Heidi Holmen

Mobile health for diabetes self-management

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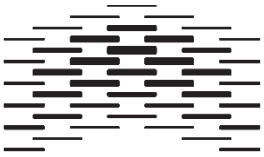

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Contents

Takk!

Denne studien ble gjennomført ved Høgskolen i Oslo og Akershus (HIOA), ved Fakultet for Helsefag, Institutt for sykepleie og helsefremmende arbeid i perioden 2011-2017. Denne avhandlingen er et resultat av hardt, men inspirerende arbeid, og det er mange som skal takkes for deres bidrag i prosessen.

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Lier, mai 2017

Heidi Holmen

Summary

Introduction

The prevalence of diabetes is increasing in Norway and globally, and daily diabetes self-management remains crucial to decreasing the risk for late-complications. Mobile Health (mHealth) might increase and support diabetes self-management, and the development of the mHealth field allows for data monitoring and communication with healthcare personnel (HCP) through smartphone apps.

Aim

Our main aim was to investigate mHealth for diabetes self-management by testing the effects of an intervention, revealing associations between stages of change for physical activity and diet and their relevant variables, and summarizing the evidence of integrated communication within mobile apps for tailored feedback between persons with diabetes and HCP. Our specific aims were as follows: I) To test whether the use of a mobile phone-based self-management system used for one year, with or without telephone health counseling by a diabetes specialist nurse for the first four months, could improve glycated hemoglobin A1c (HbA1c) levels, self-management, and health-related quality of life (HRQL) compared to standard care in persons with type 2 diabetes. II) To investigate the stages of change for physical activity and dietary habits using baseline data from persons with type 2 diabetes included in an mHealth intervention. We examined the associations between stages of change for physical activity and diet, and between stages of change for each behavior and individual characteristics, HRQL, self-management, depressive symptoms, and lifestyle. III) To systematically review studies evaluating integrated communication within mobile apps for tailored feedback between patients with diabetes and HCP, in terms of 1) study characteristics, 2) functions, 3) study outcomes, 4) effects, and 5) methodological quality.

Methods

A longitudinal randomized controlled trial (RCT) design with three arms evaluated the mobile diabetes diary app Few Touch Application (FTA) with or without health counselling (FTA-HC) after 12 months. The FTA offered functions to collect blood glucose, diet, and physical activity. Persons with type 2 diabetes, HbA1c ≥7.1%, and who were 18 years or older were eligible to participate. Our primary outcome was change in HbA1c after 12 months. Secondary outcomes included self-management (heiQ), HRQL (SF-36), depressive symptoms (CES-D), physical activity, dietary habits, stage of change in physical activity and dietary habits, and use of the intervention. Our evaluation was conducted in accordance with, and as a part of a Model for Assessment of Telemedicine Solutions (MAST). The data were analyzed using regression modeling. Findings from the RCT

informed the cross-sectional analysis of the baseline based on the stages of change. The five categories pre-contemplation, contemplation, preparation, action and maintenance were dichotomized into pre-action (the three first) and action (the two latter). We investigated associations with self-management (heiQ), HRQL (SF-36), and clinical characteristics using logistic regression modeling. Lastly, we conducted a systematic review. A systematic search was performed in medical databases (MEDLINE, PubMed, EMBASE, Cinahl, Central, Clinicaltrials.gov, and the WHO ICTRP) to evaluate the evidence base regarding mobile apps with integrated HCP communication for persons with diabetes evaluated using a controlled trial design. Risk of bias was assessed using the Cochrane risk of bias tool. The collected data only allowed for a narrative description and comparison of findings.

Results

We randomized 151 persons into three evenly distributed groups: control (n = 50), FTA (n = 51), and FTA-HC (n = 50), with no statistically significant change in HbA1c between the groups after 12 months. In the secondary outcome heiQ, we found a significantly greater change in the domain of "skills and technique acquisition" in the FTA-HC group after adjusting for age, gender, and education. Further, we found that those aged ≥63 years used the app more than their younger counterparts (OR = 2.7, 95% CI = 1.02,7.12). Baseline characteristics of the sample (N = 151) showed a median HbA1c of 7.9% (min = 7.1, max = 12.4), 90% were overweight or obese, and 20% had ≥3 comorbidities. We found that 58% were in the pre-action stage for physical activity change and 79% were in the pre-action stage for dietary change. Higher scores of self-management were associated with an increased chance of being in the action stage for both dietary and physical activity change. Further, we found an 8% reduced chance of being in the action stage for physical activity change in those with a higher body mass index (OR = 0.92, 95% CI = 0.86,0.99). Lastly, the systematic review resulted in six eligible papers reporting on 431 persons in small-scale trials with a short duration. The integrated communication was mostly individualized, non-real-time feedback. The apps had 2-9 functions, where blood glucose tracking was most common. Further, HbA1c was the primary outcome in 3 of the 6 trials. The remaining outcomes were not standardized or comparable. The risk of bias was uncertain because of poor reporting and uncertain methodological quality.

Conclusion

Based on these results, evidence regarding mHealth tools for self-management and communication with HCP remain unclear. Overall, evaluating mobile apps using traditional methods can be challenging, which should be considered in future research. Our findings may be of relevance for all HCP working with persons with diabetes.

List of papers

This thesis is based on the following papers:

I Holmen H, Torbjørnsen A, Wahl AK, Jenum AK, Småstuen MC, Årsand E, Ribu L. A Mobile Health Intervention for Self-Management and Lifestyle Change for Persons With Type 2 Diabetes, Part 2: One-Year Results From the Norwegian Randomized Controlled Trial RENEWING HEALTH. JMIR mHealth uHealth 2014;2(4):e57 doi:10.2196/mhealth.3882

II Holmen H, Wahl AK, Torbjørnsen A, Jenum AK, Småstuen MC, Ribu L. Stages of change for physical activity and dietary habits in persons with type 2 diabetes included in a mobile health intervention: the Norwegian study in RENEWING HEALTH. BMJ open diabetes research & care. 2016 May 1;4(1):e000193 doi:10.1136/bmjdrc-2016-000193

III Holmen H, Wahl AK, Småstuen MC, Ribu L. Tailored Communication within Mobile Apps for Diabetes Self-Management: A Systematic Review. JMIR 2017 (In press) doi:10.2196/jmir.7045

Abbreviations

ADA	American Diabetes Association
Apps	Applications
BMI	Body mass index
BP	Blood pressure
CBT	Cognitive behavioral therapy
CES-D	Centre for Epidemiologic Studies Depression scale
CI	Confidence Interval
CVD	Cardiovascular disease
DES-SF	Diabetes Empowerment Scale Short Form
DSME	Diabetes self-management education
DSMS	Diabetes self-management support
eHealth	Electronic health
FDA	Food and Drug Administration
FTA	Few Touch Application
FTA-HC	Few Touch Application and Health Counselling
GP	General Practitioner
HbA1c	Hemoglobin A1c
HCP	Health care personnel
heiQ	Health education impact questionnaire
HRQL	Health-related quality of life
HTA	Health Technology Assessment
MAST	Model for Assessment of telemedicine
mHealth	Mobile health
MI	Motivational Interview
MRC	Medical Research Council
NCD	Non-Communicable Diseases
PRO	Patient reported outcome
RCT	Randomized controlled trial
RENEWING HeALTH	REgioNs of Europe WorkING toGether for HEALTH
ROB	Risk of bias
SF-36	Short Form 36
SMS	Short message service
TTM	The Transtheoretical Model Stages of Change
WHO	World Health Organization

1 Introduction

Diabetes is one of the major non-communicable diseases (NCDs) threatening global public health [1]. Despite the focus on diabetes prevention, the global prevalence of diabetes is still increasing [2]. Regardless of their different etiology, prevalence of both type 1 and type 2 diabetes are increasing. Living with diabetes might be associated with a high disease burden and negative psychosocial consequences. Diabetes is a complex and time-consuming disease compared to other chronic diseases, and the consequences of hyperglycemia over time are severe. Further, the late complications of diabetes involve macro-vascular complications, such as cerebrovascular and coronary heart disease, and micro-vascular complications, such as retinopathy, nephropathy, neuropathy, peripheral vascular disease, and increased risk of foot-ulcers and amputation [2-4]. Among persons with type 2 diabetes, many have already developed late complications at the time of diagnosis due to the slow and masked progression of the disease [3,4]. However, late complications are preventable through good diabetes management. Moreover, despite advances in modern medicine, a considerable number of persons with diabetes do not meet their treatment targets [5-7]. In Norway, the "Coordination Reform" has attempted to increase the health-care provided in the municipalities for persons with chronic conditions [8]. The municipalities receive increased resources to care for their residents, aiming for a specialist health-care system for those in greater need of more specialized care. Altogether, the increase in diabetes and its late complications remains a burden for individuals and their families; it also places increased strain on the healthcare system and society. Thus, new strategies to provide care for this group are needed.

The Norwegian Directorate of Health published clinical guidelines for diabetes care in 2009 to improve the quality of diabetes care in Norway [9]. In 2016, the guidelines were revised, and including the earlier accepted HbA1c as a diagnostic tool [10]. The core of these guidelines revolves around leading a lifestyle with healthy dietary and exercise choices, achieved through support and health counseling strategies [10]. Further, medication is used when indicated for diabetes type 2, with insulin as a fundamental basis of type 1 diabetes management [10]. Self-management education and support are crucial, as living with diabetes involves many daily complex behaviors and individual medical decisions [11]. However, the individual impact of living with diabetes can be reduced by self-management [12-15]. Because of the unique lives we all lead, the amount of education and support needed to self-manage remains at the individual level. More specifically, diabetes self-management involves self-monitoring of blood glucose, taking the proper amount of medication, having a healthy diet, being physically active, and having a level of diabetes knowledge that allows individuals to make the right choices for their lives [11,16,17]. All of these steps influence each another, making self-

management a demanding task. Each individual reacts differently to the same amount of insulin, diet and physical activity, and reflection regarding one's own disease is important.

A recent review investigating interventions aiming at increasing diabetes self-management suggested that self-management education and support, with communication and feedback on individual health data, produced improved glycemic control [15]. Similarly, a randomized controlled trial (RCT) comparing health counseling over the telephone versus standard care found a significant decrease in HbA1c and an increase in treatment adherence, physical activity, and health status among those in the health counseling group [18]. These findings are supported by earlier research that found an increased effect in group-based interventions, suggesting that support is valuable when self-managing [12,14]. On the other hand, support may take various forms, such as the traditional communication with healthcare personnel (HCP) or peers in groups or individual sessions, face-to-face meetings, or through telephone calls with HCP. Support might also be valuable through automated feedback based on technical algorithms, where feedback could be a single emoticon like a smiley face [19] or a text summarizing the patient's latest actions. Such feedback can be provided at any hour, and it can be integrated into individuals' lives. Further, it might provide a basis for change or support favorable self-management, improving glycemic control [20-22]. In addition, communication and feedback have been suggested as a key preference among patients and providers [22,23], increasing the probability of intervention adherence and effect.

Mobile health (mHealth) applications (apps) are possible tools for supporting diabetes self-management [17]. Apps can offer precise information, and the ability to monitor diabetes measures, evaluate these data, and communicate with HCP or peers [23,24]. More importantly, the possibilities within technology exceed those of paper-based diabetes diaries, all in one platform that patients already carry around with them [21]. In addition, technology might increase access to information and care [25].

mHealth is increasingly recognized as important for supporting self-management in diabetes, and a high number of systematic reviews have summarized several trials testing various technology with various methodology and quality to establish the evidence of its effects [22,26-31]. Technology as a low-intensity intervention might be beneficial for diabetes self-management and glycemic control; however, some suggest that HCP support is also needed to truly prove beneficial. The effects of written HCP communication using short message service (SMS) both alone and in combination with apps are promising [32-34]. Further, new developments in the mHealth field allow for more integrated communication with others through apps, offering monitoring of health data, evaluation, and feedback from HCP or others within the same platform. Although work to improve the

conduction and reporting of technology trials has been carried out [35,36], the effects of technology remain unclear, due to problems with methodological quality [20,22,37].

Although understanding human behavior and behavior change is suggested as a prerequisite for effective interventions [38,39], the use of behavior change theories in technology research has been called insufficient [21,22,30]. There remains limited evidence regarding how behavior change theories work together with technology toward a common goal. Nonetheless, interventions for diabetes self-management should consist of components that are relevant for individuals, thus increasing their knowledge and ability to change [11]. Further, increased self-management is associated with higher levels of self-efficacy [40] and a higher stage of change [41]. Exploring these results can be valuable for understanding individual attitudes toward both behavior/self-management and behavior change. In addition, individuals' perceived benefits of participating can be discussed in close relation to both self-efficacy and self-management.

The current project was initiated in 2009 at Oslo and Akershus University College of Applied Sciences (HIOA), funded by the Norwegian Research Council. It was continued as a collaboration with the Norwegian Centre for Integrated Care and Telemedicine (now the Norwegian Centre for eHealth Research) and the European Union (EU) project REgioNs of Europe WorkINg toGether for HEALTH (RENEWING HEALTH) [42]. RENEWING HEALTH was a large collaborative initiative among nine European countries, including Austria, Denmark, Finland, Germany, Greece, Italy, Norway, Spain, and Sweden. The overall aim of RENEWING HEALTH was to produce high-level evidence and decision support for EU health policies regarding the future deployment of telemedicine services in fields where they can lead to improved care and reduced costs. Further, telemedicine solutions may support persons to be active participants in their own treatment, and aid HCP when providing self-management support [43]. RENEWING HEALTH expanded a variety of telemedicine and health counseling pilot trials guided by the concepts of eHealth and telemedicine. To ensure that evaluation were unbiased and systematic, and in compliance with health technology assessment (HTA), the Model for Assessment of Telemedicine Applications (MAST) was developed to inform the evaluation of RENEWING HEALTH [35]. MAST is a framework for assessing interventions' effectiveness and contribution to quality of care within telemedicine to assist decision makers. The process is multidisciplinary and includes preceding considerations of whether the intervention is ready for an evaluation, before the multidisciplinary assessment evaluates seven domains: 1) health problem and characteristics of the application, 2) safety, 3) clinical effectiveness, 4) patient perspectives, 5) economy, 6) organizational aspects, and 7) sociocultural, ethical, and legal aspects [35]. Lastly, a transferability assessment provides knowledge regarding the relevance cross-border, the scalability, and the generalizability. Thus, MAST provides information about the medical, sociocultural,

economic, and ethical issues of importance surrounding an intervention. The areas of MAST that will be discussed in the current thesis are mainly the health problem and characteristics of an application, the clinical effectiveness of the intervention, and safety and ethical issues.

Within the Norwegian study in RENEWING HEALTH, the current thesis builds on the 12-month RCT evaluation of a mobile app intervention with or without health counselling [44]. The app FTA was developed through a different project, and will therefore not be discussed in detail in this thesis. After the RCT, we performed a thorough baseline investigation of the sample based on their stage of change [45]. In addition, a systematic review [46] was conducted to complement the aim of this thesis. Within the Norwegian study, an RCT study protocol was published [47], and a four month evaluation [48]. Further, the association between level of acceptability of our diabetes mobile application and self-management has been explored [49]. Qualitative interviews informing two papers have been performed—one using grounded theory to develop theory about living with diabetes and behavior change, and one describing the acceptability of the intervention and qualitative methods [50,51].

1.1 Aims of the thesis

The main aim was to investigate mHealth for diabetes self-management by testing the effects of an intervention, revealing associations between stages of change for physical activity and diet and relevant variables, and summarizing the evidence for integrated communication within mobile apps for tailored feedback between persons with diabetes and HCP. The specific aims were as follows:

I To test whether the use of a mobile phone–based self-management system used for 1 year, with or without telephone health counseling by a diabetes specialist nurse for the first 4 months, could improve glycated hemoglobin A1c (HbA1c) level, self-management, and health-related quality of life compared with usual care.

II To investigate stages of change for physical activity and dietary habits using baseline data from persons with type 2 diabetes included in a mobile health intervention. We examined the associations between stages of change for physical activity change and dietary change, and between stages of change for each behavior and individual characteristics, health-related quality of life, self-management, depressive symptoms, and lifestyle.

III To systematically review studies that aimed to evaluate integrated communication within mobile apps for tailored feedback between patients with diabetes and health-care personnel, in terms of: 1) study characteristics; 2) functions; 3) study outcomes; 4) effects; and 5) methodological quality.

2 Background

Non-communicable diseases such as diabetes, cancer, chronic respiratory disease, and cardiovascular disease (CVD) are increasing, and they constitute a threat to individuals, families, the healthcare system, and society [1,52]. Understanding the individual burden of living with diabetes and chronic conditions in general is important, as the number of people living with one or more chronic diseases is rapidly increasing [52]. More sophisticated and improved treatment for several chronic diseases have changed the aim from prevention of an early death to remaining in a stable and successful disease control. This has led to decreased death rates, and individuals are now living longer with their chronic disease. Living longer with a chronic disease is further associated with multimorbidity, and in 2012, 25.5% of the noninstitutionalized adult United States (US) population had multimorbidity with two or more chronic conditions [53]. In these numbers, diabetes was frequently found in combination with other chronic diseases such as hypertension and arthritis [53]. In Norway, the prevalence of multi-morbidity with two or more chronic conditions was estimated to be 42% based on data from Helseundersøkelsen i Nord-Trøndelag (HUNT 3) (2006-2008) [54]. One reason why the Norwegian numbers are higher than the numbers reported from the US might relate to the inclusion of mental health problems, because these were not included in the US numbers. Mental health problems such as depression, anxiety, and diabetes distress are associated with deterioration of diabetes self-management, and they are therefore relevant to estimations of multimorbidity. Further, special attention is needed for maintaining high levels of HRQL when living with chronic conditions where a cure is unlikely [55]. When comparing diabetes with other chronic diseases, persons with diabetes have higher HRQL than those with other chronic diseases, but they had lower HRQL than the general population [56]. Similarly, a large cohort revealed how persons had a decline in their HRQL when moving from pre-diabetes to type 2 diabetes [57].

2.1 Diabetes mellitus

Diabetes mellitus is a chronic disease affecting the insulin producing beta cells in the pancreas. The World Health Organization (WHO) defines diabetes as “a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both” (p.2) [58]. The lack of insulin hinders the glucose uptake in the cells, causing blood glucose levels to increase and the available glucose in the tissue to decrease. These mechanisms prompt several physiologic responses, and left untreated, the lack of insulin will cause tissue damage and nerve damage. In type 1 diabetes, the lack of insulin causes ketoacidosis and eventually death [17].

The global prevalence of diabetes has been increasing for the last 15 years, and numbers from 2015 suggest that 415 million persons have some kind of diabetes—where 91% of the adults in this estimate have type 2 diabetes [59]. Global estimates based on high-quality data from several countries indicate a continued increase for the next 20 years, suggesting that 642 million persons will have diabetes by 2040 [59]. Further, global estimates for children suggest a 3% increase in type 1 diabetes each year, with 86,000 children diagnosed annually. In Norway, the diabetes register including both type 1 and type 2 diabetes for adults is unfortunately not comprehensive [60]. However, the Norwegian Childhood Diabetes Registry is a comprehensive register including 97% of those under the age of 18 who have been diagnosed in Norway [61]. For adults, the prescription registers provides the most reliable numbers for diabetes prevalence in Norway, and numbers from 2006-2011 suggest that 3.2 % of the population received anti-diabetic medication in 2011, with no increase in new users of anti-diabetic drugs during this time span [62]. Recent data indicate stability in the numbers of people being diagnosed with type 1 diabetes in Norway [63]. These numbers suggest that the overall incidence of diabetes in Norway might have stabilized, similar to the reports released by the centers for disease control and prevention in the US, where the diabetes incidence has decreased over the past six years [64]. This decrease is significant in men, but not in women, and not amongst those with lower levels of education. Unfortunately, it is anticipated that 46 % of those with a true type 2 diabetes are unaware of this; they are at high risk of complications from the lack of treatment, making diagnosing and treating those with the disease an urgent matter [59]. Altogether, diabetes remains a major concern and is in need of attention and new strategies for all parties involved, including the healthcare system. The healthcare and society expenditures for persons with diabetes are 2-3 times higher compared to those without diabetes [59]. The majority of these resources are spent on persons with diabetes-related complications that are preventable with proper self-management [65].

2.1.1 Type 1 diabetes

Type 1 diabetes mellitus is an autoimmune disease, where the beta cells are destroyed and the patient is completely dependent on insulin administration [17]. Type 1 diabetes remains as one of the most common endocrine diseases worldwide, and it is most frequently diagnosed in children.

2.1.2 Type 2 diabetes

In type 2 diabetes mellitus, the insulin-producing beta cells have a reduced function, often in combination with impaired insulin sensitivity and increased hepatic glucose production [17]. The impaired insulin sensitivity causes a secondary strain on the beta cells, as they have to produce a larger amount of insulin for the same blood glucose-lowering effect. In 80 % of the patients with type 2 diabetes, there is a primary weight problem of overweight or obesity—insulin resistance is also a

major concern [16]. Often, there remains some insulin production in the beta cells, and if the strain on these cells is decreased through more physical activity and less carbohydrates, they can produce just enough insulin to reduce the hyperglycemia and the symptoms; in some patients, medications are not necessary. To achieve this, common guidelines recommend lifestyle changes as the first and overall basic action to manage type 2 diabetes [10,17].

2.1.3 Diagnostic criteria

The diagnostic criteria for type 1 and type 2 diabetes are the same. HbA1c is the preferred diagnostic measure (Table 1) [10] related to the strong evidence for the predictive value of an increased HbA1c when it comes to late complications [17]. Internationally, HbA1c was recognized as a diagnostic tool by an International Expert Committee in 2009 [66], the American Diabetes Association (ADA) in 2010 [67], and the WHO in 2011 [68]. In Norway, the National guidelines for diabetes accepted HbA1c as a diagnostic tool in 2012 [10]; HbA1c was not a diagnostic tool when the current project was initiated in 2011. An important note regarding HbA1c as a diagnostic tool is that HbA1c ≥ 6.5% does not exclude diabetes if the diagnosis is confirmed by other tests. This relates to the nature of HbA1c and the fact that it represents the blood glucose levels over the last 2-3 months prior to the test [10].

Table 1. Diagnostic criteria for diabetes [10]

Measure	Diagnostic thresholds	Comments
HbA1c	≥6.5 %	Preferred analysis, needs confirmation in second test
	48 mmol/mol	
Fasting plasma-glucose	≥7.0 mmol/L	Needs confirmation in second test
2 hour oral glucose tolerance test	≥11.1 mmol/L	Needs confirmation in second test
Random plasma-glucose	≥ 11.1 mmol/L	+ symptoms, second test not required
		- symptoms, second test required for confirmation

2.2 Living with diabetes

2.2.1 Psychosocial impact of diabetes

Diabetes is a complex disease, and it affects more than just blood glucose. In addition to the micro- and macro-vascular complications, diabetes can be associated with psychological struggles like diabetes distress [69,70], anxiety [71], and depression [72]. Further, aspects such as fear of late complications, episodes of hypo- or hyperglycemia, changes in lifestyle, and fear of long-term consequences may compromise the quality of life among persons with diabetes [56,73]. The United Kingdom Prospective Diabetes Study (UKPDS) found that complications affected quality of life more than the complex treatment of diabetes [74]. However, several argue that the complex treatment is burdensome [57,75,76]. Moreover, emotional distress in persons with type 2 diabetes is related to a

lower frequency of taking medications as prescribed [77]. The burden of living with diabetes has received increased recognition in the last 20 years, with several studies aiming at understanding how interventions might affect quality of life [74,78,79]. Others have investigated how distress [80,81], depression [72,82], and anxiety [82] related to diabetes can be reduced. The stigma that many persons with diabetes express has recently guided the development of a new measure to assess the impact of the stigma burden among these persons [83].

Diabetes distress is distinct from depression, and relates to the worries and emotional burden of diabetes associated with knowing that diabetes is a severe chronic disease. Compared to depression, diabetes distress has many of the same negative implications on diabetes management [69,81]. In a Norwegian sample using the Problem Areas in Diabetes (PAID) and the diabetes distress scale, the authors found higher scores to be positively associated with reduced metabolic control and they emphasized the need for early detection of such problems [84]. Data from the Diabetes Attitudes, Wishes and Needs (DAWN) study I and II [85,86] reported that the majority of persons with diabetes suffered from psychological problems, and these problems compromised their self-management [87,88]. The DAWN II provides valuable reports on the significance of living with diabetes and how this influences daily living; here, 40% of the patients reported that their medication regime interfered with their social lives [87]. The study also found that 44.6% of the respondents reported having diabetes distress, measured with PAID 5 having a score ≥ 40. These findings confirm the findings of Rubin and Peyrot in 1992 [89], who reported high levels of psychosocial problems among persons with diabetes. Further, clinical indicators are suggested to be less associated with diabetes distress but more associated with how individuals are coping and how they perceive support from family or HCP [70], emphasizing the importance of support when living with and managing diabetes.

Coexistence of depression or anxiety and diabetes is of special concern among those with diabetes, as these conditions negatively influence self-management, glycemic control, and late complications [90,91]. Further, these associations are larger when standardized assessments and diagnostic criteria for depression are used, rather than self-reported measures [92]. A 2001 meta-analysis investigating anxiety and depression found an increased incidence of anxiety disorders in those with diabetes, and an almost doubled incidence of depression compared to those without diabetes [93]; these findings were confirmed in a type 2 diabetes sample [69]. Research confirms the associations between depressive symptoms in diabetes and lower HRQL scores, supporting the need for the systematic assessment of such symptoms in diabetes [94].

All aspects of living with a chronic disease such as diabetes type 2 have serious implications for HRQL [73]. Within this thesis, the understanding of health is based on the WHO's definition " [the] state of

complete physical, mental and social well-being, and not merely the absence of disease or infirmity" (p.1) [95]. However, the WHO definition of health does not comprise areas important for life besides health [73,96]. Thus, Huber and colleagues [96] suggested changing this definition to include abilities to adapt and self-manage through social, physical, and emotional challenges. These new concepts in the health definition correspond well with diabetes self-management, and recent research has striven to operationalize this dynamic definition of health [97]. However, it remains to clarify its correspondence with measures like the Short Form-36 (SF-36). Despite suggestions for improvements to the WHO's definition of health, it corresponds well with our choice of evaluation measure; the generic measure of health (the SF-36) that is frequently used to evaluate HRQL through physical and mental domains [98]. Based on data from the SF-36, a systematic review investigating HRQL scores concluded in 2011 that the effect of diabetes on HRQL has been underestimated as the HRQL scores was lower than in the normal population, as well as lower than previously reported norms [99]. Further, there is an association between complications and lower HRQL scores [56,100], and between a lower HRQL and increased mortality, and inability to work [101]. Thus, comparing HRQL between different treatments reveals significantly lower HRQL scores among those who receive intensive lifestyle changes compared to those treated with oral anti-diabetic drugs or standard care [57]. Further, qualitative work has revealed how the majority of persons with type 2 diabetes expressed feelings of stigma associated with their diagnosis [102]. These feelings might increase diabetes distress and feelings of shame, deteriorating their HRQL.

