in general practice are recommended.

This process could benefit from an overall, increased focus on familiarization and implementation of the clinical guidelines for follow up screening after GDM by the regional health authority and the organization for general practice.

The need for and importance of further reflections of ways to engage in communication and decision-making with women in general practice, have been widely discussed in this thesis and should also be given priority.

Finally, even though the focus of this PhD has been on the insufficient uptake of follow-up screening after birth, it is considered important to maintain opportunities for women with previous GDM to receive support in prevention of T2DM. This, through initiation and support of engagement in lifestyle changes in both general practice and local community based programmes.

## **5.2 POLICY IMPLICATIONS**

On a political and organizational level, the findings of this study indicate potential benefits of a shift from the current opportunistic approach to follow-up screening to a more systematic screening program. An earlier study of the difference between organized and opportunistic screening of Cervical Cancer showed that organized screening significantly increased coverage (138).

Nonetheless, the developed low cost reminder intervention is found feasible and effective in supporting follow-up screening among women with previous GDM. At the same time, as general practice clinics are experienced to have ongoing quality improvement possibilities. This could urge for regional and organizational decisions to initiate the use of electronic reminders, and in time, if warranted move towards a systematic screening program.

In 2020, The European office of WHO published an updated guide for screening programmes that acknowledge of the criteria publish by Wilson & Junger in 1968, but also underline that the decision on starting a systemized screening program is a much more complex (60). It requires a committee to carefully review the current circumstances within a country, stakeholder support, political priority, evidence of effectiveness and feasibility(60). This thesis has contributed to the proof of effectiveness and feasibility and to some extend stakeholder support. The results call for an increased political focus on the long-term health effects of GDM for women and children, to avoid the loss of healthy life years.

In the setting of this PhD project, follow up screening was offered without costs for women. Still social inequity in coverage persists in many contextually settings. In the generalization of the findings to other health care systems, it is important to prioritize free and equal access to screening, as this constitutes a significant barrier for follow up screening at a policy level (7).

Finally, does successfully implementation of patient-centered care in healthcare systems require facilitating environments (112), thus a task for decision makers at an organizational level.

### **5.3 RESEARCH IMPLICATIONS – SUGGESTION FOR FUTURE STUDIES**

This PhD study has been inspired by the British MRC guidance for development and test of complex interventions and the principles for critical realism. Following this, a program theory for a reminder-based intervention has been developed and the mechanisms of change explicated. This approach has provided an in-depth understanding of the possible working of the intervention and is highly recommendable in intervention and reminder development. Future studies should explore, test and contribute to refinement of the program theory though qualitative process evaluation, preferably applying realist evaluation methodology as well as patient-public involvement processes.

Also studies of women' experiences of receiving this or other forms of reminders and of participating in screening is warranted to qualify decisions on screening strategies and improve especially the access to care for women with low socioeconomic position.

In addition, could a longer follow-up period help evaluate change in general practice clinics, as the number of women with GDM per clinic varies greatly. Combined with further sub-group analysis and cost effectiveness analysis this could assist future decisions on content, timing and target of the reminder.

On an organisational level, more studies are needed to support knowledge transfer between health care sectors, women-clinicians' relationships and health systems approached to support screening.

An increasing number of studies from especially Australia have started to address the problem of undiagnosed T2DM after GDM on a health system level (139,140). This offers important perspectives that can be combined with the more individual and service-level approach applied in this PhD study.

## CHAPTER 6. CONCLUSION

This PhD study set out to develop and test an intervention, based on reminders, which could provide aid to women's decision regarding participation in the recommended follow-up screening in general practice, after pregnancy complicated by GDM. The study was operationalized according to three study aims which illuminated various facets related to the processes of development and pilot test of complex interventions in public health as outlined in the MRC-guidance from 2008.

The first study investigated for whom and under what circumstances reminder interventions were effective. Barriers and facilitators for the follow-up screening in general practices in the North Denmark Region were investigated in study 2.

The two first studies provided inputs for the intervention development and the intervention and program theory was underpinned by the concepts of informed choice and patient-centred care. However, conclusions from study 1 found that more research into the perspective of socially disadvantaged and overweight women is needed to avoid unintended consequences such as social inequality in service and stigmatization in future programs (7). Study 2 concluded that follow-up screening was facilitated by knowledge of guidelines and gave important input to how to create change in general practice. A significant barrier was found in lack of engagement in communication and decision-making processes with women (8).