Lastly, the diabetes burden negatively affects families. In light of the important role that the family plays in supporting the individual with diabetes in his or her daily self-management, families also need recognition [103]. A Norwegian cross-sectional study found that only 11% of persons with diabetes felt supported by their family, underlining the potential for support provided by family members [70]. Another study found that family members of persons with diabetes reported high levels of distress regarding the person with diabetes, and they worried especially about hypoglycemia [103]. This might compromise the family members' ability to support the person with diabetes, which might reduce this person's glycemic control. Thus, social support is crucial, as persons with diabetes spend most of their time on self-management without their HCP. Social support might increase glycemic control through improved self-management, which has been confirmed in a major meta-analysis investigating 148 primary studies [104]. The authors suggested that a lack of social support might be the main barrier against reaching targets; it might also increase the risk of death. Specifically, the risk of death associated with social isolation was greater than the risk associated with cigarette smoking [104].

2.2.2 Diabetes care

The overall aim of diabetes care is to achieve glycemic control, reach treatment targets, prevent late complications, and have a good quality of life despite living with a chronic disease.

The three main clinical treatment targets for diabetes include HbA1c, blood pressure, and LDL cholesterol, and several guidelines exist for the treatment of diabetes. The most influential guidelines are from the International Diabetes Federation (IDF) for type 2 diabetes [59], the American Diabetes Association (ADA) [17], the European Association for the Study of Diabetes (EASD) [16,105], and in Norway, the Norwegian Directorate of Health [9,10]. Common to all are their individualized tailored treatment targets and their consistency between diabetes type 1 and diabetes type 2. Earlier guidelines were more rigorous regarding the HbA1c target, but more recently, a main target for HbA1c in the area of 7% (53 mmol/mol) has been described; specifically, it states that the target should be more or less stringent and individually adapted for each patient, accounting for age, history with hypoglycemic events, and onset of late-complications [2,10,16,17,105,106]. The Norwegian treatment targets are HbA1c around 7%, blood pressure <135/85, LDL cholesterol < 2.5 mmol/l as primary prophylaxis and < 1.8 mmol/l as secondary prophylaxis, 150 minutes per week of vigorous physical activity, a healthy and starch-reduced diet, smoking cessation, 5-10% weight reduction when indicated, and a post-prandial blood glucose <10 mmol/l [10].

Non-pharmacological treatment

Having a healthy lifestyle remains crucial; this is particularly true in type 2 diabetes [2,16,106]. In both type 1 diabetes and type 2 diabetes, a healthy lifestyle is advocated, just like it is for the general population [10]. However, persons with type 2 diabetes tend to have poor lifestyle habits such as physical inactivity, unhealthy diet and smoking. Lifestyle changes can be efficient in balancing their blood glucose and preventing late complications [10,17]. Guidelines targeting lifestyle emphasize healthy choices, preferably both healthier eating and increased physical activity; smoking cessation and less alcohol; and weight loss for those with overweight or obesity. Food containing saturated or trans-fat, refined carbohydrates, and added sugar are discouraged, as they increase the strain on the metabolic system by increasing blood glucose, which then requires more insulin. If the patient's tissue has decreased insulin sensitivity, there will be a double negative strain. Often, dietary habits are the most challenging aspect of diabetes management, as there is a strong connection between our social and cultural lives and our dietary preferences. Physical activity can reduce the insulin production strain through increased insulin sensitivity, and it should be part of the patients' daily routines to help achieve metabolic control. Vigorous activity is not needed—an increase in heart rate is sufficient, and it remains important to break up long sedentary periods of more than 90 minutes [10,17]. Smoking increases the already high risk of CVD, and there is strong evidence of the health

risks of smoking [107]; thus, smoking cessation should be encouraged. Alcohol imposes an increased risk of delayed hypoglycemia; it also converts to sugar and can cause ketoacidosis, especially in persons with type 1 diabetes, which can be life threatening. Thus, the cornerstones of diabetes care revolve around a healthy lifestyle.

Pharmacological treatment

Although the treatment targets are the same for type 1 diabetes and type 2 diabetes, the pharmacological treatments differ due to the disease etiology. Type 1 diabetes causes all insulin production to cease shortly if not immediately after the diagnosis, and all patients are dependent on an insulin supply administered subcutaneously through pen injections or pumps. Management of type 2 diabetes often includes changing to a healthier lifestyle, whereas type 1 diabetes does not necessarily require this change. Persons with type 2 diabetes often have some insulin production left; however, the majority have other metabolic conditions that need urgent care, like excessive weight, hypertension, and/or dyslipidemia [16,105]. Primary hyperglycemia in a person newly diagnosed type 2 diabetes is treated with lifestyle adjustments, unless anti-diabetic medication is required. If the medical treatment is not satisfactory in terms of treatment targets, other anti-diabetic medications are added or an insulin regime is prescribed. The last 5-10 years has seen an increase in available medications and injections for persons with type 2 diabetes, featuring both oral and subcutaneous options [16,105]. However, a recent review investigated the available medications for type 2 diabetes and compared their effects, adverse outcomes, and safety; it concluded that Metformin remained as the first choice and had few side-effects [108]. Thus, although new medications are available, Metformin remains safe and has low risk of hypoglycemia, although most persons experience some side effects [2,10]. Metformin is the first choice in the Norwegian guidelines [109], which is in consensus with international guidelines [2,17]. A combination treatment is regarded to be beneficial in terms of reaching the treatment target of HbA1c around 7% in persons with type 2 diabetes; however, early combination therapy is associated with an increased risk of hypoglycemia [110].

Treatment targets

Managing diabetes requires more than treating a high blood glucose level, and it remains a complex task for patients and providers because of the comprehensive regime, lack of knowledge, attitudes toward the disease, and economic factors [111]. Reaching treatment targets is an ongoing task, and although the quality of care has been improving in Norway [112], the numbers of people reaching these goals are not positive. In Norway, three large studies examining the general practices indicated that only 20% of the persons with diabetes reached their treatment goals for all three goals of HbA1c, blood pressure, and lipids [7]. It has been challenging to attain structured diabetes

registrations in primary healthcare; therefor, how many persons with type 2 diabetes reach their treatment targets is somewhat uncertain. Among the persons with type 1 diabetes treated in specialist healthcare, the registered numbers indicate that only 10% reach their treatment goals [60]. Further, numbers from a single Norwegian general practitioners (GP) office indicated that 13% of all of their diabetes patients reached all three targets of HbA1c, blood pressure, and lipids [113]. Numbers from the European PANORAMA study reported that only 7.5% met all three targets for HbA1c, blood pressure (BP), and cholesterol, whilst 42.8% met only the HbA1c target [6]. Data from a US diabetes care report indicated that almost half of the adults with diabetes did not meet their treatment targets. When the study included tobacco-cessation, only 14.3% met all three targets and tobacco –cessation [5]. There have been improvements in care over the last decades, and the numbers are promising compared to earlier studies; however, diabetes management remains a challenging task.

Diabetes late complications

Strategies to prevent or delay the onset of late complications and premature death in diabetes are crucial [114-116]. Specifically, high or fluctuating blood glucose negatively affects internal organs, and micro- and macro-vascular complications occur amongst the majority of persons with diabetes. In type 2 diabetes, at least one late complication was present in 50% of the patients at the time of diagnosis [59]. Further, numbers from the Netherlands among persons with screening-detected type 2 diabetes indicated that 7.6% already had retinopathy, 10.6% had peripheral arterial disease, 13.3% had signs of earlier myocardial infarction, 39.5% had ischemic heart disease, 17.2% had microalbuminuria, and 48.1% had neuropathy with impaired foot sensitivity [3,4].

Type 2 diabetes is associated with a doubled risk of atherosclerotic CVD, with the first myocardial infarction about 15 years earlier compared to healthy controls [117,118]. Overall, there has been a strong reduction in CVD since the 1970s, largely due to the reduction of smoking and the advances in medical treatment [119]. In Norway, there was a decrease in mortality from cardiovascular events from 1984-1986 and 1995-1997, but in those with diabetes, there is still a twofold risk of mortality from CVD compared to those without diabetes; females with type 2 diabetes were overrepresented in the mortality numbers [120]. There has been extensive research on the causalities of late complications in diabetes [5], with evidence confirming that morbidity and mortality from atherosclerotic CVD disease is decreasing [121].

More specifically, intensive or complex treatment can prevent the development and progression of late complications in diabetes. In type 1 diabetes, the most influential trial was the Diabetes Control and Complications Crial (DCCT), which investigated the frequency of complications in intensive

treatment compared to standard treatment [114]. Intensive treatment included self-monitoring of blood glucose four or more times daily, injecting insulin at least three times daily or using an insulin pump, following a diet and physical activity plan and adjusting insulin accordingly, and meeting their HCP monthly. The study found that among the individuals receiving intensive treatment, the risk of retinopathy was reduced by 76%, the risk of nephropathy was reduced with 50% and the risk of neuropathy was reduced by 60%. The intensive treatment was associated with an increased risk of hypoglycemia, although not to the level that it interfered with cognitive function or quality of life. The DCCT was continued in the observational long-term follow-up the Epidemiology of Diabetes Interventions and Complications (EDIC), where the original standard treatment group was taught about intensive treatment [115]. Although the entire cohort now receives intensive treatment, results are still in favor of the original intensive treatment group, with a 58% reduction of cardiovascular events after a mean of 18 years follow-up [122]. The EDIC cohort is still under investigation via annual follow-ups, and it will continue to provide valuable knowledge about the long-term effects of intensive and standard care for type 1 diabetes.

In type 2 diabetes, the first convincing trial to describe the associations between intensive pharmacological treatment and late complications was the UKPDS, initiated in the 1970s. Intensive treatment was compared with standard treatment, where intensive treatment was regarded as pharmacological glucose lowering treatment. The UKPDS provided evidence regarding the negative effect of hyperglycemia on late complications, finding that a tight glucose-lowering regime could reduce complication rates [116]. Long-term data at 10 years from the UKPDS trial suggested a continued reduction in microvascular risk in those receiving intensive treatment and a lowered risk of myocardial infarction and all-cause mortality [123].

The Action in Diabetes and Vascular Disease (ADVANCE) study reported similar findings as the UKPDS, comparing intensive glucose lowering treatment with standard treatment [124]. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) study aimed to reduce HbA1c through intensive therapy; however, it was discontinued after the intensive pharmacological treatment of type 2 diabetes was associated with increased mortality, illustrating the possible risk of intensive treatment [125]. A meta-analysis suggested that intensive glucose lowering treatment in type 2 diabetes lowered the risk of micro- and macro vascular disease; however, there was a significant increase in hypoglycemic events in the intensive treatment group, and there was no reduction of all-cause mortality [126]. These are strong arguments supporting the individualization of diabetes treatment.

Studies investigating behavior and lifestyle adjustments for type 2 diabetes reported somewhat similar findings. The Look AHEAD: action for health in diabetes study remained as the only lifestyle

intervention study with hard endpoints for type 2 diabetes; however, they did not manage to decrease LDL cholesterol, important for the prevention of CVD [127]. Further, it did not prove significant at the 10 year follow-up, although it underwent important positive changes during the study period. One strength of the Look AHEAD was the inclusion of quality of life among the participants, where it found an increase in quality of life in the short-term. However, uncertainty remains regarding the long-term effects of an intensive lifestyle intervention on quality of life [78].

The Steno-2 study combined intensive lifestyle intervention and pharmacological intervention, providing evidence about the effect of a stepwise implementation of behavior modification and pharmacologic therapy [121]. It targeted hyperglycemia, hypertension, dyslipidemia, and microalbuminuria, along with secondary prevention of CVD with aspirin. It found a reduced risk of cardiovascular and microvascular events by about 50%.

In summary, individualized treatment remains important, as persons with diabetes have various disease histories, and not everyone benefits from an intensive-glucose-lowering treatment. Overall, lifestyle changes remain difficult, there is a great deal of stigma, and some persons have depressive symptoms throughout the course of their disease. As researchers and HCP, we must care for more than the hard endpoints. Thus, this thesis aims to describe the contribution of mHealth to diabetes self-management with and with contact with HCP.

2.3 Theory of lifestyle and behavior change

Several studies have examined the relationship between applied theory and the effects of interventions aiming at lifestyle or behavior change [39,128]. Norris and colleagues [38] suggested that in order to understand the change that individuals are going through, researchers need to have a theoretical framework that can explain these processes.

To provide an understanding of the lifestyle and behavior change within this thesis, we have based our work on the Cognitive Behavioral Theory (CBT) [129], the Transtheoretical Model Stages of Change (TTM) [130] and self-efficacy as described by Bandura [131]. These are not related in their origin, but they can be used together, as it is proposed that the Cognitive behavioral theory can mediate the self-efficacy, and that the self-efficacy drives the individual change that the individual will manifest as an increase in his or her stage of change. Moreover, self-efficacy is expected to increase as the individual moves to higher stages of change, decreasing the risk for temptation and relapse [132]. Self-efficacy is also suggested to facilitate stage progression or maintenance, indicating how these concepts relate to one another [133].

CBT is a psychotherapy originated by Beck in the 1960s. The concept of CBT is based on three automatic human thoughts: negative thoughts about ourselves, about others, and about the future. CBT has been used and researched exponentially; it was summarized in a review of meta-analyses published in 2006 providing evidence for its efficacy in psychiatric diagnoses [129]. Its application in other areas began mainly in the early 1990s, and research has suggested its effectiveness for somatic disease treatment. The use of CBT in somatic disease can target attitudes and beliefs regarding the diagnosis initially, but also how persons perceive their ability to self-manage and to discuss self-management with them [134,135]. As suggested in a recent review [135], using CBT for chronic disease management can be applied to internet interventions, and it holds promising results; however, within the mHealth field, it remains uncertain as it is rarely applied.

The understanding of behavior and disease management in this thesis is based on self-management, which again is closely related to self-efficacy, as self-efficacy is suggested to be a prerequisite for self-management [131].

2.3.1 Self-efficacy

Bandura and the Social Cognitive Model suggests that self-efficacy both directly leads to a behavior and indirectly leads to a behavior through outcome expectations, goals, and socio-structural factors [131]. Self-efficacy concerns the individual's inner thoughts and beliefs in his or her ability to perform a specific action required to attain a preferred outcome. It is not referring to a specific set of skills, but to the belief of what one can do with whatever skills one has [131]. Moreover, the Social Cognitive Model and the TTM, amongst others, have suggested that self-efficacy serves as a key construct in health psychology [136]. To measure self-efficacy, the three self-efficacy domains magnitude, strength, and generality are rated according to a specific behavior [131], and several behavior or disease specific measures to evaluate self-efficacy have been developed [137].

The evidence regarding self-efficacy indicates its value in increasing physical activity [136,138]. More specifically, evidence regarding the predictability of self-efficacy on physical activity, suggests that interventions that include feedback on actual behavior produce the largest increase in levels of self-efficacy among healthy individuals [136]. Within diabetes, self-efficacy is a relevant concept because of its relation to self-management. Interventions targeting self-management education have been shown to increase self-efficacy at 6 and 12 months [139]. Further, self-efficacy is suggested to positively correlate with self-management, mainly through a higher level of self-management in those reporting a higher level of self-efficacy [40], and that self-management interventions increase self-efficacy [137].

2.3.2 The Transtheoretical Model Stages of Change

One way of identifying an individual's perception and thoughts regarding his or her own change is the TTM, first introduced in the 1980s and later revised [130,140]. In the version from 1992, the construct placed an individual at one of five stages based on his or her thoughts regarding change in specific habits (e.g., smoking, physical activity, etc.). The stages included pre-contemplation, contemplation, preparation, action, and maintenance. In the TTM, a higher stage was associated with individuals being more likely to change or already are changing/have changed their behavior. Relapse and recycling through the stages occurred frequently when patients tried to reach the maintenance phase of change, and linear progression was rare, but adoption of information and increased awareness of their own lifestyle and condition was of equal importance in this process [130].

Since the initiation of the TTM, it has undergone a great deal of research within several areas to determine whether it reduces health risk behavior and/or increases healthy behavior. Although the TTM was developed to help the cessation of addictive behaviors, it may be relevant to lifestyle changes in persons with diabetes [141-143], and it has been found that the TTM is especially valuable among those who do not intend to change but who display health risk behavior [143]. Some suggest a linear relationship between health behavior and stage of change [41,144]; however, even though movement up the stages is evident, it is not certain that a healthy behavior will be adopted, as the movement can be an intermediate step since people are known to move both ways in the TTM [145].

Researchers in Canada investigated stages of change among persons with type 2 diabetes, and found that individuals in the action phase were more likely to be female, have a higher quality of life, and have healthier eating habits [143]. Further, when comparing individuals on insulin treatment with oral anti-diabetics, the individuals using oral anti-diabetics in the action phase were generally older, had a lower body mass index (BMI), were non-smokers, had less stress, and had a higher quality of life. These findings are important when targeting other groups with type 2 diabetes regarding the characteristics and needs of the group. Further, the same research group conducted a large RCT using a stage-matched intervention, with several positive outcomes in HbA1c, healthy eating, self-monitoring of blood glucose, and smoking, suggesting that stage-matched interventions might be effective for more than just those who are in the action stage [141]. These findings are similar to a more recent study from 2011, where the authors investigated the effects of diabetes education plus physical activity counseling tailored to stage of change compared to diabetes education only [146]. Their findings comprised the effects of education and stage-tailored counseling on behavior change, but not on HbA1c, after 3, 6, and 12 months, reporting on the effects of tailoring on the specific behavior being targeted [146].

It has been suggested that measuring the exact stage of change is challenging, and a variety of measures exist that are both validated and non-validated [145,147]. An editorial from 2006 [148] emphasized the need for context-sensitive measures, as, for example, a stage for an increase in physical activity will have different meanings for someone aiming to walk to the mail-box versus someone aiming to run a marathon. An appropriate questions might be, “Are you ready to make the following change in the following context?” [148]. Jones and colleagues [141] applied more advanced staging measures, with exploratory and confirmatory analyses to establish stage of change.

The TTM has undergone some debate [149,150]. First, it has been suggested that individuals do not belong to a single stage, but that they can be in several stages at the same time, a statement supported by Andres [145]. Further, it has proven difficult to predict a person’s movement through the stages, especially the shift from preparation to action. This is perhaps because of the many individual reasons to change, not just because it is necessary from a health perspective. The failure of stage-matched interventions when compared to non-stage matched interventions has also been discussed, and there are inconsistencies among the trials [149].

2.3.3 Motivational interviewing

A common health counseling method is motivational interviewing [151], developed as a health counseling strategy to help in behavior change. MI has principles according to CBT, and within MI, the patients identify their problems, strengths, weaknesses, and goals, which increases the patients’ reflection regarding their current situation; further, it increases their willingness to change their behavior [151,152]. Through communication skills involving open-ended questions, active and reflective listening, and supporting their autonomy, they can identify their strategy for behavior change. Often, their ambivalence toward change complicates their health counselling, but the uniqueness of MI is in its applied principles to overcome this ambivalence through empathy, rolling with resistance, and supporting self-efficacy. MI has been used in diabetes care, with evidence suggesting its effectiveness and perceived usefulness among those using this method technique [153,154]. MI has previously been used with positive results in diabetes-interventions [153-155].

2.4 Self-management

The overall concept of self-management entered the health field in the 1960s [156]; however, there is heterogeneity in how the concept has been applied and understood and a lack of a consensus definition [157]. Suggested definitions relevant for the current project are those emphasizing the strengths within the patient role—how the individuals should be responsible for their disease management with HCP support and be active participants in their own lives [137,156]. The concept relates closely to self-efficacy, and Bandura [131] emphasized that for many, self-efficacy is a

prerequisite for self-management. People are unlikely to engage in change to increase their self-management if they do not believe they have what it takes to succeed.

Through time, self-management has been associated with the emancipation of the patients, challenging the passive patient role [158]. Some suggested that increased individual responsibility could help decrease health care costs, as patients would take over some of the HCP tasks [158]. Further, the concept of "self-care," in which patients perform tasks traditionally done by HCP, has colored the field of self-management [158]. Although the concepts of self-care and self-management are used interchangeably, the definition for self-care regards everyday life activities, such as washing and dressing, and remains action-oriented [159]. The concept of self-care led to associations with the term "compliance", where the patient is obligated to follow the doctor's orders. The notion has now moved back to more patient-centeredness, where individuals must be responsible and active to manage their chronic disease in their lives, with improved quality of life as their outcome [137].

Coping with chronic illness is closely related to self-management; specifically, the description of three distinct elements of chronic illness coping has influenced the field of self-management. Corbin and Strauss [160] described three elements: 1) medical and behavioral management: e.g. taking medication, attending follow-ups, 2) role management: e.g. taking on the 'patient' role, the effect on relationships, and 3) emotional management: dealing with the fear, anger, guilt etc. that often accompanies living with a chronic illness. These three elements of coping were adapted by Lorig [156] into six basis skills required for self-management: 1) problem solving, 2) decision making, 3) resource utilization, 4) the formation of a patient-provider partnership, 5) action planning and behavior change, and 6) patients tailoring management plans to suit their needs. Relying on these basic skills might prove helpful for those involved, as the question is not whether or not to self-manage, but how to self-manage, which remains a lifelong task for the majority of those with chronic conditions [156].

Research on the self-management of chronic conditions has an increasing evidence base; however, there are inconsistencies regarding its effectiveness, where multi-component interventions seem to contribute more positively [161,162]. An investigation of self-management support strategies found that several strategies complemented each other, including peer-led groups, motivational interviewing, and health coaching [161]. These findings were supported by a recent rapid synthesis evaluating self-management interventions for 14 different long-term conditions; it highlighted that no one component was more important than others among these conditions. However, the core components included education about the condition, psychological strategies for life adjustments, strategies for treatment adherence, practical self-management support, and social support [162].

Others pointed to the heterogeneity among interventions and highlighted this as a challenge when summarizing knowledge [163]. However, small to moderate effects were found in a review across 71 trials of self-management education [164]. In addition, results from a meta-synthesis of self-management [165] suggested that recognizing the dynamic process that self-management represents might be valuable for the HCP and the patients. Various aspects of self-management vary in importance over time, and ongoing support might be valuable to meeting these needs [165]. A study on the value of outcome measures used to evaluate studies using self-management interventions was recently carried out; it attempted to determine the value of outcomes for patients, families, HCP, and those who commissioned self-management services [166]. This review summarized that common outcomes included knowledge, skills, bio-psychosocial health, and social support. However, there remained a need for outcomes that directly apply to the everyday lives of the patients. This work is similar to a review by Nolte and Osborne [167], summarizing that the reviewed outcomes might not be sufficient to measure the true impact of self-management. Thus, choosing the appropriate outcome measures to evaluate self-management interventions might have an impact on the findings.

2.4.1 Diabetes self-management

The National Diabetes Advisory Board in the US Department of Health and Human Services and the ADA have carried out the most influential work on diabetes self-management. They were the first to apply the concept of diabetes education to their guidelines beginning in the early 1980s [168]. A decade later, the concept was revised and changed to self-management. In Europe [16,106] and Norway [10], the concept of patient-centeredness has been the most influential position that the most current statements use, and it has been suggested that while patient-centeredness is the overarching principle of health care, self-management might be the strategy needed to succeed. In this thesis, the concept of patient-centered care will not be elaborated on, as self-management is the main concept studied here.

Prior to the first definition of diabetes self-management, extensive work was carried out to investigate the field of diabetes education [168], and the term diabetes self-management education was introduced, defined as “the process of teaching individuals to manage their diabetes” [169,170]. In the year 2000, the revised definition was as follows:

> “*diabetes self-management education (DSME)–An interactive, collaborative, ongoing process involving the person with diabetes and the educator(s). This process includes 1) assessment of the individual’s specific education needs; 2) identification of the individual’s specific diabetes self-management goals; 3) education and behavioral intervention directed toward helping the*

individual achieve identified self-management goals; 4) evaluation of the individual's attainment of identified self-management goals" [171].

Distinct from diabetes self-management education is diabetes self-management support. The 2007 revision of the "US National Standards," added a definition for diabetes self-management support: "activities to assist the individual with diabetes to implement and sustain the ongoing behaviors needed to manage their illness. The type of support provided can include behavioral, educational, psychosocial, or clinical" [172]. The need for diabetes self-management support came about in the work of Tang and colleagues in 2005 [173], where they acknowledged that "to effectively manage diabetes over the long term, we need to create a new generation of diabetes self-management support (DSMS) interventions that reinforce and enhance the self-management gains patients achieve with initial DSME programs." The latest revision in 2012 added self-management support to its title to emphasize the importance of ongoing support in long-term self-management; it also changed the definition to clarify the need for ongoing support when the individual is outside of formal programs of care [11].

The current "US National Standards for diabetes self-management education and support" [11] are in line with the updated recommendations of the "Standards of Medical Care in Diabetes" [17] and the latest "Position Statement for Diabetes Self-Management Education and Support [174]; a joint statement published by the American Diabetes Association (ADA), the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. There is now widespread consensus that in order to ensure continuous diabetes self-management, persons with diabetes need education to increase their knowledge and skills, so that the continuous diabetes self-management support can ensure long-term commitment.

To address the need for support, research should include psychosocial and behavioral measures that are patient-reported [175]. Currently, researchers are investigating the value of PROs integrated in the Norwegian NOKLUS diabetes register [176], similar to a Swedish working group undertaking research to investigate which areas that are most valuable to the patients, aiming to include PROs in their diabetes register [177]. This will ensure a systematic approach to the assessment of psychosocial and behavioral measures in a real-life setting. The main themes the identified through qualitative interviews with the Swedish patients were living a good life with diabetes, accounting for how diabetes affected their lives, and getting support from a diabetes care team [177].

2.4.2 Interventions for diabetes self-management

Research regarding diabetes self-management and support is well establish compared to other less complex diseases, and as a consequence, several reviews summarizing the evidence have been

conducted. The complexity within diabetes self-management is reflected in the research through the complexity of the conducted studies. Further, complex primary studies can be difficult to summarize as they often represent heterogeneity in their methods, intervention, and settings; however, the body of evidence is large enough that it has still contributed valuable information to the field.

Several systematic reviews support the effectiveness of self-management interventions, reporting improvements in HbA1c [13,15,38,163,178]. Although several reviews were conducted in the early 2000s, their results still have value due to their comprehensive reviews. In 2001, Norris [38] assessed 72 trials and found a significant decrease in HbA1c in the short term. The authors suggested that interventions with patient collaboration and involvement might be favorable. A meta-analysis from 2002 investigating glycemic control in 31 papers concluded that for every 23.6 hours of HCP contact, there was a significant predictor of a 1% effect on HbA1c among persons with type 2 diabetes enrolled in self-management interventions of various modes [178]. However, the interventions did not have sustained effects longer than a maximum of three months after the intervention ceased. On the contrary, a review by Newman [163] in 2004 found a similar effect on HbA1c, although the author found sustained effects beyond six-month follow-ups. To summarize, these early reviews were consistent in reporting a favorable decrease in HbA1c among the participants in the intervention groups; however, there were inconsistencies regarding the sustainability of the effects.

These reviews included studies with several modes of delivery—group meetings, individual meetings, phone calls, and combinations of modes. The work by Norris and colleagues reported uncertainty regarding group versus individual interventions, as the authors found mixed results from both modes of delivery [38]. These findings were confirmed a year later in a meta-analysis by the same authors testing the effects of self-management education [178]. Significant improvements in HbA1c were reported; however, there were no differences related to the intervention being individual or group-based, suggesting the positive contribution of both. One strength of the Cochrane review by Deakin and colleagues [12] was their narrow focus on only group-based interventions. Their results suggested that self-management interventions reduced HbA1c at short, mid- and long-term follow up and decreased fasting blood glucose, systolic blood pressure, need for medication, and weight; the interventions increased diabetes-related knowledge. A similar Cochrane review investigated only individual self-management interventions; however, it was unable to prove the same effects in outcomes, reporting that individual interventions had an effect on HbA1c only in those with baseline HbA1c>8% [179]. Further, the study confirmed the equal effects of individual- and group-based interventions [179].

A more recent review was a follow-up of the Cochrane review by Deakin and colleagues—conducted by Steinsbekk and colleagues [14]—they specifically included interventions using a group-based mode for persons with type 2 diabetes. They confirmed the initial findings of Deakin and colleagues [12], concluding with improvements in glycemic control at 6, 12, and 18 months as well as improved diabetes knowledge, self-efficacy and self-management skills. Similarly, both Heinrich [13] and Sherifali [15] conducted reviews on interventions for type 2 diabetes self-management—although they included different modes of interventions in their reviews, both found a decrease in HbA1c. Heinrich [13] specifically suggested multi-component interventions over single-component interventions, citing stronger evidence for their effects on a healthy diet and improved quality of life. Sherifali and colleagues [15] emphasized the importance of longer, compared to shorter, interventions. A 2010 meta-analysis of psychosocial interventions investigated their effect on HbA1c and mental health and found only modest effects but no association between the two [180]. Further, a systematic review summarizing evidence regarding interventions for HRQL found several effective interventions; however, the magnitude of the effects varied, and there was uncertainty regarding the mechanisms driving the change in HRQL [79].

Evidence on the effects of self-management interventions on outcomes related to behavior and lifestyle, dietary habits, physical activity, smoking, and alcohol consumption varies. Often, lifestyle outcomes are less standardized and are more difficult to synthesize, and it seems that diabetes knowledge is recognized as a lifestyle measure [12], making self-reported dietary habits and physical activity less attractive. On the contrary, Heinrich [13] found that measures of dietary and physical activity habits were by far the most reported. Positive effects on diet were found in 8 out of 10 studies of both individual and group-based modes, whereas only 5 out of 10 reported improvements in physical activity. Norris investigated self-reported dietary habits in 2001 and found a positive short-term effect among the reviewed studies [38].

Self-management interventions are also suggested to improve HRQL; however, the moderators of these effects remain unknown because few studies have been carried out [181]. Improved diabetes-specific quality of life was found after a two-year RCT self-management intervention, with sustained effects at the one-year follow-up after the intervention end [182]. The effects of this diabetes self-management support intervention included improvements in HbA1c and serum cholesterol, having a more healthy diet, and taking medication as prescribed. This trial was unique in its long intervention period and in the sustained effects present after one year with no intervention [182]. A more recent and shorter (four month intervention) RCT from 2016 performed a telephonic behavior change intervention in couples and in individuals and compared these with an educational intervention in

poorly controlled type 2 diabetes. It found that the couples showed a favorable improvement in HbA1c in all groups, with additional effects on BMI and psychosocial outcomes for the couples [183].

Health counseling and health coaching are often used interchangeably, and they may take various forms. Common to both are their aim to continue the education and support of persons with chronic conditions in their self-management [15,162]. The value emphasized is that the intervention can be delivered so that patients do not necessarily have to meet at the HCP office. Within diabetes, earlier research suggests the convenience and the efficacy of using telephone calls to provide health counseling aiming for self-management support and education [184-186]. The efficacy of health counselling was recently summarized in a review [15]; the authors found greater effects from health counseling when it was combined with existing diabetes care. The methods they evaluated included face-to-face meetings, telephone calls, web chats, and combinations of these. They specifically found a decrease in HbA1c in favor of the intervention, and follow-ups longer than six months had an additional effect. These findings are consistent with a previous review by Whittermore [187] investigating nurse coaching that affected quality of life and improved fasting blood glucose. The authors established that the primary strategies used to facilitate lifestyle change among the reviewed nurse interventions were educational reinforcement, psychosocial support, and motivational guidance. Research conducted among persons with type 2 diabetes in Norway suggested that HCP should balance their health counselling between empathic, confronting and non-confronting approaches to increase self-management and provide tailored ongoing support to stimulate complex self-management [188]. Polonsky and Fisher [189] argued that the feedback provided to support these patients must be tailored, accounting for individual characteristics and targets—overall, different strategies were effective for different persons. Thus, continued diabetes self-management support for more than six months might be valuable to patients with diabetes.

Regardless of the effectiveness of diabetes self-management education and support, research has concluded that the number of persons initiated in these programs is alarmingly low, partly due to geographic, cultural, language, and knowledge barriers [87]. One possible way to reduce these barriers is technology, as it may make diabetes self-management education and support available for more persons through apps in smartphones.

2.4.3 Technology to support diabetes self-management

Health technology can increase access to care and support the self-management of chronic diseases [25]. Several concepts within technology have been applied throughout the work with the current project, as the field has changed rapidly. mHealth is the applied concept for the current thesis; however, it was not applied in the field when the current project was initiated. The suggested

definition of mHealth is "*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices*" [24]. As such, the concepts of eHealth, telehealth, telecare and telemedicine all relate to mHealth (Figure 1), as mHealth can be electronic (eHealth), healthcare delivered over a distance (telehealth), curative (telemedicine), and deliver person-centered care (telecare) [190].

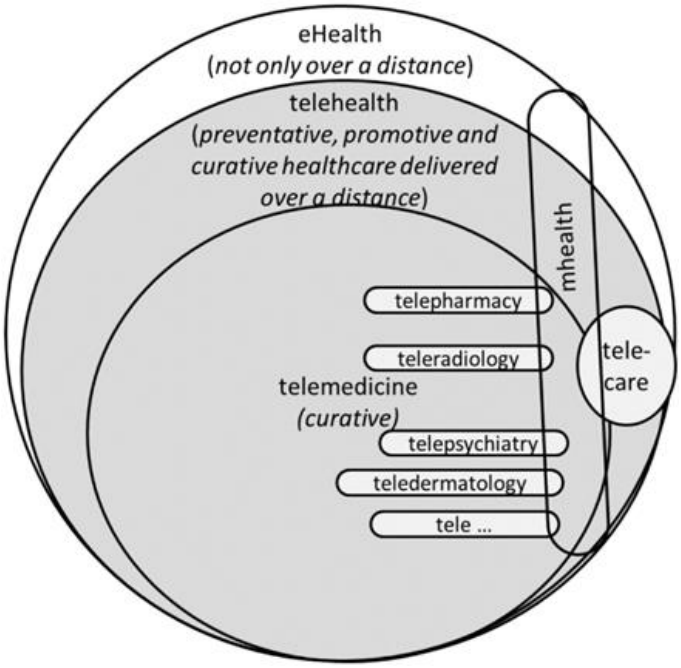

Figure 1. Telemedicine, eHealth, telehealth, telecare, and mHealth [190].

As mHealth has expanded, it has become a distinct area for research, enabled by cellphones and the internet. It has revolutionized global interconnectedness, with contributions from smartphones, defined as cellphones that can access the internet and apps [191]. Due to technological development, mobile phones and similar ubiquitous technology are more widespread than in the beginning of this decade. Numbers from 2015 show that the global median of adults owning a smartphone is 43%, while in Europe, the median is 60 %, and in the US, the median is 72 % [191]. Norway is not included in these numbers; however, numbers from the first quarter of 2016 indicated that 81 % of adults in Norway had a smartphone [192]. Owning a smartphone gives one access to a variety of possibilities regarding health tracking, communication, and information, all of which are valuable when managing a chronic condition. In 2013, research reported diabetes to be the most common condition targeted by apps in commercial stores, followed by depression and asthma [193].

The range of possibilities within a smartphone app is almost unlimited. Functions can include tracking blood glucose, weight, blood pressure, physical activity, diet, and medication/insulin; goal setting; alerts and reminders; functions to analyze and graphically visualize data; education/information; data export and communication; integration with social media or other relevant apps; and

synchronization with health records—the number of functions within an app varies [23,26]. Some apps allow for the exchange of data with peers, family, their HCP, their electronic health records, or the healthcare system, which aims at facilitating support. Behavioral, contextual, and real-time data combined with predictive analytics, engagement, and feedback may be effective in the self-discovery of some essentials of self-management [194]. Challenges with technology remain related to how to get people started with technology, how to keep them going, further understanding who the users are, and examining what engages them [22]. Moreover, dropout rates tend to be high in technological interventions [195].

Health services and researchers have embraced the area of mHealth, and a great deal of knowledge has been produced contrary to the fact that mHealth was only recently conceptualized. However, although the numbers of available apps are high, few commercially available apps have been evaluated in controlled trials [196]. Further, when searching for medical apps in app stores, there are few search limitation rules to narrow the search, making it overwhelming for both patients and clinicians to choose an appropriate app [22]. For many clinicians, formal approval of the apps they recommend is valuable, as there might be some safety issues related to the apps. For instance, patients might experience hypoglycemia if they start exercising without reducing their medication or if they change their diet following recommendations from an app. The rapid evolution of medical apps has challenged systems to validate and ensure security and privacy of the collected data of such technology [197]. The US Food and Drug Administration (FDA) regulates and approves medical technical equipment; however, with limited resources, the FDA regard most apps as “low-risk” and focuses instead on its work with more “high-risk” devices, such as the closed-loop systems where insulin is delivered automatically based on continuous glucose measures. Currently, a voluntary register where app developers can register their apps and adverse events, and where clinicians can seek guidance, is available [198]. Further, mobile apps do not require privacy regulation through the US Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which makes it difficult to ensure the privacy of health data and creates the risk of hacking. A third regulation is the Conformité Européene (CE)-mark, which ensures health, environment, and safety, but this is currently based on self-control instead of formal approval. Thus, there is a lack of official regulation of apps ensuring their quality, and there are no guarantees regarding the effects and accuracy of mobile apps [197].

As the first step in the RENEWING HEALTH project, a systematic review of reviews was conducted to establish the current evidence regarding the impacts and costs of telemedicine at the time [199]. The results guided the design and conduction of several telemedicine interventions throughout the nine project countries. Ekeland and colleagues [199] found conflicting results among the 80 included

reviews, where 21 reviews concluded that telemedicine was effective, 18 found that evidence was promising but incomplete, and the remaining studies showed limited and inconsistent evidence. They pointed to the fact that larger and more rigorous studies were needed to develop this field, that the economic questions were especially difficult to answer, and that acknowledging the complex nature of telemedicine interventions would be fruitful [199]. Moreover, this review of reviews had a significant role in informing the development of MAST.

The preceding research in the field involved home telehealth, tele-monitoring, telephone support, web-interventions, mobile interventions using SMS or phone calls, and various combinations of the mentioned interventions. Several reviews have made efforts to summarize this knowledge; however, the heterogeneity in the field affects the reviews, and it is difficult to provide evidence of effects on relevant outcomes [22]. One concern among the reviews is the inclusion of several interventions, aiming for a homogenous comparison of interventions and trials that might not be comparable. Some examples of previous research include a systematic review of persons with type 1 and type 2 diabetes that investigated the effects of using videophone, tele monitoring, messages, voice recorder, phone calls, modem transmission of data, websites, and text messages as valid interventions in its review on glycemic control and HRQL [200]. Others have studied glycemic control and adherence in type 2 diabetes using telephone calls, video messages, and automated telephone disease management [201], while another paper investigated metabolic improvement in both type 1 and type 2 diabetes looking at interventions with web-based tele monitoring, videoconferencing, feedback letters, phone calls, and SMS [202]. Also studying both type 1 and type 2 diabetes, Marcolino and colleagues [203] included monitoring, videoconferencing, educational websites, reminders, email, messages, phone calls, SMS, and discussion with peers to investigate the effects on HbA1c, BP, BMI, and LDL cholesterol. Clinical effectiveness and cost-effectiveness in type 2 diabetes were investigated including interventions using telephone, SMS, videoconferencing, websites, and transmissions and recommendations delivered over the internet [204]. As described, various designs, outcomes, participants, and combinations of interventions contributed to the uncertain evidence drawn from these reviews, although there was a general optimism in the papers. A literature review from 2009 studying isolated telephone interventions was not able to find evidence to support telephone interventions to improve glycemic control in type 2 diabetes because of the poorly designed studies it evaluated [205], reflecting the same problems with methodological quality as the more heterogeneous reviews. A lack of theoretical base in several interventions is also concerning [21,22,206]. When discussing barriers such as health literacy [207] and security and accuracy of data tracking [197], it becomes clear that although eHealth constitutes promising findings, it might not be beneficial for all [206].

2.4.4 Mobile apps for diabetes self-management

When investigating mobile apps in diabetes self-management interventions in smartphones, the majority of the current evidence is characterized by two types of reviews: 1) reviews investigating the availability and the content of the mobile apps [23,26,27,208], and 2) reviews investigating the effects of the apps on relevant outcomes [20,28,29,31,37,209]. Reviews of apps often combine other interventions such as SMS, email, or web solutions, making it difficult to isolate the contribution of the apps. The apps investigated in the primary research represented in these types of reviews can also be divided into two groups: the apps investigated in effect reviews are found in research labs, while the content and availability reviews investigate commercially available apps. A few apps are both commercially available and have been subject to controlled trials, such as WellDoc's Bluestar [210] and GlucoseBuddy [211].

One current review of reviews [22] investigated the reviews describing the content and availability of the apps, as well as the reviewed outcomes and effects of the apps in diabetes self-management. However, a lack of reviews that summarized the outcome data of apps specifically hindered their work and reflected the inconsistency present in the research field. When they summarized other review findings on the content and availability of apps, they highlighted the lack of educational and personalized feedback in apps, which several of their included reviews had pointed out. Glucose monitoring remained the number one feature in almost all apps for diabetes; however, there was a great variability in functions, which the authors discussed with some ambivalence. Either the field is specialized, offering apps with few and specialized functions, or it is more general, with several functions in one app. It might be difficult to identify who needs what [22].

Although the review of reviews [22] summarizes the field in a straightforwardly matter, other reviews contribute with valuable knowledge. Reviews investigating the effects of apps included primary studies investigating interventions with several components, making the isolated contribution of apps still somewhat uncertain. Aspects regarding personal interest, health literacy, and skills add to this uncertainty. A review assessing mHealth interventions with apps in controlled trials where some had other contacts in addition to the app found that 7 out of 10 interventions had significant effect on HbA1c, with a mean reduction of 0.83% [20]. Two quite similar reviews of RCTs from 2016 [28,209] assessed six of the same trials. Although Cui [209] assessed apps only for type 2 diabetes in 13 interventions, and Hou [28] assessed both type 1 and type 2 diabetes in 14 app interventions, they produced the same average effect of -0.4% on HbA1c in their meta-analyses. A review assessing apps for the three chronic conditions of diabetes, CVD, and chronic lung disease found that apps for diabetes were more frequent (5 of 9), and they found a significant effect of the apps overall in 5 of the 9 interventions it investigated [37]. All of the reviews concluded with a

modest but uncertain effect due to the variable quality of the primary studies, and they all called for further research in this rapidly increasing area that with no doubt will be important in future healthcare.

Qualitative studies add to the valuable knowledge in the field. A Canadian study interviewing participants after 6six months of using an app described how the app might enable change, improve relationships with a provider, and both the pros and cons of using and interacting with an app [212]. Further, time since diagnosis might have important implications for patients' needs, which is reflected in how they use technology [213]. This supports an earlier discussion of the dynamic use of apps, suggesting that apps might be useful for individual use, shared use with HCP, and use in the short or long term [214]. Recognizing the dynamic use of technology is important in evaluation research since it has implications for how the findings should be interpreted. Often, research reports a declined use of apps throughout the course of the study; however, this might relate to the patients' perception of less need for support more than a lack of interest or a low quality of the apps being tested. Current research methods might not be good enough to recognize intermittent use in a controlled manner, for instance using a traditional RCT [48]. Findings supporting the dynamic aspect of use were presented in a theory-driven qualitative interview study with 22 persons using health apps [215]. A major finding was the frequent use of an app before reaching a milestone, such as a goal of increased exercise, and decreased use thereafter. Aspects that could boost engagement with the app are its design and functionality, usability, and how the imputed data are handled [215]. The principal findings of a study investigating attitudes among young adults highlighted the importance of the app's trustworthiness through its accuracy and legitimacy, if participants' data were handled in a secure matter, effort required by the app to have some form of effect, and the app's immediate effects on, for instance, mood [216]. Data tracking and goal setting were also valued as well as getting information or advice in a real-time context. The participants did not have faith in the app's accuracy in sensing their mood, and further, connection to social media was considered unnecessary and embarrassing, contrary to other discussions in the field where social media was highly valued [22,23,213].

As part of the Norwegian Study in RENEWING HEALTH, qualitative interviews were conducted and reported by other member of the research team to inform and understand behavior change and use of the diabetes diary mobile app. Their principal aims were to obtain an in-depth understanding of users' acceptability of a mobile app for diabetes self-management and their communication with health care personnel concerning the app [51], and to use grounded theory to develop new theory about living with diabetes and behavior change [50].

3 Material and methods

3.1 A complex intervention

According to the Medical Research Council (MRC) complex interventions framework [217,218], a project's complexity may be present in its discovery, evaluation, or implementation. Further, being complex is characterized by more than one component in one or more of these phases, and modern healthcare is nothing but complex. The MRC complex interventions framework was developed to ensure research leading to thoroughly studied interventions. The process is described as circular, as there are possibilities to go back and forth, jump stages, and then return, and all of the phases in the framework are connected (Figure 2). The complexity might be present in all phases; thus, a multi-method process is required, as well as the need for different theories to inform the specific phases.

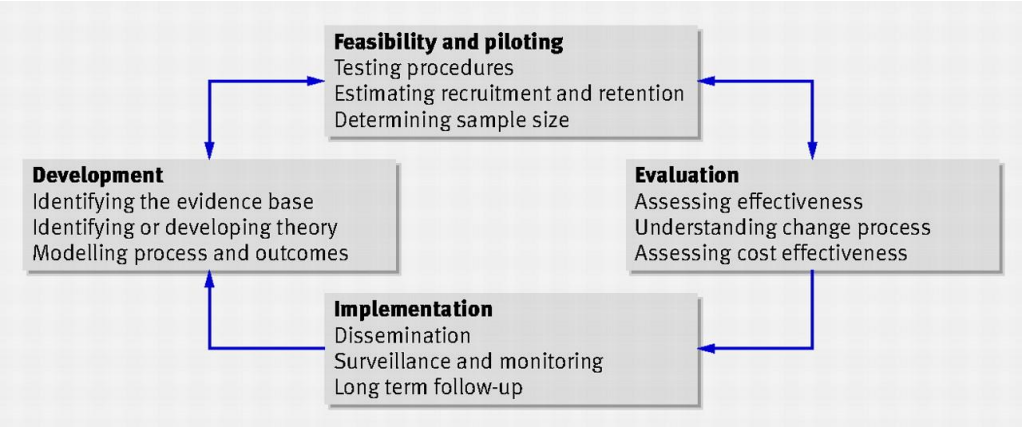

Figure 2. The MRC complex interventions framework [217]

The Norwegian study in RENEWING HEALTH is regarded as a complex intervention, and a multi-method process has been carried out. The Norwegian Study included a mobile app called the Few Touch Application (FTA), which was developed and feasibility tested through the work of Årsand during his doctoral project, disseminated in 2009 [219,220]. A health counseling intervention was developed through several phases, and the process and outcomes were outlined [47] before the Norwegian RCT pilot was carried out. The data from the RCT informed several papers, including the 12 month follow-up paper [44] and the baseline paper [45] within this thesis, but also the 4 month follow up [48], work to explore acceptability of the app [49,51], and qualitative work to identify and develop theories about living with diabetes [50]. Lastly, the results of the RCT informed a need for a renewed evidence base together with our qualitative findings and others' research, all leading to the systematic review [46] within the current thesis. Thus, the aim of the study was addressed using different designs.

The evaluation in the current project followed the Health Technology Assessment (HTA) approach according to MAST [35] and included both process- and effects evaluations. Within the EU, work began in 2009 to develop a framework for the evaluation of telemedicine tools in terms of their effects and the health service quality of the telemedicine contributions. Initially, and to inform RENEWING HEALTH, a systematic review of reviews was conducted [199] alongside stakeholder workshops within RENEWING HEALTH which led to the development of MAST [35], the framework that guided the overall evaluation of the EU project. MAST includes preceding considerations of whether the intervention is ready for an evaluation, before the multidisciplinary assessment evaluates seven domains: 1) health problem and characteristics of the application, 2) safety, 3) clinical effectiveness, 4) patient perspectives, 5) economy, 6) organizational aspects, and 7) sociocultural, ethical, and legal aspects, before a transferability assessment providing knowledge regarding the relevance cross-border, the scalability, and the generalizability [35]. For RENEWING HEALTH, the MAST domains are published in a final protocol on behalf of all the study sites, including the Norwegian study [43]. The implementation of the RENEWING HEALTH telemedicine devices in healthcare services has later been adapted in routine care in the project United4Health, with some of the most mature applications from RENEWING HEALTH tested in large scale (not the FTA). Thus, according to MAST, the current thesis will elaborate upon the health problem and characteristics of both the participants and of the application, the clinical effectiveness of the intervention, and safety and ethical issues.

3.2 The Norwegian study in RENEWING HEALTH (Paper I and II)

3.2.1 Design (Paper I and II)

The Norwegian study in RENEWING HEALTH was a three-armed RCT for persons with type 2 diabetes (Figure 3). The aim was to examine the post-intervention effect of a 12-month intervention involving a diabetes diary app in a smartphone with or without four-month health counselling by a diabetes specialist nurse (Paper I). We used a longitudinal design with three assessment points: at baseline, and after 4 and 12 months. This evaluation followed the MAST framework [35], the trial was registered at clinicaltrials.gov, and the protocol was published [47]. Further, baseline data from the RCT sample were analyzed as one cross-sectional sample (N = 151) to assess the participants' initial stage of change in physical activity and dietary habits and the associations between stages of change for each behavior and individual characteristics, HRQL, self-management, depressive symptoms, and lifestyle (Paper II). Thus, Paper I and II reported on the same sample of persons with type 2 diabetes.

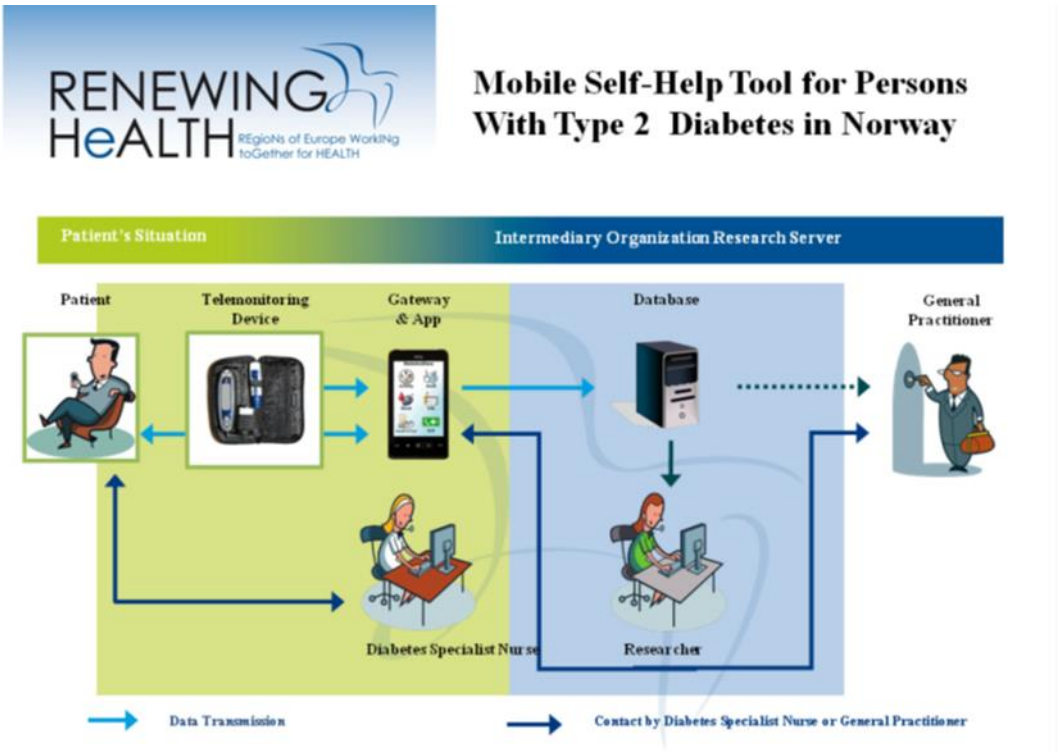

Figure 3. The RCT study process

3.2.2 Participants (Paper I and II)

This sample comprised individuals with type 2 diabetes. The inclusion criteria for the study was as follows:

- Type 2 diabetes diagnosed for over three months prior to the start of the study
- HbA1c ≥7.1%
- Aged ≥18 years
- Being able to fulfill an intervention in Norwegian and fill in questionnaires in Norwegian
- Not having any conflicting mental disorders or dementia

Recruitment was initially patients treated by their GPs in municipalities in southern and northern Norway. The research team contacted the GP offices by phone, giving information about the study and requesting their permission to send them more information. Initially, we approached larger offices to decrease the number of offices and GPs involved, but as the number of eligible participants was lower than we first assumed, we also approached several smaller offices. After a television report regarding the study, several eligible participants contacted the study team. In the spring of 2012, we sent out information regarding the study to members of the Norwegian Diabetes Association, inviting them to an open meeting that provided further information and the possibility to participate if eligible. Patients were also recruited through a specialist healthcare center, where

patients with newly diagnosed diabetes attending courses received information regarding the trial and the possibility to contact the researchers for further information if they were interested. Thus, participants were recruited through their GP (57%), an initial TV-report regarding the project (9%), through the Norwegian Diabetes Association (11%), through the healthy life center's (17%), and from courses at a specialist healthcare center for the newly diagnosed (7%). All of the participants were living in their homes and were treated by their GPs. The recruitment period lasted from March 2011-October 2012, and the last follow-up was completed in October 2013. Several patients with type 2 diabetes approached us with their interest to participate, in good faith believing that their HbA1c was at 7.1% or well above. However, when measuring their HbA1c at the point of inclusion, we had to reject some before inclusion and discontinue other participants with similar test results that were already included in the trial (n=12).

3.2.3 Procedures (Paper I and II)

Eligible patients attended a start-up meeting for thorough information regarding the study and its obligations, as well as their legal rights as participants. Those who consented to participate (Appendix I) filled their self-reported baseline questionnaires before they were randomized. For the follow-ups, the research team contacted the participants prior to the test-point to ask whether a mail survey or a meeting would be most convenient. If they wanted the mail survey, they were also provided with a prepaid envelope to return the questionnaire. If they wanted a meeting, we agreed upon a date and time. Regarding the study journals for the clinical variables that needed to be filled out by their GPs, both the patients and the GPs received them either by mail together with a prepaid return envelope, or at meetings where they were provided to the participants. Ideally, their HbA1c value was taken within a timespan from 14 days before to 14 days after the date of the questionnaire answers [47]. A phone call reminder followed unanswered requests after approximately 14 days, and additional questionnaires and/or study journals with prepaid envelopes where mailed to the participant. All data were marked with participant initials and birth year for identification instead of their randomized ID number to ensure that the data were collected for the right participant and to ensure that only the researchers knew their randomized ID number. The study team kept the connection between the IDs and the participants in a locked safe for research material at HIOA.