In study 3, the North Denmark Region served as a setting for the regional pilot test of the developed intervention in Study 3. The study participants were identified based on routine, regional patient data, and the reminder delivered by use of a nationwide secure email system linked to women's CPR number, as this enabled a robust recruitment of women, delivery of the intervention and follow-up of outcome (9).

Study 3 showed that an electronic reminder based on the principles of informed choice and patient-centred care can effectively support the recommended life-long participation in follow-up screening, after pregnancy complicated by GDM (9)

The theoretical underpinnings are considered a strength for the reminder-based intervention, that appears to work as a decision aid and support women's ability to make an informed choice and contribute to increased continuity in their care pathway. It is believed to help minimize potential unintended consequences of reminders, related to feelings of stigma and being pressured. Further important advantages of the developed intervention are related to its simplicity and low cost and documented feasibility in a Danish setting.

Overall, the findings support a more systematic approach to follow-up screening with long-term use of electronic reminders, when based on the principles of informed choice and patient-centered care.

Other attempts to further stimulate coverage and increase equity in care are desirable.

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## **APPENDICES**

**Appendix A. Search strategy study 1 ..** Fejl! Bogmærke er ikke defineret.

**Supplemental material**

**File 1: An example of the applied search strategy**

**PubMed:**

<b>1:</b>	<b>2:</b>	<b>3:</b>
<p><b>Subject terms:</b></p> <p>"Diabetes, Gestational" [Mesh]</p>	<p><b>Subject terms:</b></p> <p>"Aftercare"[Mesh] "Postnatal Care"[Mesh] "Postpartum Period [Mesh] "Diagnostic Screening Programs"[Mesh] "Mass Screening"[Mesh]</p>	<p><b>Subject terms:</b></p> <p>"Reminder Systems"[Mesh] "Patient Compliance"[Mesh] "Telemedicine"[Mesh] "Delivery of Health Care [Mesh]</p>
<p><b>Text words:</b></p> <p>(diabet* AND gestational* OR gestationel*) AND pregnan* "pregnancy diabetes**" GDM*</p>	<p><b>Text words:</b></p> <p>"postnatal care" "Postpartum follow-up**" "Follow up program**"</p>	<p><b>Text words:</b></p> <p>'reminder system**'</p>

**NOTES:** Within each block (1, 2, 3), subject terms and text words combined with OR. (Different possibilities were tried). Followed by a combination between the three blocks with AND. **Final hits: 65**

**Appendix B. Intervention to participate in study 2** Fejl! Bogmærke er ikke defineret.

## Projekt om forbedret opsporing af type 2 diabetes efter gestationel diabetes

Rektangulært klj

Et nyt ph.d.-studie ved Aalborg Universitet har fokus på at udvikle og teste en intervention, der potentielt kan øge deltagelsen i den anbefalede follow-up screening af kvinder med tidligere gestationel diabetes, da tidligere studier har dokumenteret en lav deltagelse i Region Nordjylland. Formålet med at øge deltagelsen er at styrke den tidlige opsporing og muligheden for behandling af type 2 diabetes, og derved forebygge komplikationer og nedsætte risikoen for tidlig død.

Interventionen vil bla. indeholde udsendelse af elektroniske reminders til kvinderne, hvilket i samarbejde med Region Nordjylland vil blive testet i et randomiseret kontrolleret design. I selve udviklingen af interventionen indgår, at relevante fagpersoners perspektiver belyses, og der tages højde for disse samt eventuelle kontekstuelle faktorer med betydningen for effekten.

Dine tanker, holdninger, oplevelser og erfaringer som praktiserende læge og central aktør med kontakt til kvinder med tidligere gestationel diabetes har dermed stor værdi i denne udviklingsproces og der søges derfor deltagere til interviews.

Den viden, som genereres igennem interviewene, vil blive brugt til at kvalificere interventionen og indgå i opbygningen af en programteori bag denne.

Målet er at inddrage 10-15 praktiserende læger fra forskellige typer af lægepraksisser i Region Nordjylland i et enkelt-interview på ca. 45 min.