3.2.4 Interventions (Paper I)

The RCT comprised three groups: one control group and two intervention groups (Table 2). Using three groups allowed a comparison of standard care with the FTA only and the FTA plus health counseling (FTA-HC), as well as a comparison between the two latter groups. Further, we could investigate whether a low-intensity intervention with an app as a self-management support tool might be effective, or if additional health counselling would be required. All three groups received

standard care by their GPs, as recommended by the "Norwegian Clinical Guidelines for Diabetes" [9,10]. The intervention was developed in collaboration with members from the Norwegian Centre for Integrated Care and Telemedicine (now the Norwegian Centre for eHealth Research) and HIOA. The two main components of the intervention were the mobile app developed by Årsand and colleagues and the health counselling modules developed by a multidisciplinary team from the Faculty of Health Sciences at HIOA together with a diabetes specialist nurse from Akershus University Hospital. One intervention group was provided with an HTC smartphone with the FTA installed (FTA) and one group received the smartphone with the app and telephone health counselling for the first four months (FTA-HC).

Table 2. The intervention groups

Control group	FTA group	FTA-HC group
		Health counselling for 4 months
	FTA for 12 months	FTA for 12 months
Standard care based on clinical guidelines	Standard care based on clinical guidelines	Standard care based on clinical guidelines

The control group

The participants randomized to the control group received standard care by their GP as recommended by the "Norwegian Clinical Guidelines for Diabetes" from 2009 [9]. This comprised at least two visits with HCP per year (2-6). Of these two visits, one thorough consultation should be performed with evaluation of glycemic control (HbA1c), metabolic status (blood pressure, weight, and lipids), and lifestyle status (smoking, current level of physical activity, dietary habits).

The Few Touch Application group

The FTA was a digital diabetes-diary self-help tool for people with type 2 diabetes, and an app in a smartphone (Figure 4a). The app was developed as part of a PhD project [219] in close contact with patients with both type 1 and type 2 diabetes who used various versions of the app for various periods of time [220]. The participants then gave feedback to the developers, who changed the app based on this feedback and provided an updated system for the participants to evaluate. This process went on until the version of the FTA used in the current thesis was developed, presenting a user-friendly and practical app for diabetes self-management. It consisted of five easy-access tools: physical activity registration, a blood glucose data management system, food habit registration, personal aims, and general information (Figure 4a).

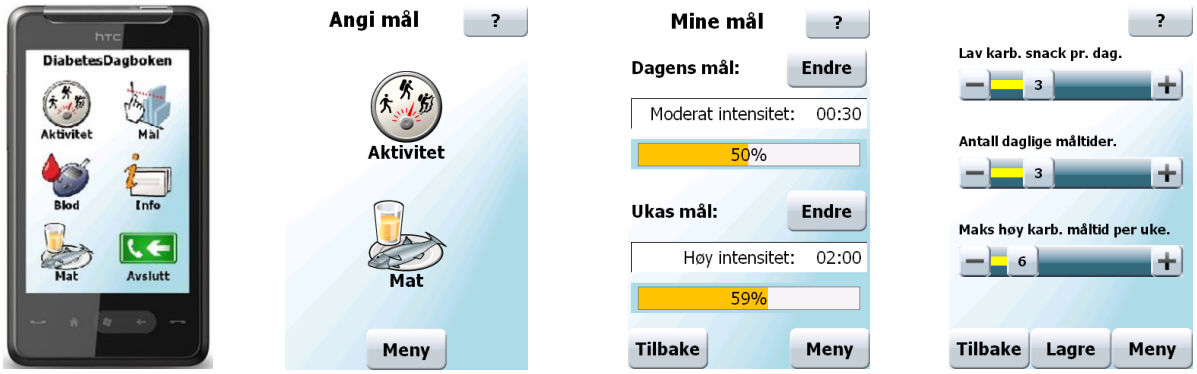

Figure 4. a) FTA display, b) goalsetting, c) activity goals, and d) dietary goals. Photo: E. Årsand

The participants were encouraged to set their own goals for level of physical activity and amount of healthy servings of food and drink (Figure 4b-d). However, the responsibility lay with the participants to both identify their areas for improvement and set goals. Regarding physical activity, their goals were set for how many minutes of activity and whether the activity should be low, medium, or high intensity. Further, the same alternative existed for weekly goals. When the participants registered their activity, yellow fields indicated how much activity they did and what percent of their goals they had reached. When they completed a goal, they were given a smiley face. Setting goals regarding dietary intake consisted of servings per day of healthy snacks (e.g., five per day), meals per day, and the maximum limit of unhealthy meals per week. Dietary goals were summarized numerically, with one line for how many healthy snacks were recorded, and the next line displaying how many healthy snacks were defined through their goals. Again, every time they completed a goal, they received a smiley face.

The display of physical activity registration comprised a stopwatch for manual use to measure activity in hours, minutes, and seconds (Figure 5a-c). Further, the participants entered their level of intensity as either high (red), moderate (yellow), or low (green) intensity. Each color code was used to display the results graphically, with one column for each level of intensity, and the height of the column indicating length in minutes. The participants could start the stopwatch when they began an activity, or they could enter the duration of their activity when they were finished. Their level of activity was displayed for the last week, the last two weeks, and the last months, indicated through colored graphs and minutes.

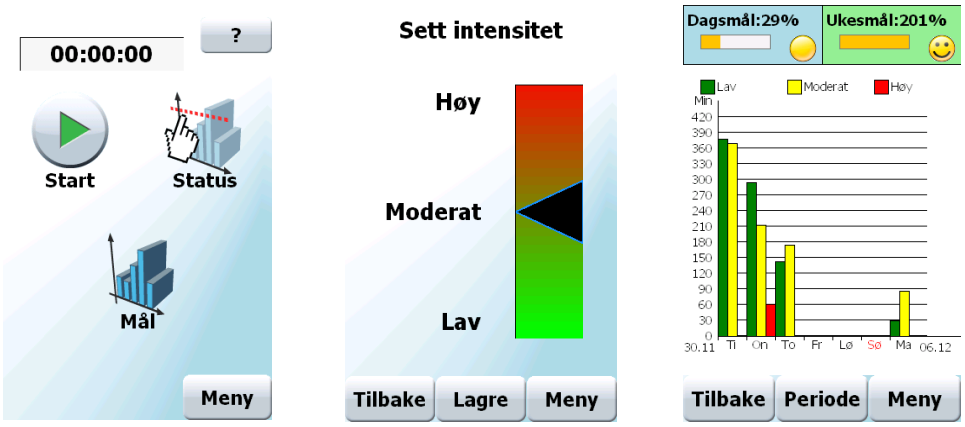

Figure 5. a) activity registration, b) intensity score, c) activity graph and goals. Photo: E. Årsand

Registrations of dietary habits were performed through monitoring three categories: snacks, meals, and beverages (Figure 6a-b). The participants would either consecutively, or at the end of the day, register the number of servings within each category. The snack category could be for the registration of small meals, between-meal snacks, or the "five-a-day"—whereas the meals category was intended for bigger meals such as breakfast, lunch, and dinner. Drinks comprised sugar-sweetened beverages or similar drinks. Dietary registrations were numerically summarized and the number of servings within each category was displayed horizontally for a specified period, individualized by the participant.

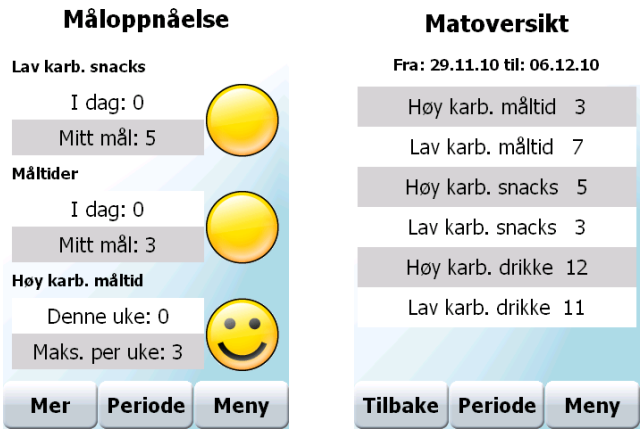

Figure 6. a) dietary registration, b) dietary summary. Photo: E. Årsand

Blood glucose measures were performed with the Lifescan OneTouch® UltraEasy® blood glucose meter, which sent the blood glucose value to the FTA via Polymap Wireless Bluetooth®. The latest measures automatically appeared on the screen, displaying the date and time of the measure, the actual value, and a color code for the blood glucose presented (red for low, green for normal, and yellow for high) (Figure 7a-b). Measures were displayed using mmol/l, which is the standard in Norway. Further, the measures could be displayed graphically. The last 50 measures were displayed

on the y-axis, and the time was displayed on the x-axis. Further, the y-axis was color-coded, and the measures were a black dot in a red, green or a yellow field. The red field was for measures <4 mmol/l, green area for measures ranging from 4-10 mmol/l, and the yellow field for measures >10 mmol/l. The developers used the treatment guidelines for diabetes when defining these ranges. The graph automatically displayed the last 50 measures, but the participants could easily tailor the time range to fit their preferences.

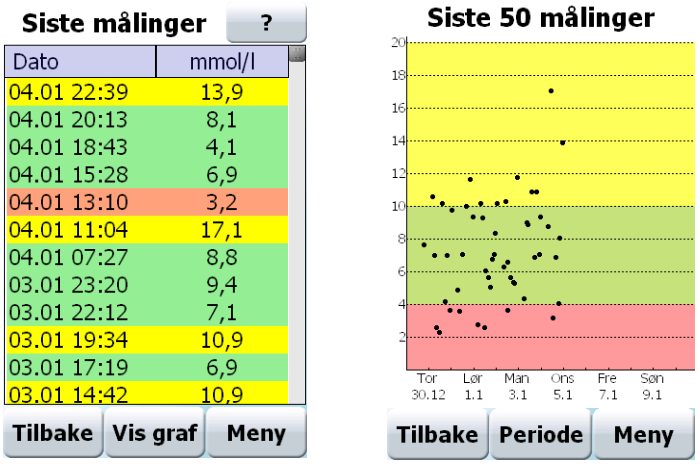

Figure 7. a) List of last blood glucose measures, b) graphical presentation. Photo: E. Årsand

The general information consisted of two parts. The first was an encyclopedia with diabetes-related information such as medication, concepts, etc., with references for further readings. The second part consisted of short tips for actions to increase diabetes self-management, such as appropriate dietary choices. These were both updated from the previous versions of the FTA to the current version tested in this study.

The Few Touch Application and health counseling group

Participants randomized to FTA-HC received the smartphone with FTA as previously described, in addition they received health counseling by a diabetes specialist nurse for the initial 4 months. Through multidisciplinary work, the health counseling intervention was developed involving scholars in the field of nursing, diabetes specialist nursing, and clinical nutrition. Further, in the initial phase of the counseling intervention, the study team received guidance from a psychologist. The primary aim was to improve diabetes self-management with support of the FTA through telephone health counselling sessions. The theoretical framework for the intervention was based on principles from cognitive behavioral therapy (CBT) [129], self-efficacy [131], and the TTM [130]. Moreover, a CBT manual for problem solving inspired the five modules [221]. Lastly, MI was applied as the primary counseling strategy used in the telephone sessions [151].

The development of the health counseling was guided by the effects of CBT on diabetes self-management [222,223]. When addressing and changing the automatic negative thoughts regarding ourselves, others, and the future long-term changes are made, and the patients achieve more realistic thoughts. Building on the CBT, we used the concept of MI to operationalize the intervention [151], and MI has previously been applied in telephone interventions with positive results [224]. Through conversations with the patients, relevant health questions were addressed, and the diabetes specialist nurse established a collaborative relationship with the patients where they described their own resources and willingness to change. Further, the diabetes specialist nurse praised the autonomy of the patients. Throughout the MI conversation, listening to and empowering the patients was important as well as not correcting their chosen changes [151]. In the current intervention, the goal was to establish change in diabetes self-management through the app and additional health counseling [47]. The diabetes specialist nurse was previously trained in MI techniques and applied the theory to practical tasks through study curricula for diabetes specialist nurses.

Lastly, the TTM [130] acted as support for the diabetes specialist nurse when providing the intervention. It has previously been suggested that the TTM and MI work especially well together, although they have separate origins [152]. Specifically, MI is used with stages of change to guide the participants toward their change and their ambivalence regarding change. When targeting this ambivalence, there is an increased possibility for the participants to move up the stages of change [152]. In the health counseling intervention, the participants' stages of change were assessed during the telephone contact, allowing the diabetes specialist nurse to clarify their stages of change, and accordingly, the intensity of the intervention (Table 3). For each session, the nurse would assess each behavior according to the stages of change if they became a topic of conversation. Thus, not all behaviors would be assessed in every session, and some were not relevant for all, like smoking.

Table 3. The note sheet used by the diabetes specialist nurse, assessing stage of change

Stages of change	Medication	SMBG	Physical activity	Dietary habits	Smoking	Use of the FTA
Pre-contemplation						
Contemplation						
Preparation						
Action						
Maintenance						

The health counseling intervention aimed to be low-intensity, providing less support than traditional interventions but making the participants more responsible for their behavior, supported by the FTA. In England, work has been carried out to develop a national program called the "Reach Out" for low-intensity interventions for persons with mental health conditions [221]. Briefly, this program consists

of seven areas for low-intensity intervention: behavioral activation, cognitive restructuring, medication support, exposure therapy, problem solving, managing panic, and sleep hygiene. We adopted the "Reach Out" problem-solving manual comprising five steps described in Table 4 and it was targeted through MI. The problem-solving steps were regarded as relevant for persons with diabetes, and they consented to its use with the MI method, requiring participant engagement in problem solving. The "Reach Out" curriculum has been applied to other chronic conditions with promising results and has mostly been delivered using telephone, in compliance with our study.

Table 4. Areas of behavior targeted by the nurse in a step-by-step process

Motivational interviewing	Notes
Problem-identification	
Possible solutions	
Pros and cons of the chosen solutions	
Choice of solution (choose one, prioritize)	
Plan for implementation (step by step)	

The intervention modules comprised four themes covered in five module phone calls (Table 5). The first week after enrolment, the diabetes specialist nurse called the participants to establish a relationship, provide brief information regarding the intervention, and to answer any questions. If there were problems or questions regarding the mobile app, she would kindly refer the participants to the technical team. There was flexibility regarding the time of day for the phone calls, and each session ended with a new appointment for the next session, where the participants could choose to be called during the day or in the evening.

Table 5. The five modules of the health counselling intervention

Module	Theme	Timing
1	Introduction	1st week following randomization
2	Living with diabetes	1st month
3	Goal setting	2nd month
4*	Diet and physical activity	3rd month
5	Looking back and continuing forward	4th month

* delivered partly by a clinical nutritionist to support the diabetes specialist nurse

In preparation for each module and phone call session, the diabetes specialist nurse sent a secure SMS. The SMS was sent through the system "*Sikker Dialog*" (Secure Dialogue) which was developed in Norway for communication between participants and the diabetes specialist nurse. Thus, the SMS function was not an integrated component of the FTA. The module theme was sent to each participant; however, the participants were encouraged to discuss their needs when the nurse called, and not necessarily to follow the schedule. The secure SMS function was available for two-way communication, if patients needed counseling or had questions throughout the four-month period. However, the SMS function was rarely used, although the participants expressed their interest in it. A

possible reason might be the high level of security the system used, making access somewhat complicated.

Training of intervention-participants

Training of those randomized to the intervention groups occurred at the initial information meeting, with training provided after randomization. The rationale for this procedure was to minimize the time that the participants had to spend at the meeting and to reduce travel time and expenditures, as participants often came from a distance. Both intervention groups were trained in the provided equipment: an HTC HD mini smartphone with the FTA installed, a One Touch® UltraEasy® blood glucose meter paired with Bluetooth® for connection with the app, and user manuals in print and in a USB memory stick. The user manuals comprised both a quick seven-page introduction to the FTA and a much more extensive manual with relevant tips, examples, and information on suggested use of the FTA. All phones used the operating system Windows Mobile 6.5. In addition, MOZO Professional was installed in all of the phones, allowing for distant updates, administration of files, and support [225]. Further, all of the participants tried to measure their blood glucose and transfer this at least once during the meeting under supervision. Those randomized to health counseling received brief information regarding the diabetes specialist nurse, the modules of the intervention, and her phone number. The secure SMS was demonstrated, and all of the participants made at least one successful login attempt under guidance.

The user manuals consisted of troubleshooting procedures for the participants if they encountered any technical issues. In addition, technical support was available via telephone on all weekdays from the study team in Tromsø [225]. If participants were not able to sort out their difficulties alone, a meeting with relevant researchers was arranged to solve these problems. Technical support was recorded thoroughly in relation to each problem, but not to participants' IDs, making it difficult to investigate the magnitude of technical problems. However, 155 support cases were identified by the research team in Tromsø. These regarded troubles with the Bluetooth® pairing, keyboard problems, general user problems, changing the equipment, and other various problems [225]. We do not know however, whether the same patient called several times for the same problem, or if many patients called one time for the same issue.

Compensation

The RCT was an unpaid trial. Participants did not receive any incentives for participation, but the participants received written information before consenting to participate stating that those who completed the 12 months trial could keep the smartphone with the FTA if they wanted, without additional costs ("*Dersom du gjennomfører studien vil du få beholde telefonen*", "If you complete the

study, you will get to keep the phone"). However, this only applied to the intervention groups. They also received written information regarding the possibilities of additional costs related to the data traffic (roaming), estimated at 100-200 NOK for one year.

The GPs who recruited the participants received an honorarium for each participant of 2.500 NOK, or in those cases where several GP's were involved, each GP received 830 NOK for each consultation. The GPs were responsible for filing these claims for reimbursement.

3.2.5 Outcomes (Paper I and II)

The assessment was guided by the MAST framework [35], developed in preparation for the RENEWING HEALTH collaboration project. Further, according to the complex intervention framework [218], we applied measures for a broad evaluation of the intervention at three assessment points. A common dataset provided by RENEWING HEALTH was used [226], complemented by additional variables in the Norwegian pilot study [47]. All self-reported measures can be found in Appendix II in the back of the thesis, but they are only in Norwegian. The Consolidated Standards of Reporting Trials (CONSORT) checklist [227], the CONSORT extension for pragmatic trials [228], and CONSORT eHEALTH [36] were used in the reporting of the RCT. We did not specifically apply the CONSORT PRO extension for reporting of trials using PROs [229]. However, assessing our reporting according to CONSORT PRO revealed a high degree of reporting the items they demanded, such as evidence regarding the reliability and validity of the PRO measures we used [229]. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) informed the reporting of paper II as a cross-sectional sample [230].

Primary outcome

The primary outcome in the RCT was a change in HbA1c between the groups at 12 months. HbA1c was measured mainly at GPs' offices, and within a timeframe of 14 days before and to 14 days after an assessment point [231]. When possible, the HbA1c was measured using the Siemens DCA Vantage®, which the study team used in cases where the participants had difficulties meeting their GP or for their own convenience. HbA1c reflects average glycemia for the last three months, approximately [17]. Further, HbA1c has a strong predictive value of late-complications [232], and it is frequently used as an outcome in studies investigating diabetes.

Secondary outcomes

The secondary outcomes of this trial included self-management, HRQL, depressive symptoms, empowerment, dietary habits, physical activity, stage of change for dietary habits, stage of change for physical activity habits, and demographic and clinical variables (Appendix II). The Norwegian study in RENEWING HEALTH comprised data collection of other variables that are not reported in the

current thesis. Among them were data for cost-effectiveness collected after 4 and 12 months, the Hospital Anxiety and Depression Scale (HADS) measured only at 12 months, usability of the app using the System Usability Scale (SUS) at 4 months, the acceptability of the app using the Service User Technology Acceptability Questionnaire (SUTAQ) after 12 months, and qualitative interviews after 12 months. The measures relevant for the current thesis are thoroughly presented below.

3.2.6 Measures (paper I and II)

The health education impact questionnaire version 2 - heiQ

To evaluate self-management, the heiQ was included by the research team in the Norwegian pilot. The heiQ was included in the current project because it reflects self-management competence, and it evaluates self-management programs [233] like the current intervention. The heiQ v2 comprises 40 items on a 4 point Likert scale from "strongly disagree" (1) to "strongly agree" (4). A total of 4 to 6 items form each of the eight domains, capturing the effectiveness of self-management interventions and health education. The eight domains are positive and active engagement in life, health-directed activity, skill and technique acquisition, constructive attitudes and approaches, self-monitoring and insight, health service navigation, social integration and support, and emotional distress (well-being in version 1). All scales indicate better status with a higher score, except for emotional distress which has a reversed scale. The target group includes persons with chronic conditions, and it is regarded as a generic measure [233]. The heiQ was translated into Norwegian by a different research team prior to inclusion, and the current sample contributed to the validation of heiQ as a Norwegian measure, with a Cronbach's alpha ranging from 0.72-0.90, except for the domain self-monitoring and insight which had a lower Cronbach's alpha at 0.61 [234]. These analyses are based on data that include our sample. Overall, the heiQ is a user-friendly measure that has been adopted in several languages and cultures [235].

Short-Form 36 version 2 – SF-36

For self-report of HRQL, and according to the RENEWING HEALTH dataset [226], we used the SF-36 to measure generic HRQL [98,236]. This measure contains 36 questions summarizing eight conceptual domains. Each domain has scores from 0-100 and comprise physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health [98,236]. Four domains regarding physical functioning form a physical component score and the remaining four domains regarding mental health form the mental component score, and scores typically range from 20-60 [101]. Version 2 has undergone psychometric evaluation, has been translated into several languages, and culturally, has been well received [98]. It is one of the most applied surveys when measuring HRQL, and for people with diabetes, the domains are mostly relevant [101,237]. It has

been translated to and validated in Norwegian [238]. The Cronbach's alpha from our sample at baseline ranged from 0.80-0.97.

Depressive symptoms

The Centre for Epidemiologic Studies depression scale (CES-D) is a tool for measuring depressive symptoms, not for diagnosing depression [239]. This measure contains 20 items scored on a 4-point scale from rarely or none of the time (0) to most or all of the time (3). Total scores range from 0-60, and four items are reversed. A cut off of 16 points or higher has been used extensively [240], including in the current trial. The CES-D was chosen because it quickly assesses the behavioral, cognitive, and affective symptoms of depression, and it has undergone several reliability and validity tests. It also measures sleep disturbance and loss of appetite, which can be important signs of depression and have a major impact on diabetes management. It has been translated into Norwegian from English based on the Swedish version using a professional translation firm, with translation back to English. The CES-D in Norwegian has been used in earlier research projects [241]; unfortunately, there is not a published validation available. The Cronbach's alpha among our sample at baseline, where the CES-D had good internal consistency, alpha = 0.77, although alpha above 0.8 is highly desirable [242].

Table 6. Standardized questionnaires in the questionnaire booklets

Measures	Scales/ Variables	Score	Time	Paper
heiQ			T1, T2 and T3	Paper 1 (T1+T3) and paper 2 (T1)
	Health-directed activities	1-4		
	Positive and active engagement in life	1-4		
	Emotional distress (reversed)	1-4		
	Constructive attitudes and approaches	1-4		
	Self-monitoring and insight	1-4		
	Skill and technique acquisition	1-4		
	Social integration and support	1-4		
	Health service navigation	1-4		
SF-36			T1, T2 and T3	Paper 1 (T1+T3) and paper 2 (T1)
	Physical functioning	0-100		
	Role physical	0-100		
	Bodily pain	0-100		
	General health	0-100		
	Vitality	0-100		
	Social functioning	0-100		
	Role emotional	0-100		
	Mental health	0-100		
	PCS	0-100		
	MCS	0-100		
CES-D			T1, T2 and T3	Paper 1 (T1+T3) and paper 2 (T1)
	Depressive symptoms continuous	0-60		
	Depressive symptoms dichotomous	≥16 symp.		
DES-SF			T1, T2 and T3	Not reported
	Empowerment	8-40		

T1=baseline, T2=after 4 months reported elsewhere, T3=after 12 months.

Physical activity and dietary habits

Measures of physical activity were collected by the questions used in the HUNT 1, 2, and 3 [243,244]. These items included measures of physical activity frequency, duration, and intensity, whether a normal day contained 30 minutes of activity, and how many hours on average were spent sitting still during a day [243]. Combining the frequency, intensity, and duration provided a dichotomized variable of "active" or "inactive" [245], which we used as an overall physical activity variable.

Measures of nutrition and dietary habits were collected by the same questions as those used by the Cancer Registry of Norway in the NORCCAP study, and they involved recommended and traditional food items from a Norwegian diet [246,247]. This included servings of fruits, vegetables, berries, potatoes, poultry, fish, meat, bread, and milk. In compliance with the NORCCAP trial, we merged vegetable, fruit and berry consumption into one variable for mean daily servings of greens [247].

Stage of change in dietary habits and physical activity

To assess each participant's self-reported stage of change toward dietary habits and physical activity, two separate items were formed (Appendix II), based on earlier research regarding dietary stage of change [141,143] and physical activity stage of change [248]. Participants indicated which one of five statements they agreed with most. Each statement regarded one of the stages, ranging from pre-contemplation to maintenance. For analysis purposes, the five stages were dichotomized into two: pre-action, containing the first three stages (pre-contemplation, contemplation, preparation), and action, containing the last two stages (action and maintenance) [143].

Empowerment

To include a measure on diabetes empowerment, the diabetes empowerment scale-short form (DES-SF) [249] was translated into Norwegian and used in this study [250]. The DES-SF is an overall brief assessment of psychosocial self-efficacy in persons with diabetes, with eight items developed using the highest correlated item into a subscale in the eight original domains of the longer version [251]. It contains eight questions with a 5-point Likert scale, ranging from "strongly disagree" (1) to "Strongly Agree" (5). Scoring involves averaging all completed items, giving a possible range from 1-5; a cut off score is not described, but higher scores indicate greater levels of psychosocial efficacy, and the DES-SF has been found to be reliable. Population norms are not available. The DES-SF was translated to Norwegian for the current trial [250]. Our translation included forward and backward translation and interviews with patients; however, a test-retest was not performed as we experienced a ceiling effect after the initial use on the baseline data collection, and regarded this measure as non-applicable friendly in the current form. Despite this, we found a Cronbach alpha at 0.80 in our sample at baseline.

Use of the Few Touch Application

Retrospectively, log data from servers at the Norwegian Centre for Integrated Care and Telemedicine (now the Norwegian Centre for eHealth Research) were used to characterize usage of the app. A dichotomous construct was created: high-frequency users and low-frequency users. To qualify as a high-frequency user, at least 6 of the 12 months had to be as an active user, involving five or more blood glucose measurements during each of these six months, and had 50 or more hits in the parts of the app not meant for data collection, e.g., information.

Use of the health counseling

The diabetes specialist nurse took notes during and after each phone call comprising the number of attempts to call, timing of the call, length, and notes in the note-sheets. These data are summarized in a master's thesis [252] currently in preparation for a paper manuscript to be published.

Sociodemographic variables

The sociodemographic variables (Table 7) were based on the common dataset provided by RENEWING HEALTH [226] and according to MAST [35]. They comprised birth date, gender, marital status, cohabitation, educational level, and employment status prior to the diabetes diagnosis and in the last 12 months.

Table 7. Socio-demographic variables in the questionnaire booklet

Scales/ Variables	Score	Time	Paper
Age	Years	T1	Paper 1 (T1+T3) and paper 2 (T1)
Gender	Female/male	T1	Paper 1 (T1+T3) and paper 2 (T1)
Education	<12 years 12 years >12 years	T1	Paper 1 (T1+T3) and paper 2 (T1)
Cohabitation status	Yes/no	T1	Paper 1 (T1+T3) and paper 2 (T1)
Employment status	Employed Unemployed Retired	T1	Paper 1 (T1+T3) and paper 2 (T1)
Comorbidities	0 1-2 ≥3	T1	Paper 1 (T1+T3) and paper 2 (T1)
Physical activity with stage of change	Pre-Action/ Action	T1, T2 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Dietary habits with stage of change	Pre-Action/ Action	T1, T2 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Smoking	Yes/no	T1 and T3	Paper 1 and paper 2 (T1)
Alcohol	<monthly or never/ 1–3 times per month	T1 and T3	Paper 2 (T1)
Familiarity with PC and/ or smartphones	Yes/no	T1	Paper 1
Participation in other courses/ programs during the study	Yes/no	T3	Paper 1

T1=baseline, T2=after 4 months reported elsewhere, T3=after 12 months.

Major life events were also included: being married or starting to cohabit, having a child, death in the near circle of family or friends, having serious problems related to living or economy, or other major life events. Familiarity with a personal computer and/or mobile phone was also reported. The

presence of daily tobacco or snuff use was reported in a dichotomized scale of "yes" or "no", and alcohol use was self-reported on a scale from "daily" to "never." In the data collection after 12 months, an additional question was used to assess whether the participants had participated in any other organized activities that could interfere with the current study. These included courses at the healthy life centers (*Frisklivssentraler*), the Centre for Learning and Mastery (tr. *Lærings- og mestringssentra*), or other centers. It also included whether they participated in courses to increase physical activity, change their dietary habits, quit smoking, or changing other behaviors. Age was dichotomized according to early retirement age in Norway ≥63 for some of the analyses.

Clinical characteristics

Data collected from the journals at the GPs' offices (Table 8) included medical treatment, medication, dosage, frequency, administration mode, and length of treatment period. Further, height, weight, BP, and waist circumference was collected. A description of blood pressure measurement and waist circumference was provided within the study journal to achieve the same measurement procedure. Laboratory status included HbA1c, LDL, HDL, total cholesterol, and triglycerides. Lastly, the GP's were asked to indicate the frequency of hypoglycemia. At baseline only, the GPs recorded any history of other relevant diagnoses and comorbidities such as atrial fibrillation, intermittent claudication, cerebrovascular disease, coronary disease, and micro albuminuria. Together with the self-reported data, we aimed at summarizing a Framingham risk score for CVD [253] based on their age, total cholesterol, smoking status, HDL cholesterol, and systolic BP; however, a high number of missing among the laboratory analysis made this impossible.

Table 8. Clinical variables from the GP offices and the questionnaire booklets

Scales/ Variables	Score	Time	Paper
HbA1c (inclusion criteria and primary outcome)		T1, T2 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Diabetes medication		T1 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Change in medication		T2 and T3	Paper 1 (T3)
Medication in general		T3	Paper 1 (T3)
Height	Cm	T1	Paper 1 (T1+T3) and paper 2 (T1)
Weight	Kg	T1 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Waist circumference	Cm	T1 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Blood pressure	mmHg	T1 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Late-complications		T1	Paper 1 (T1+T3) and paper 2 (T1)
Self-monitoring of blood glucose	Yes/no	T1	Paper 1 (T1+T3) and paper 2 (T1)
Hypoglycemia		T1, T2 and T3	Paper 1 (T1+T3) and paper 2 (T1)
Duration of diabetes	Years	T1	Paper 1 (T1+T3) and paper 2 (T1)
Use of health care, expenses		T2 and T3	Reported elsewhere
GP classification of diseases		T3	Reported elsewhere

T1=baseline, T2=after 4 months reported elsewhere, T3=after 12 months.

Some clinical characteristics were included in the self-reported questionnaires at baseline, including disease-specific parameters such as year of diabetes diagnosis, and whether the diagnosis was based on symptoms or by coincidence. Whether or not they performed self-measurements of blood

glucose were assessed with a “yes” or “no,” and if “yes,” how often in a normal day. Any difficulties with blood glucose control were indicated at a range from “very difficult” to “very easy.”

Further, we collected self-reported data regarding hypoglycemia: “Have you ever experienced a hypoglycemic event?” If they answered “yes,” they were asked how often the last week. Three questions covered any diabetes related visual impairment or late complications through “Has your doctor said you have visual impairments caused by your diabetes?” “Are you regularly attending diabetic retinopathy screening?” “Have you ever had laser treatment on your eyes related to diabetic retinopathy?” The data regarding foot problems, common for diabetes, were collected by asking “Have you ever had foot ulcers for more than three weeks before they healed?” “Have you ever had an amputation of either toes/feet, calf/knee, or thigh?” If they answered “yes,” they were asked to indicate what year this took place.

Lastly, a list of other relevant disorders was included in the questionnaires, including heart disease, brain disease, chronic obstructive pulmonary disease (COPD), rheumatism, stomach ulcer, gastro-intestinal disease, liver disease, stroke with any paralysis, kidney failure, cancer, AIDS, mental health problems, or any other disease. This list was based on the Charlson comorbidity index (CCI) [254]; however, the scale was reduced by the EU team and provided in a revised version in the RENEWING HEALTH common dataset [226].

3.2.7 Sample size and power calculation (Paper I)

Power calculation was performed prior to recruitment, providing estimate of the sample size needed to reveal statistically significant differences based on change in HbA1c, which was used as the primary outcome. Given an effect size of 0.30 difference between groups, a significance level of 0.05, a standard deviation of the outcome variable of 0.5, a power of 0.90, and a two-sided significance test, we estimated 88 persons in each group. Initially, we decided on 100 per group (total = 300) to attain the power to detect true differences in the SF-36 in addition to the primary outcome, HbA1c. However, we had to abandon this number due to inclusion difficulties. Reducing the power to 0.80, using the anticipated effect-size of 0.30, a standard deviation of the outcome variable of 0.5, a significance level at 0.05, and two-sided testing, we estimated that we would need 45 individuals in each group. To adjust for possible dropout and multiple testing, the sample was set at 50 per group and 150 in the total sample. A change in HbA1c of 0.3 points, which is equivalent with 3 mmol/mol, was regarded as a clinically relevant change in HbA1c for the studied group [255].

3.2.8 Randomization (Paper I)

The Centre of Randomization at the Unit for Applied Clinical Research at the Norwegian University of Science and Technology in Trondheim provided us with a web case report form (WebCRF) for

randomization. Patients who met the inclusion criteria and signed the consent form was randomized into one of three groups using block-randomization with blocks of three and an allocation ratio of 1:1:1; the procedure was carried out in the start-up meetings. Participants were informed of their randomized group after they had filled in the questionnaires.

3.2.9 Blinding (Paper I)

The RCT was a non-blinded trial, where neither the participants, the GP's, nor the researchers were blinded with regard to group allocation or outcomes.

3.2.10 Statistical methods (Paper I and II)

To conduct the statistical analysis, we used the Statistical Package for the Social Sciences (SPSS) versions 16-21. To ensure a high quality dataset, all HbA1c values and every fifth data line in the dataset was controlled by two researchers. For future reference, all questions were sorted out and noted in the paper copies of the questionnaire.

Paper I

Of the data from the one-year follow-up paper, continuous data were reported as mean and standard deviation (SD) and categorical data as counts and percentages. Baseline data were analyzed to assess the comparability of the randomized groups using one way ANOVA for the continuous data and the chi-square test for the categorical data. Unavailable data were regarded as missing and no imputation was performed; the one-year findings were based on intention to treat analysis. The first step of the follow-up data analysis was completed with the Student's t-test. To adjust for possible confounders, linear and multiple logistic regression was used to fit the final models. All of the final models were adjusted for age, gender, and educational level. Additionally, BMI, comorbidities, diabetes duration, changes in anti-diabetic medication, and depressive symptoms were added one by one into the final models to investigate confounding effects. If they were not statistically significant within the model, the covariate was not presented in the final model in order to increase statistical precision of the estimates and statistical power. All tests were two-sided, with p-values <0.05 regarded as statistically significant.

Paper II

The baseline findings were analyzed regardless of the initial intervention groups, and as one sample of 151 participants. The majority of the baseline data were skewed, therefore the continuous data were presented as medians with minimum and maximum values, and the respective categorical data were reported as proportions and percentages. The Mann-Whitney U test was applied to the non-normally distributed groups, and the chi-square test was applied to compare pairs of categorical data for the first crude associations. Logistic regression was used to fit the final models, investigating

associations between the dependent binary outcome and selected covariates. Two final models were fitted: one for stage of change in physical activity as the dependent, and one for stage of change in dietary habits as the dependent variable. Univariate logistic regression was performed for each of the following: all domains of the heiQ separately, all domains of the SF-36 separately, the CES-D dichotomized and continuous, and the lifestyle variables. Consecutively, one by one variable were entered into the multiple logistic regression model (one model for each domain), alongside age, gender, and educational level to adjust for possible confounders. Our study was regarded as exploratory; hence, we did not correct for multiple testing, and we considered p-values < 0.05 as statistically significant. All tests were two-sided.

Missing data (paper I and II)

The analyses were based on the available data, and no imputation of missing data was performed as such computation is associated with increased bias. We used intention to treat in the analysis of paper I: the RCT. Thus, all the participants within this trial were analyzed based on the group they were randomized to regardless of their use of the intervention (either FTA or FTA-HC).

Effect sizes (paper I)

Cohen's method [256] was applied to calculate the effect sizes. First, the effect size within each group was calculated by dividing their mean change in HbA1c from the T1 baseline to the T3 (one year) by the SD at one year. Calculating the between-group effect sizes was performed by finding the differences between the mean change in the FTA and the control group and the FTA-HV and the control group, and dividing this by the average SD at T3. The evaluation of the effect sizes followed Cohen's range: 0.2 = small, 0.5 = medium, and 0.8 = large effect size [256].

3.3 The systematic review (Paper III)

3.3.1 Design

A systematic literature review of controlled trials assessing the use of mobile apps with integrated communication and feedback from HCP and examining the functions and effects of such apps in diabetes type 1 and type 2 was conducted [46]. A priori, the review protocol [257] was registered in the International Prospective Register of Systematic Reviews (PROSPERO) [258]. The systematic literature review was performed using methods from the *Cochrane Handbook of Systematic Reviews of Interventions* [259] according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [260] and the PRISMA-Protocol (PRISMA-P) guidelines [261,262]. Further, the protocol was presented and discussed in a conference proceeding with experienced researchers in the field [263].

3.3.2 Data sources and search methods

We applied a comprehensive search strategy to ensure the identification of all relevant trials to be included in our systematic review.

Developing, refining, and validating the search terms

The search strategy was informed by earlier reviews and studies conducted in the field regarding mHealth for the self-management of diabetes. We also searched the Medical Subject Headings (MeSH) for appropriate terms in addition to the chosen keywords. We performed a pilot search in December 2015, before the full search was applied after adjustments. The search terms included "mobile applications," "cell phones," "mobile phones," "smartphones," "portable applications," "mobile technology," "portable technology," and "app." These were then combined with "diabetes mellitus" and/or "diabetes mellitus type 1" and/or "diabetes mellitus type 2" and/or "diabetic ketoacidosis." The search strategy was tailored to each database for optimal results, and organized in collaboration with a librarian at the Oslo and Akershus University College of Applied Sciences and a librarian at the University in Oslo. Because automated databases may be incomplete, we reviewed reference lists of relevant reviews and studies as well as hand-searched relevant journals of the field. In addition, we discussed possible studies with senior researchers in the field.

Databases

Medical literature published beginning in January 2008 was searched in January 2016, with an updated search in September 2016, using MEDLINE, PubMed, CINAHL, Embase, Cochrane Central, clinicaltrials.gov, and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP). We did not set a language restriction.

Eligibility criteria

The eligibility criteria was sorted using PICO, and informed our search (Table 9).

Table 9. PICO for inclusion and exclusion

PICO element	Our criteria
(**P) Population**	
Included	Persons with diabetes, at the age of 16 years or older.
Excluded	Prevention of diabetes Gestational diabetes Closed-loop systems
(I) Intervention	
Included	Studies testing a mobile app (software in a smartphone) with an integrated communication function for communication between patients and providers based on individual patient data. The mobile app had to have at least two functions relevant for diabetes.
Excluded	External communication, such as SMS, e-mail, phone calls, face-to-face, web pages, and web-apps. Apps giving feedback only based on artificial intelligence algorithms.
(C) Comparison	
Included	Trials with a control group, either randomized, quasi-randomized or a controlled clinical trial.
Excluded	Those without a comparison group.
(O) Outcome(s)	
Included	All outcomes relevant for persons with diabetes included in a mHealth trial.
Excluded	

We did not set a language limitation; however, we did set a limitation on publication year, as we regarded technologies prior to 2008 to be unlikely to be mobile apps. Communication was conceptualized as HCP providing any kind of feedback based on patient data, including real-time, chatting, individualized algorithms, or individualized trend analyses. The reason for excluding studies for those with gestational diabetes, with closed-loop, and studies for prevention was that we regarded these individuals to be unique in how they perceived change.

3.3.3 Article screening and selection

All of the final searches were downloaded into Endnote so they could be saved in place and allow for deduping. Two reviewers (HH and LR) independently reviewed all of the titles and abstracts from the search. We applied our inclusion and exclusion criteria set a priori. For possibly eligible studies, a full text copy was retrieved, and reviewed independently by the PhD candidate and LR. Discrepancies were resolved through discussion, or with the involvement of a third reviewer (AKW). The authors were contacted consecutively regarding study clarification, and one reminder was sent to the non-responders. Data were extracted for all eligible studies using a structured form. The extraction included descriptive information, design, outcomes, and follow-up with results as well as any data regarding theoretical frameworks or a guideline-based approach in the app development. One reviewer (HH) performed the data extraction, whilst a second reviewer granted quality assurance and approval (LR). The aim was to extract and ensure that the correct information was collected. Ultimately, six papers were included for systematic review.

3.3.4 Analysis and quality assessment of the included trials

Due to the heterogeneity of the included trials in the systematic review, we were unable to perform any meta-analysis of effects, and only descriptive information was summarized. The information reported in each article was used to assess the methodological quality of each study using the Cochrane methodology for Risk of Systematic Bias (ROB) [259]. ROB is a generic tool that assesses seven relevant areas of importance to avoid biased publications: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. Before each study was assessed and scored according to ROB, the PhD candidate elaborated each domains relevance for the current objective to ensure a uniform assessment (Appendix III). The ROB scoring was performed individually by three researchers (HH, AKW, and LR) and discussed until consensus was reached. Review Manager (RevMan) was used to systematize the risk-scores.

3.4 Ethical and legal considerations

The current research project followed the Health Research Act of 20 June 2008 No. 44 [264] and the associated guidelines from the Ministry of Health and Care Services [265] demanding that research follow the principles of justifiability, committee assessment, autonomy of the participants, and proportionality. These standards are compliant with the Helsinki Declaration, protecting the participants against coercion, fraud, and hazardous and poor research [266] as well as the four principles of medical ethics: respect for autonomy, beneficence, non-maleficence, and justice [242].

The Regional Committees for Medical and Health Research Ethics South-East Norway reviewed and approved the study with a few requests for change during the project period (reference number: 2010/427). The application with requests for change and approvals are available upon request. The RCT was reported in March 2011 to clinicaltrials.gov (NCT 01315756). All of the participants received written and oral information regarding the trial (Appendix I), were informed of their right to withdraw at any time without any reason, and were told about the potential risks and benefits of the intervention before consenting. Written consent was provided from all of the participants, and they were assured of their confidentiality. All participants were given the research team's contact information in case they had questions or concerns at any time during the study.

4 Summary of results

This chapter provide a brief summary of the results, and more details from each paper can be found in the original articles in the back of this thesis.

4.1 The Norwegian Study in RENEWING HEALTH

Overall, in the Norwegian study in RENEWING HEALTH, we assessed 298 persons with type 2 diabetes for eligibility. Before randomization, we excluded 82 persons because they were not eligible for various reasons and 52 persons who did not want to participate after they received the study information (Figure 8). Additional information regarding the characteristics of those who did not consent to participate does not exist, as we did not specify these data in the regional ethics committee documents. We randomized 164 persons, but throughout the first period of inclusion, we had to exclude 12 persons whose HbA1c was below the inclusion criteria ≥7.1%. One person withdrew consent, leaving us with 151 persons successfully randomized to one of the three groups.

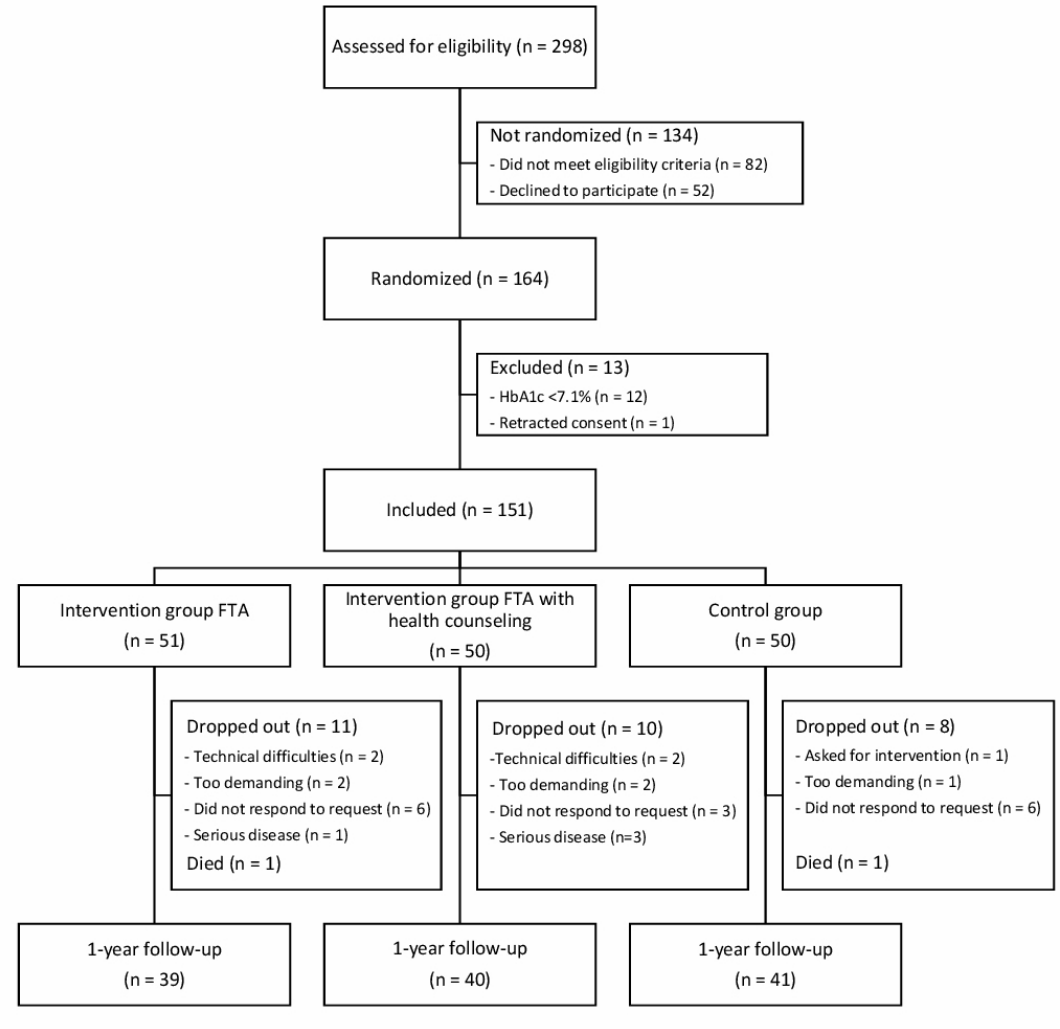

Figure 8. Flow of the RCT [44]

Characteristics of the sample can be found in Table 10. The overall sample comprised individuals with a mean age of 57 years. Slightly fewer females participated (41%). The participants' mean HbA1c was 8.2%, and the mean of duration since they got their diabetes diagnosis was 10 years.

Table 10. Baseline characteristics of participants in the Norwegian study

Variable	All participants N=151[a]		
	N (%)	Mean (SD)	Median (min-max)
HbA1c (%)		8.2 (1.1)	7.9 (7.1-12.4)
Diabetes duration (years)		10.09 (7.1)	9 (1-36)
BMI (kg/m^2)		31.7 (6.0)	
Comorbidities			
0	24 (16)		
1-2	97 (64)		
>3	30 (20)		
Age (years at inclusion)		57.31 (12.0)	58 (20-80)
Gender, male	89 (59)		
Education			
<12 years	83 (55)		
12 years	17 (11)		
>12 years	51 (34)		
Stage of change in Physical Activity			
Pre-action	88 (58)		
Action	63 (42)		
Stage of change in Dietary Habits			
Pre-action	119 (79)		
Action	31 (21)		

[a]Inclusion criteria HbA1c ≥7.1%, age ≥18 years

Paper I reports on the Norwegian study in RENEWING HEALTH, which comprises the sample of 151 persons after randomization and compares change in outcomes during the 12-month follow-up. Paper II reports on the baseline characteristics of the 151 participants before randomization.

4.1.1 Aim I

Paper I reports on the 12-month RCT follow-up. A total of 151 adult participants with type 2 diabetes and HbA1c above the national guidelines treatment target (>7.0) were randomized into one of three groups: FTA, FTA-HC, or the standard care control group (Table 11).

Table 11. Baseline characteristics of the intervention groups in the RCT

Variable	N	FTA	FTA-HC	Control group
HbA1c (%), mean (SD)	151	8.1 (1.1)	8.2 (1.1)	8.3 (1.2)
Diabetes duration (years), mean (SD)	138	11.2 (7.3)	9.6 (8.4)	9.4 (5.5)
BMI (kg/m^2), mean (SD)	129	32.4 (6.5)	30.7 (5.6)	32.0 (6.0)
Comorbidities, n(%)	151			
0		6 (12)	8 (16)	10 (20)
1-2		33 (65)	32 (64)	32 (64)
>3		12 (23)	10 (20)	8 (16)
Age (years at inclusion), mean (SD)	151	58.6 (11.8)	57.4 (12.1)	55.9 (12.2)
Gender, male, n(%)	151	34 (67)	25 (50)	30 (60)
Education, n(%)	151			
<12 years		26 (51)	26 (52)	31 (62)
12 years		4 (8)	10 (20)	3 (6)
>12 years		21 (41)	14 (28)	16 (32)
Stage of change in Physical Activity, n(%)	151			
Pre-action		27 (53)	31 (62)	30 (60)
Action		24 (47)	19 (38)	20 (40)
Stage of change in Dietary Habits, n(%)	150			
Pre-action		43 (84)	38 (76)	38 (78)
Action		8 (16)	12 (24)	11 (22)

The aim was to evaluate whether the intervention could produce significant changes in the primary outcome: HbA1c. Further, secondary outcomes were evaluated, including self-management (heiQ), HRQL (SF-36), depressive symptoms (CES-D), and clinical and lifestyle variables. There were no statistically significant differences between the three randomized intervention groups, except for the presence of connective tissue-/ rheumatism disease, which was significantly higher in the FTA group ($p < 0.03$). The proportion of persons with depressive symptoms was larger in the control group ($p < 0.04$).

We experienced some attrition during the 12-month follow up. Among the control participants, 12 dropped out, in the FTA group, 13 dropped out, and in the FTA-HC group, 12 dropped out (Table 12). There were no differences between the discontinuers (n = 32) and the completers (n = 119) of the trial in the study variables, except for in the domain role-emotional in the SF-36, where the discontinuers had a lower baseline score (mean = 58.9, 95% CI = 49,68) than the completers (mean = 67.9, 95% CI = 64,71, $p < 0.049$).

Table 12. Baseline characteristics of the completers and discontinuers

Variable		Completers (n=120)	Discontinuers (n=31)
HbA1c (%), mean (SD)		8.2 (1.2)	8.2 (0.9)
Diabetes duration (years), mean (SD)		10.1 (6.7)	9.9 (8.8)
BMI (kg/m^2), mean (SD)		31.5 (6.3)	32.4 (4.3)
Comorbidities, n(%)	0	19 (16)	5 (16)
	1-2	79 (66)	18 (58)
	>3	22 (18)	8 (26)
Age (years at inclusion), mean (SD)		58.0 (10.9)	55 (15.5)
Gender, male, n(%)		71 (59)	18 (58)
Education, n(%)	<12 years	67 (56)	16 (52)
	12 years	10 (8)	7 (23)
	>12 years	43 (36)	8 (26)
Stage of change in Physical Activity, n(%)	Pre-action	69 (58)	19 (61)
	Action	51 (42)	12 (39)
Stage of change in Dietary Habits, n(%)	Pre-action	94 (79)	25 (81)
	Action	25 (21)	6 (19)

Primary outcome: change in HbA1c

After 12 months, there were no statistically significant differences in the primary outcome change in HbA1c among the three groups (Table 13). The FTA group had a mean change of –0.31 (95% CI = –0.67,0.05), the FTA-HC group experienced a change of –0.15 (95% CI = –0.58,0.29), and the control group had a change of –0.16 (95% CI = –0.50, 0.18). After 4 months, all of the groups experienced a decline in HbA1c [48]; only the FTA group sustained its decline at 12 months. The FTA-HC group and the control group both increased slightly at 12 months, but not to the baseline level. Adjusting the change in HbA1c for age, gender or education did not affect the results; neither did change in glucose-lowering medication during the 12 months, diabetes duration, BMI, depressive symptoms, or comorbidities.

The between groups effect size on change in HbA1c was 0.19, which was a small effect size. Within-group effect sizes are presented in table 13.

Table 13 Mean scores and effect size of the primary outcome HbA1c, and the heiQ domain skill and technique acquisition

Outcomes	Group	*n*	Baseline Mean (SD)	1 year Mean (SD)	Mean change from baseline to 1 year[a]	Cohen T1 - T3 within group	Cohen T1 – T3 between groups
HbA1c	FTA	39	8.1 (1.1)	7.8 (1.43)	-0.31 (1.1)	0.21	
(primary	FTA-HV	40	8.1 (1.1)	8.0 (1.02)	-0.15 (1.4)	0.15	
outcome)	Control	41	8.4 (1.2)	8.2 (1.32)	-0.16 (1.1)	0.12	
							0.12
Skill and	FTA	38	2.9 (0.3)	2.9 (0.6)	-0.04 (0.5)	0.06	
technique	FTA-HV	40	2.9 (0.4)	3.1 (0.4)	0.2 (0.4)	0.5	
acquisition (heiQ)	Control	41	2.9 (0.3)	2.9 (0.6)	-0.00 (0.4)	0.0	
							0.3

[a]Unadjusted change.