Tid og sted for interviewet vil være fleksibelt og kan tilpasses den enkelte læges mulighed for at deltage. Det kan fx gennemføres i den enkeltes praksis og efter dagsarbejde. Interviewene ønskes fortrinsvis gennemført inden den 22. september 2018.

Interviewet vil blive foretaget af Ph.d-studerende Jane H. Nielsen og resultaterne vil blive publiceret i en videnskabelig artikel, og i forbindelsen med Ph.d.-afhandlingen.

Hvis du har mulighed for at deltage i interviewundersøgelsen, kontakt venligst Ph.d-studerende, cand.scient.san.publ, Jane H. Nielsen på tlf: 28896104 eller Mail: Jhy@hst.aau.dk

## Appendix C. Informed consent study 2

Fejl! Bogmærke er ikke defineret.

## Informeret samtykke til forskningsprojekt

### Forskningsprojekt om forbedret opsporing af type 2 diabetes blandt kvinder med tidligere GDM

#### *Erklæring fra den, der afgiver information:*

Jeg erklærer hermed, at jeg giver mit samtykke til, at data fra interviewet må anvendes i forbindelse med et interventionsstudie med fokus på follow-up screening af kvinder med tidligere Gestationel Diabetes Mellitus, og at jeg har fået tilstrækkelig skriftlig og mundtlig information om formål, metode og brug af data for at kunne sige ja til at deltage.

Jeg er informeret om og indforstået med:

- At deltagelse er frivillig
- At jeg til enhver tid kan trække mit samtykke tilbage og udgå af undersøgelsen
- At min deltagelse er anonym, hvilket betyder, at jeg ikke nævnes ved navn eller andre former for personhenførbare identifikation
- At lydoptagelse/noter samt udskrifter heraf opbevares et sikkert sted, som er utilgængeligt for uvedkommende
- At anonymiseret data/resultater vil blive formidlet i skriftlige publikationer i internationale tidsskrifter

Projekt deltagerens navn: \_\_\_\_\_

Dato: \_\_\_\_\_

Underskrift: \_\_\_\_\_

#### *Erklæring fra den, der afgiver information:*

Jeg erklærer, at informanten har modtaget mundtligt og skriftligt information om projektet.

Projekt deltagerens navn: \_\_\_\_\_

Dato: \_\_\_\_\_

Underskrift: \_\_\_\_\_

**Appendix D. Application for approval of study 3Fejl!** Bogmærke er ikke defineret.

Kære Kirsten Fonager

Du har ved mail af 17. januar 2019 forespurgt Den Videnskabetiske Komité for Region Nordjylland om anmeldelsespligt af dit planlagte projekt.

Vi forstår det således, at alle kvinder med tidligere GDM tilbydes screeningsundersøgelserne. Projektet går ud på, at nogle kvinder får en påmindelse om tilbuddet og andre gør ikke. I vil derefter måle på, om udsendelse af påmindelse gør, at flere kvinder får foretaget screeningsundersøgelsen – ligesom I vil vurdere på, om påmindelsen har forskellig effekt i subgrupper. Der er således ikke nogen af deltagerne der får frataget mulighed for screeningsundersøgelse. På baggrund af de fremsendte oplysninger, er det sekretariatets opfattelse, at projektet ikke er omfattet af komitélovens (LBK nr. 1083 af 15/09/2017) definition på et sundhedsvidenskabeligt forskningsprojekt og derfor ikke skal anmeldes til og godkendes af komitéen, jf. komitélovens § 14, stk. 1, jf. § 2, nr. 1-3.

Projektet kan iværksettes uden yderligere tilbagemelding fra Den Videnskabetiske Komité for Region Nordjylland.

Klagevejledning:

Afgørelsen kan, jf. komitélovens § 26, stk. 1, indbringes for National Videnskabetisk Komité senest 30 dage efter, afgørelsen er modtaget. National Videnskabetisk Komité kan, af hensyn til sikring af forsøgspersoners rettigheder, behandle elementer af projektet, som ikke er omfattet af selve klagen. Klagen samt alle sagens dokumenter sendes til: National Videnskabetisk Komité – dketik@dketik.dk (sikker mail).