Secondary outcomes

Considering the secondary outcomes, there was a statistically significant increase in the heiQ domain skills and technique acquisition in the FTA-HC group (B = 0.21; 95% CI = 0.01,0.40, p < 0.4) when adjusted for age, gender and education, compared to the control group (Table). Further, a significantly smaller mean change was revealed in the domain of health service navigation in the FTA group compared to the control group, however, when adjusting for age, gender, and education, this finding was no longer statistically significant (B = –0.19, 95% CI = –0.38,0.01, p < 0.06). In addition, we assessed depressive symptoms regardless of intervention group. We found that those reporting depressive symptoms at baseline (CES-D ≥16) had a higher change in the heiQ domains positive and active engagement in life (B = 0.24, 95% CI = 0.01,0.46, p < 0.04) and social integration and support (B = 0.22, 95% CI = 0.03,0.41, p < 0.02) compared with those with CES-D <16; all results adjusted for age, gender, and education.

There were no statistically significant changes between the groups in the eight domains, the two component scores of the SF-36, or the CES-D. Further, there were no statistically significant changes between the groups in the lifestyle variables, or the clinical variables.

Analyses regarding the use of the intervention the participants were assigned to revealed that those aged 63 years and older used the app significantly more than the younger participants did (OR = 2.7, 95% CI = 1.02,7.12, p < 0.045). Overall, 20 out of 51 (39%) participants randomized to the FTA group were categorized as substantial users. In the FTA-HC group, 17 out of 50 (34%) used the FTA part of the intervention substantially and also attended ≥4 health counseling sessions. Among all of the participants in the FTA-HC group, we found that a great majority, 42 out of 50 (84%) attended ≥4 health counseling sessions regardless of their FTA use.

To summarize, in this paper, our data revealed that after one year of intervention consisting of FTA only, or FTA-HC, there were no statistically significant differences in the primary outcome change in HbA1c among the three groups, which is reflected in the small effect size.

4.1.2 Aim II

Paper II aimed to provide an investigation of the baseline characteristics of the RCT sample (N = 151), and the associations with the pre-action and action stages of the TTM (Table 14).

Table 14. Baseline characteristics for stage of change in physical activity and dietary habits

Variable	Physical activity (N=151)		Dietary habits (N=150)	
	Pre-action (n=88)	Action (n=62)	Pre-action (n=119)	Action (n=31)
HbA1c (%), median (min-max)	7.9 (7.1-12.4)	7.8 (7.1-11.6)	7.9 (7.1-12.4)	7.7 (7.1-10.3)
Diabetes duration (years), median (min-max)	10 (1-34)	8 (1-36)	9 (1-34)	11 (1-36)
BMI (kg/m^2), median (min-max)	33 (24-53)	30 (20-53)	31 (20-53)	30 (21-44)
Comorbidities, n(%)				
0	10 (11)	14 (22)	16 (13)	8 (26)
1-2	56 (64)	41 (65)	81 (68)	16 (52)
>3	22 (25)	8 (13)	22 (19)	7 (23)
Age (years at inclusion), median (min-max)	57 (29–80)	61 (20–79)	58 (20–80)	60 (29–78)
Gender, male, n(%)	49 (56)	40 (64)	73 (61)	15 (48)
Education, n(%)				
<12 years	47 (53)	36 (57)	65 (55)	17 (55)
12 years	12 (14)	5 (8)	13 (11)	4 (13)
>12 years	29 (33)	22 (35)	41 (34)	10 (32)
Stage of change in Physical Activity, n(%)				
Pre-action			75 (63)	13 (42)
Action			44 (37)	18 (58)
Stage of change in Dietary Habits, n(%)				
Pre-action	75 (85)	44 (71)		
Action	13 (15)	18 (29)		

First, we dichotomized the original 5 point response scale of stage of change in dietary habits and change in physical activity. Pre-contemplation, contemplation, and preparation were grouped into "pre-action". Further, action and maintenance were grouped into "Action". For both change in physical activity and dietary habits, there were more persons in the action stage compared to the pre-action stage (Table 14). We found that being in the action stage for physical activity change was associated with a higher chance of being in the action stage for dietary habits change (OR = 2.50, 95% CI = 1.10,5.88, $p < 0.03$).

Comparing pre-action and action for change in physical activity revealed that being in the action stage for physical activity was associated with a statistically significantly higher chance of a lower BMI compared to pre-action for physical activity; this was also found when the analyzes was adjusted for age, gender, and education (OR = 0.92, 95% CI = 0.86,0.99, $p < 0.019$).

Further, being in the action stage for physical activity was associated with higher scores of self-management in six of the eight scales in heiQ after adjusting for age, gender, and education. These scales included health-directed activity (OR = 14.6, 95% CI = 5.69 ,37.49; $p < 0.001$), positive and active engagement in life (OR = 4.08, 95% CI = 1.75 ,9.53; $p < 0.001$), constructive attitude and approaches (OR = 2.73, 95% CI = 1.37,5.45, $p = 0.004$), skill and technique acquisition (OR = 4.50, 95%

CI = 1.77,11.43, p < 0.002), social integration and support (OR = 2.86, 95% CI = 1.47,5.55, p < 0.002), and health service navigation (OR = 2.64, 95% CI = 1.27,5.45, p < 0.009).

Similar findings emerged between the action stage for physical activity and domains and component scores of the SF-36. Higher scores on the four physical domains of physical functioning, role physical, bodily pain, and general health were individually associated with an increased chance of being in action for physical activity change (OR = 1.01-1.03, 95% CI = 1.00,1.05, p < 0.03-0.005), including the physical component score (OR = 1.17, 95% CI = 1.06,1.29, p < 0.002). Further, higher scores on the mental domains of vitality, social functioning, and mental health were also associated with a higher chance of being in the action stage for physical activity (OR = 1.02-1.04, 95% CI = 1.01,1.07, p < 0.008-0.002), but not the mental component score.

The data revealed that those with a low score for depressive symptoms had a higher chance of being in the action stage for physical activity. Similarly, those who had high levels of self-reported physical activity had a higher chance of being in the action stage for physical activity.

Regarding the stage of change in dietary habits, the same analyses, as for stage in physical activity, was carried out. Being in the action stage for dietary habits were associated with a higher chance of higher scores on four of the eight heiQ domains. These were health directed activity (OR = 1.19, 95% CI = 1.02,1.38, p < 0.026), self-monitoring and insight (OR = 7.72, 95% CI = 2.09,28.6, p < 0.002), skill and technique acquisition (OR = 3.74, 95% CI = 1.32,10.64, p < 0.013), and health service navigation (OR = 2.52, 95% CI = 1.05,6.02, p < 0.038).

Concerning the SF-36 domains, none was statistically significant between the pre-action and the action stage except the mental component score, which revealed that those who were in the action stage for dietary habits change had a higher risk of a lower score of mental HRQL (OR = 0.96, 95% CI = 0.92,0.99, p < 0.039), adjusted for age, gender, and education.

Lastly, being in the pre-action stage for dietary habits change was associated with a higher chance of no self-reported dietary change the previous year (OR = 0.37, 95% CI = 0.16,0.89, p < 0.026). Further, being in the action stage was associated with a higher intake of greens compared to the pre-action stage (OR = 1.27, 95% CI = 1.05,1.54, p <0.012). These analyses were also adjusted for age, gender, and education.

To summarize, we found that the action stages of change in physical activity and dietary habits was associated with a higher chance of positive scores in self-management, HRQL, and lifestyle variables. However, being in the action stage for dietary habits change was associated with a higher risk of lower scores of HRQL.

4.2 The systematic review

4.2.1 Aim III

The aim of this study was to systematically review studies evaluating mobile apps with an integrated communication with HCP. The apps had to be for persons with diabetes, and we assessed the characteristics of the studies, the functions within the app, the study outcomes and effects, and also the methodological quality of the included primary studies.

Through the systematic search, we identified 2.822 papers (Figure 9).

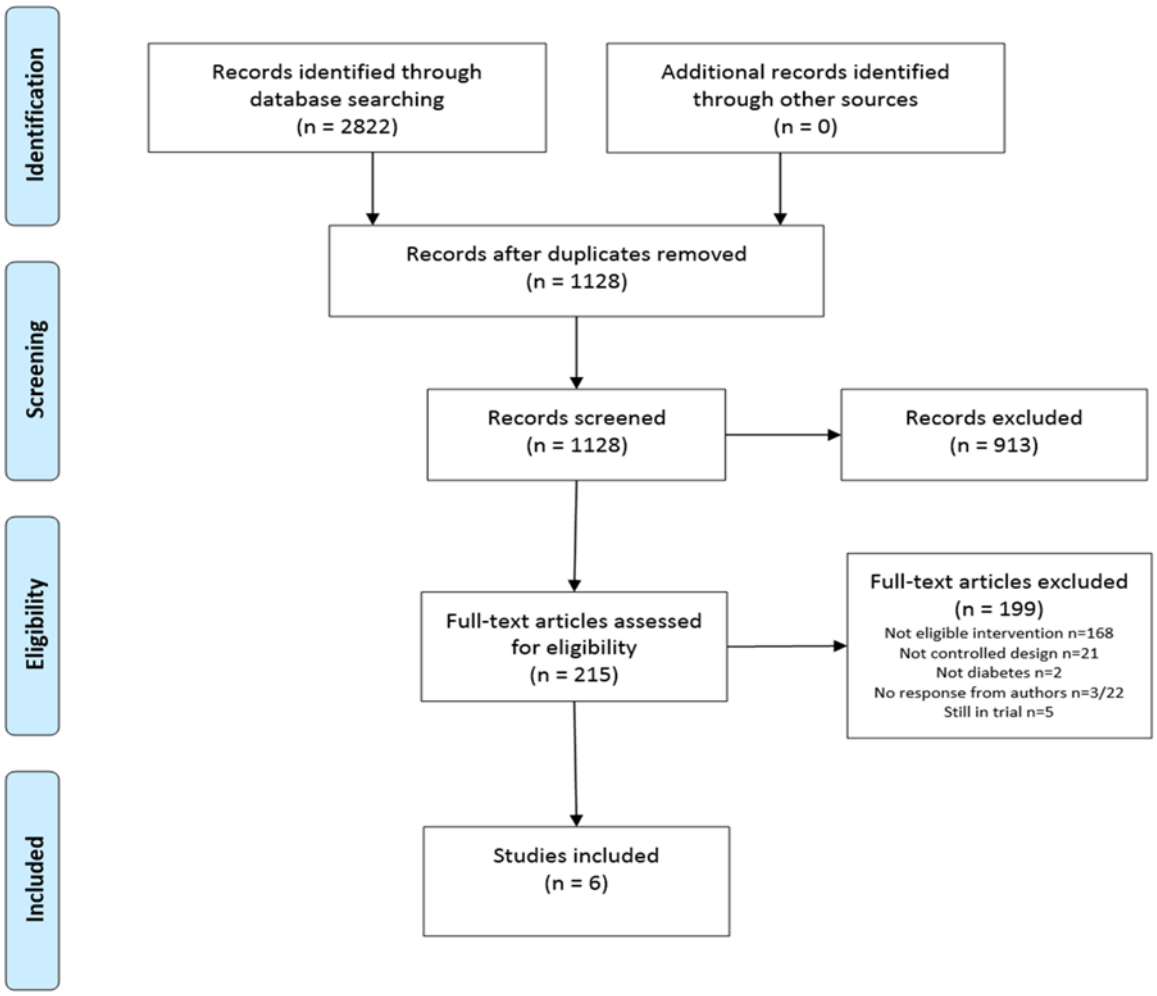

Figure 9. Flow of the systematic review [46]

After two independent researchers performed the screening process, we assessed 215 citations in full text to clarify the study details. For clarification, we contacted 22 authors regarding their papers or conference abstracts—18 responded immediately, one responded after one reminder, and the rest never answered. After the termination of the search, six citations [267-272] were included for review. The main reasons for exclusion were research related to the prevention of diabetes, mobile apps without communication, and other media used for communication including email, phone calls,

and SMS. Several studies were identified that had an intervention consisting of a mobile app with communication, while some of these had additional contacts such as phone calls, web apps or web chat, or face-to-face meetings, and were therefore excluded [210,211,273-275].

The six papers included in this review reported on data from 431 persons, participating in small-scale trials (N = 40-110) with short duration (1-12 months).

The integrated communication functions in the studied apps were mostly individualized, giving non-real-time feedback. All six apps provided individualized feedback, but only Fioravanti [267] stated that the feedback was according to a behavior change theory, namely the TTM; Waki [271] had feedback based on treatment guidelines. Four of the six provided messages, whilst one allowed for a two-way chat function [267]. Only one app, presented by Waki [271], had fully automated data collection in the app, while three apps had a completely manual input of data. Takenga [270] had automatic and manual data collection, and Logan [269] had data transfer only through Bluetooth®. Overall, the included apps consisted of 2-9 functions, were blood glucose tracking was the most common function.

The main outcome measure was HbA1c, chosen as a primary outcome in three of the studies and included as a secondary outcome in five of the studies. One study had mean daytime ambulatory systolic blood pressure as the primary outcome, and one reported that feasibility was the primary outcome. One trial did not state its primary outcomes; it only referred to outcomes in general. The remaining outcomes were not standardized or comparable. There was significant improvement in the primary outcome in three of the six included studies, two had a reduction in HbA1c, and one had a reduction in mean daytime ambulatory blood pressure. Positive usability or feasibility post-intervention was described in five studies, using various unstandardized measures.

We assessed the ROB among the included studies using the Cochrane tool [259]. Each of the seven items, including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias, with scored with either “low”, “high” or “uncertain” ROB. Overall, there was uncertain ROB among the included studies due to a high risk of selective reporting, lack of blinding among participants and personnel, and uncertainties in the allocation concealment and completeness of the outcome data.

To summarize, there were few controlled trials evaluating apps with integrated communication for HCP. Further, the methodological quality of the included trials made it difficult to provide reliable results.

5 Discussion

The present thesis expands the knowledge field regarding diabetes self-management assisted by mHealth technology. The following sections discusses the methodological considerations and consequences for validity and reliability, the main findings, and the ethical considerations in this thesis. Lastly, some future directions are proposed.

5.1 Methodological considerations

Applying different designs increases the ability to highlight different aspects of relevance to the overall aim and broaden the researchers' perspectives [218]. Based on our findings in our RCT (Paper I) and the baseline investigation (Paper II), we recognized a need for a new review of the evidence (Paper III). Although the MRC describes as circular process, it also suggests that going back and forth is possible. Our RCT did not prove a statistically significant effect on change in HbA1c between the intervention groups, and we experienced low usage of the FTA, and almost no usage of the secure SMS function for communication. Participants revealed in the qualitative interviews that they were satisfied with the opportunity to contact the diabetes specialist nurse through SMS, although they did not use this. Further, some called for communication and feedback on their data in the FTA, in which the diabetes specialist nurse did not have access to, as the intervention (app) was based on self-monitoring without integrated communication in the solution. Based on these arguments, and the characteristics revealed in the baseline investigation showing a need for change, we conducted the systematic review on integrated communication in mobile apps for diabetes self-management. Overall, we have striven to reduce the risk of bias in our studies and to enhance our internal and external validity and reliability [242,276]. These discussions will be elaborated on in the following sections.

5.1.1 Study designs

We conducted an open, un-blinded RCT. Studies investigating technology are susceptible to participant preferences because the interventions are challenging to blind, interfering with the randomization [37]. Challenges with blinding have been debated since that late 1980s, especially in trials requiring active involvement in the intervention or are driven by preferences [277-280]. The aim of blinding is to reduce performance bias, which is more easily accomplished in medication trials when the control group can receive a placebo drug. Several parts of a trial can be blinded, but we did not blind the participants, the research team/assessors, or the GPs and staff involved. Among the trials included in our systematic review, only one trial reported blinding the outcome, while three did not mention blinding, and two expressively stated that they did not blind any parts of their trials [46]. Similarly, our RCT could have been blinded on what outcome we studied. Despite our lack of blinding,

we had the ability to compare our intervention components with a control group and with each other. Thus, we could evaluate the risk of performance bias and detection bias because persons tend to act differently when they know they are being monitored. Researchers can also treat participants differently [242]; for example, the GPs could withhold medication from the intervention groups and treat the control group more intensively. However, our data suggest that no such discrimination occurred, with no significant changes in medication between the groups. The research team had an equal amount of contact with all of the participants throughout the data collection, but those experiencing technical difficulties with the intervention had more contact through the technical support team.

Research in general is often considered to be a static task and research methods evaluating dynamic use of apps are lacking. mHealth research is often characterized as dynamic rather than static, meaning that the app is used based on the current needs, and the app itself can be used more in periods with a fluctuating blood glucose, and less in stable periods. To evaluate this usage, dynamic research designs are called for in a recent review that supports our discussion of the RCTs value to mHealth research [281]. Sociotechnical factors can affect app usage, such as disease burden and health literacy [207,282], in addition to factors such as preferences and acceptability, and factors that engage use [22]. These factors are important to facilitate change, and apps with these characteristics are dynamic, advanced, with a robust functionality, providing continuous and timely care [281]. If an app is tailored specifically to an individual's preferences and needs, it becomes dynamic compared to other participants' apps. Further, the real-life context is dynamic, thus, methods evaluating dynamic use of intervention is needed.

The main concerns of the current project are randomization, blinding, and preferences. The randomization should produce comparable groups in terms of preferences toward or against technology, although consent indicates a preference toward technology. A common assumption is that preference towards an intervention will facilitate use, while a lack of interest might hamper how useful an intervention can be [278,283]. Thus, randomization in un-blinded trials can be problematic because of participants' interest in the intervention, with a high risk of disappointment such as ours [283]. Previous research has investigated the possibilities of randomization based on preferences; here, those who want the intervention will be in the intervention group, those not interested in the intervention will be in the control group, and those who are neutral will be randomized [278]. Using this alternative randomization could have been valuable, as we assume not all of our participants where as eager to use the technology. In addition, if eligible participants are left with a choice of what group they would partake in, recruitment could possibly have been easier. Using a preference based randomization would allow for intervention usage more similar to a management strategy

they would consent to in real life, and the control group would similarly manage their disease through other strategies.

Another concern is the time used to conduct an RCT. The time-consuming RCT is costly, which can compromise the methodological quality, forcing researchers to include fewer participants or abandoning the control group, thereby threatening the statistical power to detect change. Although one strength of the RCT is the investigation of between-group differences related to time, the traditional timeline of an RCT does not correspond well with mHealth research because on average, it takes 5.5 years from inclusion to publication [281], and we took 3.5 years in our RCT. Our follow-up period was 12 months, compared to the average follow-up time of four months in our systematic review [46]. A follow-up longer than 12 months could have provided valuable information regarding sustained or different effects, which is valuable, as diabetes is a chronic, lifelong condition. However, the technology might become outdated through the study period, as we experienced. Also, the value of the research that has been conducted might be questioned as the field moves past the initial focus. Thus, implementation is not a natural next step, as suggested by the MRC framework [217,218].

The field currently discusses the need for updated methods to evaluate mHealth interventions [20,22,281], a discussion we engaged in through our 12-month evaluation paper [44]. To ensure a thorough evaluation of complex interventions, the MRC framework suggests feasibility and piloting before the large scale evaluation of effects [217,218], corresponding well with the broad evaluation through MAST [35]. However, both frameworks might benefit from the adjustments related to the challenges with the traditional RCT, in which both frameworks recommend should be used as the gold standard [35,217,218]. Especially valuable information can be revealed during a feasibility study, providing insights regarding the intervention and its relevance to the participants [217,218,242]. If we had pursued this phase more rigorously, through conducting and publishing feasibility studies on, for example, the recruitment of participants, the health counseling, and the evaluation of DES-SF, our intervention could have been better prepared. Further, qualitative interviews reveal more in-depth value of an intervention because they examine patients' perceptions, as seen through the qualitative work conducted at the end of the Norwegian study [50,51]. It has been suggested that the traditional evaluation methods do not correspond with mHealth trials especially because they neglect the complexity of the intervention, thereby losing information regarding the sociotechnical aspects like preferences, acceptability, and usability [281]. Thus, both MAST and the MRC framework can enable a more thorough evaluation prior to the RCT, comprising both quantitative and qualitative work and providing a broader foundation for decision makers [35,217,218].

A stronger design compared to the RCT is the crossover design, where the participants are compared to themselves in their role of exposed versus non-exposed, ensuring that all participants receive the intervention [276]. This is valuable if withholding the intervention is unethical, and if the researchers feel the intervention will do more good than harm. However, there is a large risk of contamination for those who crossover from intervention to control, because we must assume that the intervention will affect their self-management. Thus, a variation of the crossover design is the stepped wedge design, where each patient is his or her own control [284]. The participants start as controls before they crossover to the intervention based on their clusters. Crossover designs might be valuable in interventions prone to performance bias, as they are driven by the participants' preferences toward the intervention such as ours. However, the stepped wedge is more time-consuming, it is difficult to compare more than two groups, and there is a larger risk of contamination compared to a traditional RCT [284].

Researchers often fail to find a statistically significant effect of mHealth interventions between the randomized groups [22,30]. Correspondingly, our RCT is one of many studies within the mHealth field that was unable to detect a between group difference. A consequence of this can be an underestimation of an intervention's effects, and previous research suggests a dose-response relationship between an app and its effects [37]. This suggestion is confirmed by additional analyses of our data, where there was an association between substantial use of the FTA and likelihood of a decreased HbA1c [285]. In addition, a frequent finding in papers is a statistical significant within-group change, but they have deteriorated scientific value. Following protocol is crucial to maintaining the scientific rigor of research [227]. Further, publishing trials without significant findings has value, especially reducing publication bias in systematic reviews [286]. Trials without significant findings in the primary outcome but with positive subgroup analysis often lead to attention regarding the subgroups, deviating from their protocols and risking faulty conclusions with a high risk of publication and attrition bias [227,242,276]. Thus, the consequences can be selective reporting and misinformed stakeholders that initiate interventions that are not as effective as suggested; the lack of appropriate evaluation might hinder the implementation of interventions that are actually beneficial.

5.1.2 Study sample and setting

Our participants differed from the general type 2 diabetes population mainly because they comprised a self-selected group that chose to participate in the current trial. When the current study started recruitment in 2011, smartphones were still uncommon, and apps were not a common concept. Thus, the novelty of our intervention could have caused self-selection, as highlighted by Polit [242]; this is similar to preferences toward or against technology, which threatens our internal validity.

A specific inclusion criterion for our RCT was an elevated HbA1c through blood sampling performed within the health care system [47]. The collection of HbA1c confirmed their type 2 diabetes diagnosis, which was a strength compared to self-reported diagnosis. Clearly defined inclusion and exclusion criteria strengthened whether the targeted sample was recruited, and it strengthened the replicability of the sampling and the external validity [242]. We recruited a convenience sample, which is contrary to strategic sampling. Initially, we planned to screen all of the patients at the GP offices with reference to our eligibility criteria. Unfortunately, we had to abandon this strategy because of recruitment difficulties and several smaller GP offices. Our recruitment was based on GPs and their contact with patients; we must assume that some participants declined the offer made by their GPs, and that the GPs have selected some patients that were not asked for various reasons. Despite these factors, our sample represents a sample of participants living and self-managing their diabetes at home provided with care through the GP in the municipality and not by specialist healthcare. Lastly, the recruitment compromised our knowledge regarding non-participation, as this information was unavailable. Stronger contact with a few larger offices could have improved these limitations, but we made an effort initially, however, to achieve such contact.

The intervention was planned outside of standard care, but the GPs was not asked to contribute in the planning of the intervention. We suggest that their lack of ownership to the project could have reduced their engagement in recruitment and data collection, and including all end-users in a project planning can reduce these challenges [218]. In the Norwegian pilot, the GPs were not involved from the beginning, unlike many of the other trials in RENEWING HEALTH [43].

We restricted the sample in the RCT to those aged 18 years or older with an HbA1c at 7.1% or higher. They also had to be able to read and write in Norwegian, which limited the generalizability of this group [287]. Our results cannot therefore straightforwardly be applied to ethnic minority groups, as they were not present in our sample. The intervention was only available in Norwegian, as were the self-reported questionnaires. Data indicate an even higher prevalence of type 2 diabetes among ethnic minority groups in Norway [288], and future research should take this into consideration. Furthermore, gender aspects in technology research are rarely reported or discussed among systematic reviews [20,23,27,30,31,37]. A recent review highlighted the gender perspective and found a higher proportion of men among the studied samples (60% male) [29]. Our RCT sample was 41% female versus 59% male, which we argue is a fair sample of females compared to previous research, that reported similar or lower numbers of females [22,29]. Among the six trials in our review, there were more males in all of the trials compared to females [46]. Thus, the amount of women participating in our RCT represents a strength in the field, as they are commonly underrepresented.

Prior to recruitment, we estimated the sample size needed to detect a statistically significant change in HbA1c, reducing the risk of performing a type II error [242,276]. The initial sample size of N = 300 could have allowed the statistical power to detect changes in the secondary outcomes, such as the heiQ and the SF-36; this is relevant when investigating self-management. However, as we had to abandon the first sample size, we were not powered for change in the secondary outcomes, although we found a statistically significant change in the heiQ domain of skills and technique acquisition. With a higher sample we could have increased the statistical probability of a true or false effect, but it is unethical to include more participants than needed based on power estimates. Further, a larger sample could have reduced our generalizability because the effects of self-selection would be even stronger [242]. On the contrary, unpowered research leads a high risk of type II error, and the research then constitutes waste. As long as studies are adequately powered, it is important to report the findings regardless of their results [242,276]. Compared to other mHealth trials such as some of the trials included in our systematic review [267,270,271], our sample size was sizeable. In the baseline investigation in paper II, we did not perform power calculations for differences in heiQ or SF-36, as the sample was collected for the RCT. However, we detected statistically significant differences when we dichotomized the sample based on stages of change in dietary habits and physical activity.

mHealth interventions conducted outside a laboratory such as ours are particularly vulnerable for contamination. Treatment diffusion can occur because researchers cannot control the environment or unconscious human behavior [242]. Similar interventions near the patients, or if our participants knew someone in the other groups and they exchanged tips, may have contaminated our intervention. Other lifestyle-changing activities, such as cooking classes or exercise classes, could further contaminate our self-management intervention. The likelihood of participants using other apps than the one we provided was considered, especially among those in the control. After one year, we collected data regarding these contaminations and used these as control variables in the statistical analyses to evaluate any contribution to change in HbA1c without any additional change. We assumed that if any effect was evident, it was equal among the groups. Furthermore, we were aware of the risk for compensatory rivalry, threatening the construct validity, related to the control group's desire to demonstrate their ability to manage just as well as the intervention group [242]. In the current trial, the participants were not reimbursed; however, the participants in the two intervention groups could keep the smartphone with the app after the study ended if they wanted.