Vær opmærksom på at der kan være andre myndigheder, der skal godkende dit projekt. Komitéen kan ikke være behjælpelig med vejledning herom, men skal dog gøre opmærksom på, at der kan være krav om forudgående tilladelse fra Styrelsen for Patientsikkerhed, hvis du ønsker at anvende oplysninger fra patientjournaler til projektet – læs her for mere information.

Med venlig hilsen

Ulla Bay Hansen

Sekretær

SEKRETARIATET for DEN VIDENSKABSETISKE KOMITÉ for REGION NORDJYLLAND

Niels Bohrs Vej 30

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**Appendix E. The developed reminder . Fejl! Bogmærke er ikke defineret.**



### **Pas på dig: tilbud om tjek af blodsukker efter tidligere graviditetsbetinget diabetes**

Jeg skriver til dig, fordi du tidligere har fået konstateret graviditetsbetinget diabetes. Selvom graviditetsbetinget diabetes typisk forsvinder igen efter fødslen, så betyder det, at du er i større risiko for at udvikle type 2 diabetes, selv mange år senere.

Jeg vil derfor minde dig om, at det anbefales, at du får tjekket dit blodsukker årligt. Det giver mulighed for at opdage en type 2 diabetes tidligt, hvilket har stor betydning for din sundhed og mulighed for at undgå andre sygdomme, forbundet med type 2 diabetes. Det har også betydning for en eventuel fremtidig graviditet.

Tjek af dit blodsukker foregår ved, at du bestiller en tid ved din egen læge, og får foretaget en blodprøve (HbA1c), der viser langtidsblodsukker. Det tager ikke lang tid og din egen læge vil give dig svaret på blodprøven.

Din egen læge kan fortælle dig mere om blodprøven, hvilken betydning type 2 diabetes kan have for dig, og også om hvilke muligheder der er, hvis du gerne vil minimere din risiko for at udvikle type 2 diabetes.

Hvis du allerede har fået tjekket dit langtidsblodsukker inden for det seneste år eller er i behandling for type 2 diabetes, skal du bare se bort fra denne henvendelse.

Denne påmindelse er en del af et forskningsarbejde mellem Region Nordjylland og et tværfagligt forskningsteam\*, men har du spørgsmål/bekymringer vedrørende denne mail, er du meget velkommen til at skrive eller ringe til mig på [Jhy@ucn.dk](mailto:Jhy@ucn.dk), tlf: 72690995

På vegne af teamet.

Med venlig hilsen

Jane H. Nielsen, jordemoder og forsker



\* Forskningsarbejdet vil også omfatte en undersøgelse af oplevelsen af at modtage en påmindelse. Det er derfor muligt at du på et senere tidspunkt vil blive spurgt om du har lyst til at deltage heri. Det tværfaglige forskningsteam består af repræsentanter fra:

- Forskningsgruppen for Folkesundhedsvidenskab og Epidemiologi
- Center for Almen Medicin, Aalborg Universitet
- Socialmedicinsk Enhed, Aalborg Universitets Hospital
- Jordemoderuddannelsen, University College Nordjylland

## Appendix F. Interview stakeholder involvement

Fejl! Bogmærke er ikke defineret.

<b>Spørgsmål til kvalitetsvurdering af reminderen:</b>
1. Hvad bliver der efter din mening skrevet til dig (Det centrale budskab)?
2. Har du tillid til den faglige anbefaling?
3. Hvilke overvejelser giver det anledning til hos dig?
4. Hvad er vigtig information for dig heri?
5. Er der noget der ikke er relevant for dig? (Eller noget der ikke giver mening?)
6. Er der nogle spørgsmål som du ikke får svar på når du læser den? (Mangler du oplysninger)
7. Hvilke følelser giver reminderen anledning til?
8. Hvad syntes du om længden på reminderen? (layout)
9. Hvordan opfatter du afsender? (Herunder; personlig afsender+ brug af billede)
10. Hvad tænker du om tonen i sproget? (Formel/uformelt, for meget/for lidt heraf)
11. Er der noget du ikke forstår? (ex. uforståelige ord, vendinger, kompliceret sætninger)?
12. Er det tydeligt hvilke muligheder du har efter du har læst reminderen?

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