The sample in the cross-sectional baseline assessment in Paper II was not from a strategic sample [276], and we have limited generalizability towards the general type 2 diabetes population in Norway. We analyzed the data regardless of the randomized groups, collected before they were

familiar with which randomized group they were drawn to. We regarded the participants to be part of one cohort of persons with type 2 diabetes with preferences toward the current project. In addition, the inclusion criteria for our RCT caused a selection of these persons. Thus, our cohort had limitations, but our aim was to conduct a thorough investigation of our current sample—an aim we met in Paper II.

5.1.3 Data collection

Standardized procedures for HbA1c testing, involving internal quality control and external control by NOKLUS [289], aimed to ensure reliability, increase internal validity, and reduce systematic errors among the measures. However, we lacked the information regarding obedience toward the standardized procedures and calibration protocol. Because we had several recruitment sites, we could assume that different methods for analysis of HbA1c were used, and the measurement of our primary outcome, HbA1c, might have been prone to bias. To ease the participants' burden and to collect HbA1c analyses with the same apparatus, the research team in Oslo used a Siemens DCA Vantage® for all HbA1c analyses performed from June 2012 to October 2013. However, the number of analyses was not large enough to decrease the risk of biased measures. We could have collected data regarding which laboratories or apparatus each GP office used, to determine any associations with our study outcome. Further, we did not collect data regarding the conditions affecting the hemoglobin or the erythrocytes altering the HbA1c, such as kidney disease or anemia [17], and we assumed that the GPs analyzed HbA1c according to protocol. The bias-risk applied to the remaining blood samples. We assumed that the blood sampling was done according to protocol; however, we lacked specific data to confirm these assumptions beyond our trust in the GPs. The cholesterol and triglycerides were subject to many missing values, threatening our internal validity; unfortunately these measures had little value.

The procedures for physical measures, such as waist circumference, weight, height, and blood pressure, should be thoroughly tested to ensure that the same procedure is maintained throughout the study period. These measures are prone to inter- and intra-personal variance, affecting the reliability [242]. We provided instructions to the GPs through every "*studiejournal*", according to the National guidelines for diabetes [10]. However, we were not familiar with whether or not they had been followed, which might affect the specificity of our data [242]. Our data regarding waist circumference indicated faulty and many missing measures, and it was thus not reported or used in the analysis. Medication was also a subject of the data collected from the GP offices, and there were some limitations related to missing values. In addition, we lacked information regarding whether the patients actually used their medication as prescribed. This could reduce the value of these variables as an outcome and as a control variable with the primary outcome analysis.

We experienced a high number of complete self-reported questionnaire packages with few missing items, strengthening our internal validity [242]. A possible reason for the high response rate was that the questionnaires felt relevant, enabling the participants to share their experiences, and the high level of interest in the mobile intervention among the participants could provide some explanation. For all test points, the researchers tried to accommodate a convenient meeting with the participants to minimize travel and time spent. To those unable to attend, we offered to mail the questionnaires with a prepaid envelope for return, to ensure no additional costs for the patient. The researchers were possibly more eager to collect data from the intervention groups compared to the controls because we had an open trial, causing a risk of performance bias [242]. However, as we maintained equal numbers of persons from the three groups at 12 months, this risk was small. Further, the participants might have wanted to please the researchers initially, which could affect their responses. Using the same questionnaires for all test points of this study might have caused a learning effect or increased reflection, which would be a threat to the internal validity. This was relevant in our self-management intervention, as the intervention per se might have increased their knowledge, changing their responses in relation to their knowledge change instead of their lifestyle change. Self-report is prone to both recall and response bias [276] and misinterpretation of the questions, even though reading and writing in Norwegian was an inclusion criteria [47]. However, self-report is a valid procedure for data collection [242].

5.1.4 Outcome measures

Our primary outcome was HbA1c based on its predictability and cutoffs for late complications [114,116] as well as on comparability with other studies. A relevant discussion regarding HbA1c relates to the size of the change. We aimed at a change in HbA1c of 0.3% (3 mmol/mol), suggested to be clinically relevant for persons with type 2 diabetes [255]. However, 0.5% (5.5 mmol/mol) was suggested as a clinically relevant change in a sample with both type 1 diabetes and type 2 diabetes, or type 1 diabetes separately [290,291]. Suggesting 0.3% (3 mmol/mol) might be modest; however, it might be unlikely that participants will experience a larger change when using a low-intensity mobile app compared to change in HbA1c when using a new drug. Our RCT sample comprised only persons with type 2 diabetes, but unfortunately, we were not able to restrict our systematic review to only type 2 diabetes. Previous research largely included both type 1 and type 2 diabetes [20,22,37], but a comparison can be problematic because insulin is required in all persons with type 1 diabetes. Although lifestyle and behavior are important, they play a larger role in the management of type 2 diabetes, where a sedentary lifestyle can trigger a pre-disposition for hyperglycemia [17,59].

Others have suggested that we were unlikely to find an effect in HbA1c as our mean HbA1c was 8.1 %, and the majority of participants had an HbA1c <9% [194]. A higher HbA1c could facilitate change;

however, we assumed that a higher HbA1c was associated with more support and HCP contact than a self-management app could provide. Furthermore, the “Standards of Medical Care in Diabetes 2017” [17] highlight the difficulties of changing clinical parameters such as HbA1c when the duration of diabetes has been long, and in the current sample, the mean diabetes duration was 10 years. Corresponding with these arguments, a change in HbA1c might be difficult because the participants had a high disease burden. Thus, finding the appropriate HbA1c level for an intervention should be performed according to the intensity and functions of the app.

A run-in period prior to randomization can stabilize outcomes, although it demands time and resources [292]. We considered a three-month run-in for the stabilization of blood glucose-lowering medication and blood glucose readings; however, due to a time limit, we abandoned this strategy. Possibly, our HbA1c could have changed differently if we used a run-in period, especially among the controls, as their attention effect could have been reduced. Further, it has been proposed to use run-in for technology trials to remove those participants that do not wish to use the intervention as planned. However, this demands a higher number of participants, because such studies has to plan on an estimate of 40-60% dropout [195].

Another relevant question in mHealth trials for diabetes is whether HbA1c is the best primary outcome [20,44]. Providing an intervention aiming at a change in self-management leading to a secondary decrease in HbA1c might be challenging because of the nature of the intervention—a behavior change outcome evaluating the self-management could be more appropriate. Accordingly, HbA1c has to be complemented by other outcomes to get a more thorough understanding of intervention effects. The participants welcomed this, as there is more to diabetes self-management than just HbA1c. Glucose management is complex, and a change cannot always be measured in the HbA1c [275]. These arguments support our choice of secondary outcomes relevant to evaluating diabetes self-management, and they comprise parts of the multidisciplinary assessment of MAST through clinical effectiveness and patient perspectives [35]. HbA1c and our PROs were measured in addition to describing the magnitude of diabetes as a health problem in our sample according to MAST [35].

Among the strengths of the current study, is the application of a self-management instrument. We applied the generic measure heiQ to evaluate self-management [233,234]. The domain of heiQ that is especially valuable for persons with diabetes are social integration and support, because a lack of a social network is associated with a deteriorated glycemic control [103,104]. Further, for many persons with diabetes, skills and techniques represent major areas of their self-management through their self-monitoring of blood glucose and administrations of insulin, or other glucose-lowering

injections. As heiQ is a generic measure, it allows for comparison between disease groups, which can be a strength in interventions that can be relevant for more groups, e.g. apps with general functions such as weight and BP registrations, and disease specific add-ons such as blood glucose monitoring. Similarly, the Patient Activation Measure (PAM) represents a generic measure for self-management [293] that has 22 items in the original and 13 items in the short form; this is compared to the 40-item heiQ [233]. The PAM comprises 13 items scored through "disagree strongly," "disagree," "agree," "agree strongly," and "not applicable." It provides one summary score indicating one of four levels of patient activation, which is readily understood. The PAM-13 is validated in Norwegian [294,295], and could be an alternative to the heiQ.

Neither the DES-SF, the SF-36 v2, nor the CES-D have been validated in Norwegian, which is an obvious threat to our construct validity. The DES-SF was translated for the purpose of the current project [250] and was chosen as a diabetes specific measures. It has relevant and few items (n = 8) [249], which we regarded as important when the questionnaire package was assembled. We performed a rigorous translation, with procedures for back and forth translation and test-retest interviews on a subsample of our participants [250]. Unfortunately, we found a ceiling effect, and chose not to report the findings in this trial; thus, we cannot report data from a disease-specific measure. The DES-SF contained items regarding the participants' attitudes toward their diabetes and diabetes empowerment [249] and we anticipated valuable data and positive changes in this measure.

The remaining self-reported variables comprised measures provided by the RENEWING HEALTH common dataset [226]. Use of unstandardized measures decreases the ability for relevant comparisons; however, we used variables that had been previously used or that were provided to us through the EU project. RENEWING HEALTH applied the Charlson comorbidity index (CCI) [254] with the possibility to estimate mortality and/ or use of resources. However, the CCI was reduced by the EU team and provided in a revised version in the common dataset [226], and we were unable to calculate the index. Further, it accounts for illness severity at hospital admission, while our participants were recruited through their GPs. The items we were missing included presence of metastatic solid tumor or other tumors, severity of liver disease if present, and severity of diabetes with or without end organ damage; thus, important nuances were removed from our data-collection. The CCI was originally developed to assess mortality and resources used among persons who were hospitalized, and it was thus not relevant among our sample, or among the RENEWING HEALTH sample. We attempted to collect data to calculate the Framingham risk score to assess the likelihood of developing CVD [253]. This score is based on gender, age, smoking status, total cholesterol, HDL cholesterol, and systolic blood pressure, but because of the missing data collected from the GPs, we were unable to calculate this score.

5.1.5 Intervention

A relevant discussion is whether our intervention could be sufficient for our sample despite our a priori power calculations. Our intervention consisted of two separate components: the app component offered through the smartphone with FTA, and the app with health counseling and secure SMS offered in the FTA-HC. The specific functions within FTA will not be specifically discussed because this app is already redesigned, however, the discussion will be a general discussion around FTA and the apps within our systematic review. The strengths of our intervention were the scientific development of the FTA and the theoretically founded development of the health counseling. Scientifically developed end evaluated apps are rare [22,281], and in comparison, none of the included trials in our systematic review referred to such a rigorous development. The FTA was developed through a different project [219,220], providing little flexibility to tailor the app content towards the needs and preferences of the participant, although the use were individually based. End-users were involved in the initial development of the FTA, which is a strength [217,218]. Within the FTA, the areas for monitoring to support diabetes self-management were blood-glucose, physical activity, dietary habits, and goal setting and evaluation to monitor progress [219,220]. These features are consistent with the core of diabetes self-management [11,17]. In addition, the information function contained practical information on how to use the functions in the app for those uncertain of the possibilities, what relevant goals might be, and general diabetes relevant information supporting any need for knowledge. These factors can increase both health literacy [207] and eHealth literacy [296,297], thus facilitating self-management [207,282,298].

Based on recommendations from clinical experts in the field of CBT, the multidisciplinary research team developed the health counseling intervention, involving a psychologist, diabetes specialist nurses, a dietician, diabetes and nursing researchers, and PhD candidates [47,252]. However, the patients and the GPs did not participate in the development of the health counseling, as recommended by the MRC framework [217,218]. Each health counseling session aimed to be individually tailored to the participant's agenda to increase self-management by using MI [151]. However, we cannot prove the diabetes specialist nurse's fidelity to MI, as the conversations were not recorded and controlled according to MI, although she took notes during and after each session. She was previously trained in MI through her diabetes specialist education, and received counseling by a psychologist in the initial phase of the intervention to support the MI. In addition, the diabetes specialist nurse's evaluation of the participants' stage of change related to his or her behavior being subject to counselling was vulnerable. Some limitations of the TTM has been suggested [149,150], such as the information lost in the discrete stages and the lack of standardized measures to define the stage a person is in. However, we argue that feedback based on stages of change can facilitate a

starting point for discussion. Thus, we aimed at delivering a scientifically based intervention that was developed involving multidisciplinary experts from the field to evaluate the impact on diabetes self-management.

The low-intensity strategy we adopted from the "Reach Out" project [221] aimed to be less burdensome for the patients, with less support in both duration and frequency; it provided a lower dose of the specific treatment. Accordingly, we did not demand a specific number of interactions with the app and only monthly health counseling. We emphasized use of FTA based on the participants' own identified needs, representing a low degree of tailoring. Participants engaged in dynamic use of the app through a frequency suitable for their daily lives and their self-management rather than at times defined by the research team. However, only 34-39% of the participants used the FTA substantially, making us question their use of the app, and whether co-morbidities, disease knowledge, health literacy, or the app and the technology contributed to the low use among the remaining 60%.

Conflicting co-morbidities might deteriorate participants' ability to self-manage in several ways, for example through performing blood glucose measures or assessing ones need for monitoring specific dietary choices. Persons with depressive symptoms might need a stronger intervention in order to benefit from it, which is especially relevant in diabetes, where depressive symptoms are a common co-morbidity [72]. We used the CES-D to evaluate depressive symptoms [239], but we did not tailor the intervention accordingly. We could have provided a higher number of health counseling sessions to those with depressive symptoms, as they might have needed increased support compared to what our low-intensity intervention provided [221]. Further, we could have set a minimum of interactions with the app to increase the likelihood of an improved self-management based on our dose-response finding.

Use of an app can be affected by disease knowledge and ability to use this knowledge in practice via an app, which is reflected through health literacy [207] and eHealth literacy [296,297]. Thus, if the content is too advanced, it threatens accessibility to the technology, creating a divide in available mHealth self-management [22,27]. Socioeconomic factors such as high cost [20] can increase this divide; however, smartphones are common among almost all groups. Sociocultural factors can be relevant to health literacy, as more education is often associated with more health-literate individuals [299,300]. In our sample, 55% had less than 12 years of education, suggesting a large group that possibly had low literacy. On the contrary, 34% had more than 12 years, suggesting our sample represented both extremes. We did not include a measure of health literacy; thus, we lacked specific data on knowledge transfer in their self-management and how they might benefit from the

intervention. Health literacy measures should be endorsed in the future, and a recent review suggests using health literacy measures for persons with type 2 diabetes to determine health outcomes [299]. If such measures indicate a lower level of disease knowledge or insight, an intervention could have been tailored accordingly.

This was a complex intervention, where several factors could contribute to the effects. Our health counseling could easily be tailored to the participants based on their contributions to the diabetes specialist nurse and her understanding of their disease insight. Providing the diabetes specialist nurse with more information regarding the participants could have increased her specific counseling more than just basing it on the phone calls. Such information could be both disease-specific data regarding their diabetes and comorbidities and PRO, including self-management and health literacy.

Our app was a "one-size-fits-all" app, which is common for self-management because it can be more cost-effective. The app's functions and content could be tailored based on the same information as with the health counseling; disease-specific data and PRO, as suggested in earlier research [22,27]. These factors could increase the effectiveness of the app, but the current research evaluation methods more easily evaluated the effects because all of the participants were granted the same app. Another factor related to the effects of an app is the usage of the app. The technical characteristics of the app and the platform facilitated proper use through participants' eHealth literacy [296,297], and the acceptability related to the contribution of the app for self-management and whether the app intruded in their daily routines [213]. Most of our participants had experience with cell phones and computers, but the minority had experience with smartphones. We encountered some technical difficulties in our project, most likely affecting the use and the acceptability of the app, as described elsewhere [51]. However, technical support data were not systematically collected, making it difficult to analyze the magnitude, reflecting a limitation of the current study. Collecting data related to technical difficulties are of interest to assess whether the technical difficulties are present among several users, the severity of the problems, the frequency of the issues, and whether the smartphone presented an unethical burden to the users. Our qualitative interviews indicated that among some participants, the app was used or abandoned regardless of technical issues [51]. Some of the high-frequency users experienced technical issues, but they still used the app and experienced benefits. In our intervention, the use of a voluntary shell (*skall*) to their home-screen limited the number of functions that were available and increased the icon sizes in the smartphone home-screen. Accordingly, we emphasized some tailoring and made adjustments for those with limited technology experiences to increase practical usability. However, this only affected the home-screen of the smartphone, whereas the FTA had the same appearance regardless of mode with or without shell. The previously described technical issues were mostly related to the use of first

generation smartphones, but independent of cause, such issues are probably handled better by persons with a higher eHealth literacy and stronger preferences [27]. A strength of the FTA was the automatic transfer of blood glucose from the blood glucose meter and to the app, making the data entry easier, and the risk of error smaller. Similarly, physical activity could be automatically tracked, but intensity had to be entered by the participant, as well as all dietary monitoring. Previous research has discussed manual versus automatic entry, were both can be beneficial [27,211]. Manual entry is suggested to increase the reflection regarding the data, whereas automatic entry is associated with less risk of faulty measures. Using apps is associated with a loss of interest in the app over time which can decrease use, as could altered needs; both have been described in other work [37]. Thus, the available tools should be useful for the target group regardless of knowledge, sociocultural level, urban or rural areas, and competing conditions [35]. The strength of the intervention and the intervention fidelity has implications for the results, and the low uptake of the intervention could affect our findings.

Our intervention was based on self-monitoring. Our qualitative interviews performed after the 12 month intervention revealed a wish among some of the participants for more monitoring by HCP, and someone looking at their measures and providing direct feedback on their actual self-management [51]. This suggests a stronger intervention compared to our low-intensity intervention. These statements correspond with previous research in the field, expressing a need for tailor-made feedback and communication with HCP [20,22,37]. The expressed need for communication and feedback could be incorporated as a function in a tailored app, and it nurtured our discussion regarding the intensity of the intervention. In addition, it contributed to our systematic review aim where we investigated communication functions for diabetes self-management support.

5.1.6 Choice of data analysis

In Paper I, our choice of the parametric model was based on the normality assumptions for the residuals, which is crucial in linear regression modeling. We calculated a mean change score in HbA1c which was normally distributed as is often the case for change variables within an individual, and used this as a dependent variable in multiple linear regression. As the calculation of mean change from baseline to 12 months follow-up is based on both values, we did not need to include baseline levels of the outcomes in the linear regression analysis. Thus, the change variable was used as dependent variable. Using regression allowed for the controlling of possible confounding variables.

In the baseline investigation in paper II, we used logistic regression modelling, where the dichotomized stage of change in dietary habits was modeled first with relevant covariates. Then, the

same procedure was carried out for the dichotomized variable for stage of change in physical activity. We did not correct for multiple testing as our study was considered an exploratory study.

All of the analyses were based on all available data, and we have not performed any imputation of missing values as we in general had few missing values in the questionnaires. In Paper I, we performed intention to treat analyses, where the participants were analyzed according to their randomized group regardless of their use of their assigned intervention [242]. Because usage of technology is especially dynamic similar to intervention usage in everyday living, basing the analyses on intention to treat is a strength. A suggested weakness of the intention to treat is an underestimation of the treatment effect, however, this risk is larger when missing data is imputed [276]. An alternative is the per protocol method, analyzing participants only based on whether they actually received or used the intervention, and a weakness is related to a lower number to analyze and a greater risk of selection bias [276]. Paper I analyzed the complete dataset, meaning that the change in Hba1c was calculated only for those participants with available HbA1c at both times. The same was applied for the secondary outcomes, which provided a different number to analyze for the primary outcome HbA1c (n = 120) and the secondary outcomes (n = 119), as in some cases, we were unable to collect both.

5.1.7 Methodological considerations in the systematic review

We aimed for controlled trials in diabetes, but not an RCT design because of the lack of randomized mHealth trials. Including trials using a non-randomized design is a limitation, and it is evident through the risk of bias scoring. However, based on this pragmatic choice, and the rapid evolution of the mHealth field, we anticipated more eligible trials then the six controlled trials we included. We realized that uncontrolled design, and non-integrated communication such as e-mail, SMS, face-to-face consultations, or phone calls were widespread, causing a high number of trials to be excluded from our review [210,211,273-275]. The relevance of our systematic review is therefore twofold; we regard integrated communication and feedback to be crucial in the future because of both patient demands and technologic possibilities. However, as we identified though the review process, other methods of communication are alive and well. Perhaps there is no natural divide between integrated or self-standing communication, and both will be demanded and used in the future. On the contrary, an important argument to investigate and implement communication that is integrated in an app relates to security and the danger of sensitive health data being available for a third party. Maintaining a high security level could be easier if all of the data are transferred to one app rather than through emails, SMS, or several platforms. Including chronic illnesses other than diabetes would have increased the number of eligible trials; however, self-management of diabetes is uniquely complex and uses app functions that are rarely relevant for other diseases, such as testing blood

glucose. Thus, the aim of our review specifically targeted diabetes apps with integrated communication.

Prior to the ROB assessment by three independent researchers, an interpretation of the Cochrane ROB was written in Norwegian to attain an even assessment (Appendix III). We did not perform an inter-rater agreement of this scoring; however, very few items, except "other," were subject to discussion. Within the domain of "other" in the ROB, we agreed to assess other problem areas that were not covered in the remaining domains, such as risk of less free research and economic interests in patents. These areas are unclear among the papers, and accordingly, we gave a "low" ROB in "other" if we doubted the presence of irregularities. The methodological quality of the field provided through ROB might have some shortcomings. Similar to the ROB, and with some overlap, is the Grading of Recommendations Assessment, Development and Evaluation (GRADE) [301,302], which aims at grading the quality of evidence and the strength of recommendations made in healthcare. While the ROB assess methodological quality within each trial and summarizes this, the GRADE assess quality of evidence regarding each individual outcomes used in the trials, and ROB one of the factors assessed in GRADE. GRADE is often used to assess the value of the evidence in current healthcare, and it was used in the Norwegian "National Guideline for Diabetes" from 2016 [10], and evidence was used to evaluate the impact and quality of scientific results before they were recommended for use in Norwegian healthcare through guidelines. Furthermore, the results aimed to be worthy of being applied to a real-life clinical setting with recommendations that were useful for clinicians, GPs, nurses, and other HCP. Previous mHealth reviews have used GRADE to summarize the value of review findings beyond their methodological quality [28]. Using GRADE in our systematic review could have added value regarding the usefulness of the findings and their relevance in the healthcare system, but the value would have been compromised because of the low methodological quality. GRADE considers all RCTs to be "high quality," as evaluated through study limitations, the inconsistency of results, the indirectness of evidence, imprecision, and reporting bias [301,302]. Based on these assumptions, together with the criteria for GRADE quality regarding confidence in the estimates, our review can never reach any high GRADE quality because of the individual preferences associated with the effects of mHealth and apps in outcomes.

To evaluate the quality of our systematic review, we applied the A Measurement Tool to Assess Systematic Reviews (AMSTAR) checklist [303], and we found a score of 8 out of 11 points. Our strengths were the a priori protocol in PROSPERO [258], the study selection and extraction performed by two independent researchers, a comprehensive search, the characteristics of the trials, the assessment of scientific quality using the ROB, the conclusion based on scientific quality, and the conflict of interest statement. Our review paper did not specifically state how we handled grey

literature, although we did search among conference proceedings and trial registers provided through the search strategy. Further, the criteria for pooled analyses and publication bias among the papers included in the pooled analyzes were not applicable for our review. Because the number of excluded trials was high, we did not included a complete list; however, we provided some examples, and we provided a complete list of all of the included papers. Thus, our review applied relevant methods to conduct a high-quality systematic review. The included trials affected the possibilities for pooled analyses, representing methodological challenges within the mHealth field in general.

5.2 Ethical considerations

Several ethical issues can arise in research, and some are genuine in technology research. With MAST, equality of access to technology care, ability to use the technology, participants' dignity related to constant monitoring, and participants' right to refuse the technology are areas that are highlighted [35]. In addition, randomization in open trials such as ours has nurtured several discussions, and it was challenging to provide written and oral information regarding the intervention before revealing the randomized groups, especially to those in the control group. We were explicit about the chance of being in the control group, and the fact that we could not know whether the intervention would be beneficial. Further, some of the GPs expressed concerns and hesitation to recruit to a trial where their patients could possibly end up with "nothing," reducing the number of participants from some GPs. As suggested, a design enabling all participants in the interventions can reduce these concerns [276,284]. Others provide the intervention or a substitute to the control group after the study end, and one year after the study ended, we informed all participants that the revised FTA, called "*Diabetesdagboka,*" was freely available.

The current trial was regarded as being of minimal risk. However, we were clear about the clinical safety [35] and the possibilities of hypoglycemia for those intending to take major steps to lower their blood glucose with support of either of the intervention components FTA or FTA-HC. These risks were included in the written and oral information prior to the study start, and the diabetes specialist nurse in the FTA-HC was aware of this issue. There was also a risk for those in the FTA-HC group to receive advice contrary to their GPs advice because the intervention was not integrated into the standard care in the municipality. We encouraged the participants to discuss this with the diabetes specialist nurse or with their GPs when relevant.

Ethical issues genuine to mHealth research include technical safety [35] and technical problems; a possible increase in the phone bill due to data traffic use of the application; security, privacy and confidentiality; risk of hacking; third party involvement; and lack of rigorous evaluation and regulation [197]. We transferred patient data from the mobile phones to a secure server for storage,

and ensured encrypted transfer and anonymous storage; we also took backup of data in the FTA in case a participant lost his or her smartphone. The support-tool MOZO professional enabled distance support and deletion of all data in the phone if it got lost or stolen [225]. To ensure privacy, we encouraged using a pin code to access the phone's home screen. Simply recognizing an app on a person's phone can identify them as having a certain disease they may wish to keep private. To meet the technical and product security through high-quality tools and ease the burden on the intervention group participants, a standard risk evaluation was carried out by the researchers in Tromsø prior to the study start. Further, using a technological intervention could be burdensome if the participants experienced technical problems or they did not manage to use the intervention as expected by the researchers, and some participants expressed occasionally stress caused by the smartphone.

The participants in the FTA-HC group had the opportunity to contact the diabetes specialist nurse through secure SMS. However, we experienced a lack of usage of this function, because of the tedious process to login. Ensuring privacy is important, but as the security in this case required too much effort, it possibly deprived participants this opportunity of communication. Thus, investigating integrated functions for communication using easier login functions could be valuable.

Whether mHealth will challenge or increase the participants' autonomy is a timely question that summarizes our ethical considerations. If the participants experience support from the app, and they are certain of their security, privacy and confidentiality, the app might increase their autonomy. Further, their autonomy might increase if there is a low strain or burden due to the intervention, there are only minor problems, and if the app presents their data and goals as meaningful for them in a dignifying way. Events contrary to these might threaten their autonomy and dignity, removing the support they need. Thus, the right to decline the use of mHealth must be upheld.

5.3 General discussion

Our RCT was the first to evaluate mobile apps and health counseling for diabetes self-management in Norway when it was initiated; there were not many other international experiences for comparison. However, others have produced much knowledge in the field of mHealth during our study period, although the evidence remain uncertain [20,22,37]. Our study has brought new knowledge regarding mHealth for diabetes self-management and support, although we did not produce a statistically significant change in HbA1c between the three groups. Accordingly, an essential question is why our intervention and others' interventions have failed to detect effects in the primary outcome. The previous methodological considerations elaborated some of these aspects, and some new aspects are introduced in the following.

5.3.1 mHealth for diabetes self-management

We found that the FTA-HC group had a statistically significant increase in the heiQ domain of skills and technique acquisition, although we were not statistically powered to detect a significant difference between the groups in heiQ. A higher heiQ score indicates higher health competence or self-management, with no established cutoff-points [233]. The skills and technique acquisition domain comprised the knowledge-based skills and techniques used to manage their symptoms, for example, self-monitoring of blood glucose to avoid hyperglycemia, exercising cautiously to avoid hypoglycemia, reducing stress, or being familiar with what food items are beneficial [233]. We found an increase of 0.19, increased from 2.89 to 3.08, in the FTA-HC group compared to the control group. The effect size of 0.5 within the FTA-HC group is rated as a medium effect size, whilst the between group Cohen size of 0.2 is regarded as small. Whether these changes in heiQ are clinically relevant is a discussion featuring uncertainty; however, we argue that any change in self-management might be meaningful for the individual. Recently described benchmarks for individual and group changes for interpretation of heiQ scores [304] suggested an effect size of 0.5 in skills and technique acquisition, although the authors emphasize that the benchmarks does not describe a clinically significant change. Compared to our effect size between groups, our change was small. However, compared to our within-group change, we had a medium and comparable effect size. These results were interpreted to cautiously indicate associations, as we regard between-groups changes to be the primary aim.

Interestingly, our short-term findings reported elsewhere indicated a decrease in HbA1c after four months; however the decline was experienced among all three groups [48]. A subsequent increase in HbA1c was experienced at one year, where the control group had an increase back to their baseline HbA1c levels and the intervention groups did not. This initial decline speaks to attention bias through study effects from the trial, and it demonstrates the importance of the control group. Our additional analyses showed an association between substantial use of FTA and the increased likelihood of a reduced HbA1c [285]; thus, there was a significant association between use of the app and effects on HbA1c. In addition, we found that participants aged ≥63 years used the app significantly more than their younger counterparts, contrary to previous research [26]. However, we did not find that those aged ≥63 years who used the app substantially had an increased chance of a decrease in their HbA1c, and we suggest that we might have to demand a higher usage by the elders to detect a change in HbA1c. Assuming that age and diabetes duration are associated [16], and that substantial use of the app and the likelihood of an effect are associated, our participants would not be able to produce significant changes in HbA1c because of their long duration of diabetes and their high disease burden. These arguments find support in the baseline investigation in Paper II. However, despite

these factors, some participants experienced increased self-management, as we found in our secondary outcome measure, heiQ that showed increased skills and technique acquisition among the participants that received FTA-HC.

Psychosocial variables and PROs are acknowledged as important in research [20,27,86] and in practice [176,177,305]; they provide information on how the persons with diabetes are self-managing instead of merely producing a number of their self-management, like HbA1c. Blood glucose levels and HbA1c can be affected by several physiologic, unconscious and conscious actions, and the person cannot always explain why his or her blood glucose and HbA1c has increased or decreased [17]. The participants can, however, express their understanding of their situation, their level of knowledge, how they experience their coping, and how these phenomena affect their self-management. Because not self-managing is not an option [156].

The finding of increased scores in skills and technique acquisition among the participants in the FTA-HC group supports use of the app in combination with health counseling, and that a low intensity intervention can increase self-management skills. However, because of the complex nature of mHealth interventions, proving causality is difficult [281], although the same effect was not found in the FTA group. This finding supports the notion that feedback or support could be beneficial, as suggested by the literature regarding diabetes self-management support [11] and by some of our participants' statements calling for feedback on their real-data [51]. What is contradictory is the recent uncertain evidence regarding the limited glycemic efficacy of a personalized feedback module [31]. Through a taxonomy, Wu and colleagues [31] investigated the contribution of each individual app function to effects on HbA1c, and while complication prevention and a structured display contributed to HbA1c effects, personalized feedback modules represented limited evidence, confirming the limited evidence we found in our review (Paper III). However, the value of ongoing support, communication, and feedback on self-management has been suggested to be beneficial on measures such as HbA1c, HRQL, and self-management behaviors [11]; in mobile apps, they can be made available in one platform. Our systematic review was based on these arguments, specifically targeting apps that had an integrated function within the native app for HCP communication. Further, clinical guidelines emphasized the importance of individualized feedback and targeted education, and mobile apps should aim to provide features to support behavior change and comprehensive self-management, rather than mirroring paper-based tools [21]. A recent literature review by Deacon and colleagues [306] suggested that mobile interventions that encouraged self-monitoring as well as clinician feedback could be more successful at decreasing HbA1c in adolescents with type 1 diabetes. Despite being related to type 1 diabetes, these findings corresponded with our intervention; namely, self-monitoring and health counseling. However, the GPs, the diabetes

specialist nurse, and the researchers did not monitor our participants' data, as suggested by Deacon [306] and in the interventions in our systematic review (Paper III); this was because we aimed for self-monitoring. The rationale for self-monitoring was to evaluate a low-intensity intervention, which can be more cost-effective, and also to evaluate an intervention of low burden to the participants. Further, our health counseling was founded in the self-management tradition, where through MI, patients are recognized as experts in their own lives [151]. If persons with diabetes are provided with tools like an app to increase their knowledge regarding their diabetes, their increased knowledge could improve their outcomes. Our health counseling encouraged the participants to identify their challenges and possible solutions, which the diabetes specialist nurse supported. She also challenged their thoughts, thus increasing their self-reflection. Similar strategies have been suggested as favorable to increase the impact of behavioral interventions [307]. In addition, the expert position held by HCP is a major challenge in self-management support for chronic conditions, and encouraging HCP to switch from expert clinician-centered to patient-centered strategies can be important [307]. The expert role of the patient corresponded well with the self-management tradition [137,156] and the MI [151] adopted for our intervention [47]. Thus, recognizing that the patient is the expert can increase positive outcomes, which is crucial for the individual and society and uses fewer resources. These arguments suggest that low-intensity counseling can increase self-management, and they are supported by our self-management findings among the FTA-HC group.

Despite the emphasis on self-management, and the positive contributions to diabetes care, the self-management process remains complex and several factors should be involved to increase the likelihood of positive patient outcomes. As suggested by the Chronic Care Model (CCM) [308], self-management support is just one of six factors that are necessary to manage chronic conditions, and it takes place in the municipality, health care system, and in the provider organizations, not just in the individual. Seen together with the increasing burden of diabetes and other NCDs', strategies to accomplish change are needed. Some have suggested that behavior change no longer can be seen as an individual task, but rather as a governmental responsibility through policies, food producers, retailers, and schools [309]. These claims has also been proposed in The Norwegian Social- and Health Directorate Actionplan against social inequalities in health [332], suggesting that managing with health problems alone can be compared to the mythology of Sisyphus. Sisyphus was deemed to roll an enormous boulder uphill, and every time he reached the top, the boulder would roll down. Comparing the boulder with health challenges, and the hill with society's adaptation toward healthy choices, it was suggested that the government has to make the hill less steep in order to increase the individual disease management [332]. Thus, behavior change represents an individual and public health task, where the society has shared responsibility for health together with the government and

the individual. Accordingly, if the individual is left with less unhealthy choices, disease management can be easier because the available food will be healthier, and the society and environment will make the healthy choices more available.

Findings from our baseline investigation suggested that change in dietary habits could compromise HRQL. Contradictory to our expectations, we found a lower chance of a high mental HRQL among those in the pre-action stage for dietary change. Previous research suggested a higher quality of life in the maintenance stage, compared to the preparation and action stages, but similar to our finding, those in the action stage demonstrated a significantly lower quality of life when the five stages were analyzed separately [143]. As we used a dichotomous construct of the stages (pre-action versus action), we might have lost some of the differences between action and maintenance. We argue that self-management support is crucial in interventions addressing dietary change because changing behavior can interfere with quality of life. Dietary habits are influenced by culture and tradition, and changing dietary habits might be emotionally challenging. Others' evidence consistent with ours, suggesting that HRQL can be compromised during change [57], suggesting that intensive diabetes management interferes with quality of life. Mobile apps might provide some of this support, through data collection, goal setting, and feedback messages.

Compared to our low-intensity intervention, the interventions assessed in our systematic review largely involved more functions in the app in addition to a communication function. Despite their higher intensity, we were surprised by the few statistically significant effects between groups in their primary outcomes of HbA1c (n = 3), mean daytime systolic blood pressure (n = 1) or feasibility (n= 1). None of the interventions reported a tailoring of the content based on the disease-specific needs related to disease duration and disease severity, health literacy, eHealth literacy, and preferences. Thus, perhaps tailoring the interventions would provide a higher likelihood of effects compared to the intensity of the intervention.

App functions to set goals for increased physical activity can be endorsed, also using motivational feedback when the goals are met. Overweight is a common and complex problem among persons with type 2 diabetes, and in our sample, 90% reported overweight, compared to previous research reporting that 80% of persons with type 2 diabetes had overweight [16]. To manage a high weight, monitoring in an app might not be enough, but app functions to monitor physical activity and diet might be useful. Identifying change thoughts can be valuable, as we did through the health counseling using MI and TTM. We found that being in the pre-action stage for physical activity change was associated with an increased risk of a higher BMI. Associations between BMI and physical activity change might reflect the obvious, that those who engage in physical activity have a reduced

chance of a high BMI, or that those with a low BMI have an increased likelihood of being physically active. On the contrary, these findings are valuable because they describe the positive associations between the action stage of change in physical activity, and health benefits, and these might represent possible subjects to communicate through an app. Further, the decreased chance of a high BMI and the increased chance of higher health competence among those who are changing their physical activity can support efforts to increase the number of persons who change their physical activity habits. Lastly, using this information to tailor the content of the information in an app can be useful for those striving to increase their health competence through apps.

We argue that health technology can be beneficial for persons with type 2 diabetes. To identify users that might benefit from technology, an individual assessment of disease-specific needs and preferences could replace characteristics to exclude participants, like an HbA1c level cutoff or an age requirement. However, no one should be forced to use technology. An app should aim to ensure the proper self-management of the most advanced diagnoses, target the outcomes most likely to change, or address to any preferred outcome identified by the individual in terms of what matters most for his or her life. If the persons accepting and using technology for healthcare have effects, this can free up time for the HCP, making more time available for those with increased need for HCP support. This might be one of the most important argument for why reaching implementation for technology is important. To ensure its use, previous research has suggested that HCP interaction was the biggest factor in whether patients felt supported by their device or not [310]. These findings correspond with our review aim (Paper III) and some of our participants' statements about personalized communication and feedback beyond our rarely used SMS-function [51]. Further, allowing participants to self-tailor the app can be effective [194]. Programs need to be designed and implemented based on their preferences and diabetes-related needs to ensure use. Then, technology might be beneficial for some, but not all; human contact will be required in any healthcare based on individualized technology.

5.3.2 Applicability of behavior change theory in mHealth research

The lack of theoretical assumptions regarding behavior change is a limitation within the technology field [21,22,30]. The value of behavior change theory lies within the fact that behavior theory might be one of several components explaining a complex intervention such as ours [217]. The MRC framework regards the theoretical fundament as crucial, both by using existing theory, and by developing new theory within the current project [218]. The theoretical foundation of our RCT comprised a strength within health technology interventions. Applying behavior theory is associated with an increased likelihood of effects [39], and more importantly, it may give an understanding of how and why individuals change and how to facilitate behavior change [38]. Further, within disease

management, the intervention has to target the core behaviors relevant to the disease and the individual. Our intervention aimed to correspond with the diabetes self-management literature, as well as including elements suggested to increase change.

The lack of behavior change theory in the eHealth and mHealth field in general [311] might relate to the background of the developers in this field, which is mainly technology engineering, but there has also been debate about whether a theoretical base is necessary [39]. Several papers in the field of mHealth interventions in diabetes pointed to this lack of theoretical framework [21,22,312]. To compensate for this, the technology field has adjusted and adopted certain theories. First, the Theory of Reasoned Action was extended into the Technology Acceptance Model (TAM) in the late 1980s; it helps researchers to determine user acceptance of computers [313]. Kim [314] built upon this work and created the Health Information Technology Acceptance Model (HITAM), which includes the Health Belief Model in addition to the Theory of Reasoned Action. The models' value in understanding patients' experiences of mobile apps for health tracking was suggested in a qualitative paper; it discussed the importance of such research in informing developers to increase sustained use [215]. However, although both the theory of reasoned action and the health belief model are frequently used in various interventions, they have been criticized for their inability to address the crucial impact of habits, self-control, emotional processing, impulsivity, and associative learning in behavior change [315]. Still, the TAM and HITAM remain the most thorough theoretical frameworks to understand change supported by technology [215]. Unfortunately, we were not familiar with these initially, and there was no consensus regarding which theory that would apply better to explaining behavior change through mobile apps.

A different theoretical perspective that might be valuable when understanding behavior change in technology trials is the Behavior Change Wheel [315]. Building on the previous Capability, Opportunity, and Motivation-Behavior model (COM-B), three fundamental areas of the COM-B were extended in the behavior change wheel (capability, opportunity and motivation) [315]. Contextual factors were added to understand sources of behavior, intervention functions and the policy categories in order to enable relevant interventions [315]. If we were to apply this model to our FTA and FTA-HC intervention, our intervention would target reflective motivation and psychological capability through education, training, and modeling. A recent systematic review [37] pointed to how little we know about support and motivation through an app in the areas of healthy eating, physical activity, and adherence to medication, all of which are important for HbA1c. Further, the review pointed to the importance of future research with a theoretical framework and involving users. Thus, research needs to investigate how behavior change theory can be more applicable and available for

current and future mHealth projects. mHealth is groundbreaking in the understanding of new, dynamic information on behavior, rather than the earlier static understanding of behavior [316].

To further understand the lack of findings between groups in change in HbA1c after our intervention, we turned to the baseline data and the theoretical assumptions embracing our intervention. The TTM was used to characterize the participants according to stages of change in physical activity and dietary habits. With support from previous research [141,143], we constructed a dichotomized variable comprising the three first stages in "pre-action" and the two highest latter in "action." Although this construct was valuable in our analyses, it certainly had its limitations. Previous research suggested that when comparing the five stages, those in the pre-contemplation stage share characteristics with those in the maintenance stage; these common characteristics involve a higher quality of life compared to those in the preparation stage [143]. The findings from the qualitative interviews with our participants, analyzed using grounded theory, confirmed this, suggesting that those in the middle of the extremes struggle the most between what they "want to" and what they "ought to" change [50]. Thus, merging the groups into a dichotomous variable can be problematic. Vallis and colleagues [143] further highlighted that among persons with type 2 diabetes in their sample, differences between the five stages were found in terms of gender, disease-specific variables, percent calories from fat intake, and number of daily vegetable servings. Others critiqued the stages overall, saying that the stage construct was not applicable for complex behaviors such as diabetes self-management [149]. Despite these limitations, we argue that the model provides understanding regarding the characteristics and associations in our sample.

The traditional ways of imposing change are increasingly challenged, as researchers are just beginning to recognize the importance of the intellectual mind, not just the physiologic responses and emotional struggle that persons with type 2 diabetes experience. Some additional perspectives on the difficulties of change can be found in the philosophy of science. The baseline characteristics of the current sample do not facilitate change, and we have discussed how to best meet their needs. Despite the high risk of further deteriorated health, change is not easily achieved, and behavior change can decrease quality of life as suggested in Paper II [45], and by others [57,143]. The individuals' inner thoughts regarding the diagnosis can influence health outcomes, and it may affect how he or she engages in change [102]. Further, how HCP communicate treatment strategies to meet the patients' needs, and how the society identifies the diagnosis as a disease, can be factors that both facilitate and hamper behavior change. These claims can be supported within the perception of type 2 diabetes as being either an illness, a disease, or a sickness [317] as identified by the individual with type 2 diabetes, the healthcare system, or the society. Further, this perception might influence the individual's stage of change in his or her lifestyle and aid the discussion of why

change might be difficult in this group. Discussing the perception of a diagnosis in an individual and how this affects his or her change is relevant. A starting point might be the discussion of whether persons with type 2 diabetes feel that they have “health” or if they have “disease” [318]. Which side individuals are on can affect how they change their behavior and how they self-manage. Maybe having “health” is a more positive starting point when lifestyle change is necessary. Possibly, individuals that have “health” largely succeed in their change compared to those on the “disease” side. If a person’s perception of health and disease are identified, through either conversations with HCP or through PROs, their change strategies can be individualized toward their capacity and needs, and change that is more successful might be achieved and maintained. Attitudes towards diabetes and diabetes self-management can be measured using PROs such as the heiQ [233], and an app could be tailored according to attitude, similar to preferences toward care. Thus, change in type 2 diabetes might not easily be reached, and several factors such as an appropriate and mature intervention, participants preferring the intervention, and appropriate measures to evaluate the measurement of this work.

5.4 Future directions

Despite the lack of findings in our primary outcome, I believe that technology will be an important part of patients’ lives in the future. Research to increase understanding regarding use of technology will be significant for patients, relatives, HCP, and stakeholders. To increase our knowledge regarding technology users, future research should explore preferences, literacy, and needs according to the discussion in this thesis in addition to the social, personal, and sociotechnical factors related to apps [281]. These factors can affect the usability and acceptability of mHealth, and with greater individualization of the apps, their self-management can increase.

To meet the needs and demands of the future patients, I believe that the development of some “app-bases” with uniform relevant functions would be highly valuable. Then, additional functions can be attached based on the needs related to disease duration and disease severity, health literacy, eHealth literacy, and preferences. Increased individualization could be met through preference-based app content, individualized visual content, colors, and add-ons in addition to its functions. Thus, one could allow for functions toward relevant psychosocial aspects of diabetes, such as level of distress, depressive symptoms, and anxiety by using PRO. Previous research supporting such an “app-base” is scarce; however, the different needs of different groups have been highlighted, where those who are newly diagnosed possibly needs and wants other features than those who have had diabetes for some time [213]. Similarly, we could argue that the content and language could be tailored to the level of health literacy, using more plain language and basic health knowledge, compared to a more advanced app. The same applies to eHealth literacy, where the app panel can

have a modified or simpler appearance for those with lower eHealth literacy. In addition, the individual stages of change could represent behavior change efforts, but whether the stages of change can be used to tailor an app intervention has not been discussed. However, effort has been made to establish evidence regarding the effects of tailored interventions in general on stages of change [141,319]. The TTM is based on the assumption that persons in the different stages need different interventions [130,140], which could be a basis for tailor-made app content.

Our research is based on individual self-management, through individual interventions. However, providing interactions with others going through the same experiences can increase self-management [194]. Previous research suggested that group-based interventions for self-management could reduce HbA1c in addition to improving clinical outcomes and diabetes knowledge [12,14]. Thus, whether support from an app alongside group-based education would increase the effect in behavior change in persons with type 2 diabetes is a relevant topic for research, currently under investigation at the Norwegian Centre for eHealth research [320]. On the contrary, although we argue that diabetes self-management interventions are beneficial for all, we must keep in mind that group interventions might not be for all persons with type 2 diabetes, based on their preferences [321].

mHealth in diabetes self-management has potential value, but there remains an uncertainty about for whom. The Norwegian Directorate of eHealth demands a more active patient role, where mHealth contributions will be significant in the future by enabling persons to take increased responsibility in their own lives [322]. In diabetes self-management, the active role is even clearer [11,174], suggesting that mHealth can be a positive contribution to the active role. In our intervention, we experienced active patients despite the technical issues. Possibly, if the trial had started today, the participants would have had more experience with the smartphone technology, increasing their active role. However, using technology might change or challenge the current patient role. And, as active patients are emphasized, we need to keep in mind that it might not be realistic that any given patient or participant will want, or need, to track his or her health data at all times. Thus, we need methods accounting for the dynamic, real-life use of health technology. The current methods are not optimal because diabetes self-management and use of mHealth are complex; further, intervention usage is often dynamic and frequently altered rather than static and constant. Others pointed out that the minority of apps have been scientifically evaluated, threatening the information provided to decision makers because they have limited evidence regarding the decisions they should make. Currently, participants with type 2 diabetes tailor the "*Diabetesdagboka*" in terms of their needs and preferences regarding medication, physical activity, diet, weight, BP, and through

goal setting, all of which is evaluated in a randomized crossover trial [323], that will possibly provide valuable experiences for future research.

The goal of health research is the implementation of methods to improve current care [218], but important work remains to effectively implement mHealth. Connecting data from apps to electronic health records will increase the usability of patient data. Increased use of mHealth is recommended by the Norwegian government in its white paper "The Primary Health and Care Services of Tomorrow" [324], although mobile apps are lacking as a tool for patients in the Norwegian "National Guideline for Diabetes" [10]. The Norwegian patient portal "helsenorge.no" contains the "*Kjernejournal*" and can be accessed through both the web and a mobile app [325], and it adds possibilities to save data collected through mobile apps in the future. However, the recent feature "digital dialogue with your GP" is only available through the web-portal "helsenorge.no" [326]. Possibly, the next step is to connect mHealth PRO to this access. Looking to Sweden, a study based on the Swedish Rheumatology Quality Register, with reference to the How'sYourHealth system in the US [305], allows every patient and HCP access to a patient portal. The quality register contains different PROs for data collection that are automatically saved in the electronic health records. Patients track their health between visits and can initiate electronic contact; the HCP can evaluate data accordingly. The timing, duration, and content of appointments can be individually tailored to the needs and priorities of the patients, and as a result, more time will be available for those in need of urgent care, because some might not need their appointment if they are in a more stable period. The benefits can be economic in terms of increased efficiency: the patients are satisfied, and the HCP do not spend more time compared to the traditional systems [305].

In the field of diabetes, a Swedish working group is investigating which PROs to include in their national diabetes register to ensure a systematic approach to the assessment of psychosocial and behavioral measures in a real-life setting [177]. Similarly, in Norway, a feasibility study on PRO measures is currently being carried out [176]. Their aim is to assess data collection through PCs in a waiting area, how the data are transferred to the patients electronic health records, how the PRO measures are experienced as relevant for the patients, and whether there are any associations between self-reported health, problem-areas in diabetes, and diabetes knowledge. This might be the first and most important step towards the remote collection of PRO using apps for persons with diabetes in Norway. Moreover, in the diabetes research field, there has been more value placed on PROs in addition to HbA1c when the effects of interventions were evaluated [79], also among medication trials [327]. There is more to a life with diabetes than HbA1c, and psychosocial variables can be associated with glycemic control, thus, such outcomes are crucial [175].

Some have suggested that technology will increase access to care [25], and smartphones are in almost every patient's pocket. By using patient portals and apps in combination, effectiveness might be increased compared to separate use [25]. However, security and privacy regulations at the hospitals or health care centers often reduce the possibilities of mHealth implementation, and commercialization is difficult. This might explain why apps are less scientifically tested than other medical solutions [22]. Apps should be regulated in terms of their effect, security and privacy. To date, the US FDA, the self-certificate CE-mark, and the HIPAA offer some international regulations [20,22,197,198]. Thus, current legislation regarding mHealth needs increased attention, especially regarding implementation of mHealth tools. In the Norwegian whitepaper "The Primary Health and Care Services of Tomorrow", privacy is almost absent when mHealth and welfare technology is discussed, raising questions regarding the few demands to safety and privacy among those developing and delivering mobile apps. Hopefully, the Norwegian Directorate for eHealth that opened in 2016 will inform higher demands, as they are working specifically towards information technology security [322]. In general, mobile apps are still a concern in terms of privacy, confidentiality, and risk of hacking [197]. However, the patients' possibilities to self-manage a chronic disease and communicate this process to their HCP cannot be on the opposite side of security; rather, security and self-management must be equally ensured. The implementation of apps requires new legislation regarding safety and security as well as cooperation with existing healthcare systems.

The increased implementation of technology interventions in practice also implies a change in rights for all users, and it will require a change in the political and social context [43]. The changes in the political context and among stakeholders will rely on an evidence base suggesting that mHealth is worth the effort. As suggested, current methodology for evaluating mHealth might benefit from some adjustments to help clarify its true effects among those who are interested in such interventions. Recently, the lack of consistent frameworks to assess the usefulness of health interventions to society was highlighted and debated [328]. Health policy makers and stakeholders as well as HCP and patients should be aware of the current lack of evidence regarding the effects of apps to support diabetes self-management. In addition, mHealth is not of significant focus in the "eHealth report" of 2016 [322], and corresponding with previous Norwegian whitepapers and reports [329,330], the primary focus is electronic health records and welfare technology.

Based on our findings in Paper II, we argue that change can be both positive and negative. There is no reason to believe that behavior change will come more easily in the future, but for some, a mobile app for diabetes self-management will increase their glycemic control. On the contrary, for some patients, it can be challenging to invest time and energy in behavior change because the available medications for type 2 diabetes are improving every day. A recent trial [331] found that the new oral

glucose-lowering agents were better compared to insulin in reducing the risk of all-cause mortality, CVD, and severe hypoglycemia. There is no doubt that taking oral glucose-lowering agents is easier compared to insulin, and when the effects are better, such medications will play an increasingly important part in treating type 2 diabetes, possibly by deteriorating individual behavior change.

Either way, I argue that technology can never be more than a supplement. Human contact and relationships will continue to be important, and appointments like the ones we have today will exist in some form in the future. However, and based on the discussion regarding preferences, some people will prefer more technology compared to HCP contact and will self-manage well, while others will prefer the opposite. Furthermore, it will still be the HCP's responsibility to evaluate the disease specific treatment needs of the patients.

6 Conclusion

The aim of this thesis was to investigate diabetes self-management with mHealth for persons with diabetes, providing information regarding the complexity of mHealth interventions and diabetes self-management.

After our evaluation of the diabetes diary mobile app with or without health counseling, we suggest that using mHealth for diabetes self-management might be beneficial for some, although our trial did not detect significant changes in HbA1c between the randomized groups. Our findings suggest that the mobile app with or without health counseling may be equally as effective as standard care for HbA1c. However, we did find that the group receiving the mobile app in combination with health counseling had a statistically significant greater change in the heiQ domain skills and technique acquisition, representing the knowledge-based skills used for diabetes-related symptom relief and management. Neither the RCT nor the cross-sectional study could detect causality in the current thesis, because this complex intervention consisted of several active components, making it difficult to distinguish active components leading to effects. We suggest that the field might benefit from a scientific methodological discussion, regarding the appropriateness of RCT and its components such as blinding. Assessing the characteristics of the sample in which the mHealth intervention targets can be especially valuable when the intervention consists of a mobile app. Contrary to common beliefs, we found that those aged 63 years and older used the app significantly more than their younger counterparts suggesting that nobody should be assumed to benefit from apps. Based on a theoretical model for behavior change, we characterized our participants and identified positive associations with being higher in the stages of change compared to being in the lower stages. The exception was dietary change, which was associated with a lower HRQL, interpreted as a need for more support in a challenging period. Thus, several areas for tailoring the app content were identified; preferences, disease-specific needs, and health literacy tailoring might be beneficial for the patients.

Lastly, we argue that personal communication remains crucial although technology is increasingly highlighted. Our systematic review aimed to assess mobile apps with integrated contact with HCP. Although the mHealth field is rapidly evolving, our search identified few eligible trials, and because of the poor methodological quality of the primary studies, we did not have any clear evidence. Important aspects of apps in the future revolve around the safety and privacy of health data and how collect, store and share this, and these factors might make the research field less attractive to researchers. Overall, we believe that the stakeholders need to be informed of the methodological challenges within the mHealth field, before they implement new health technology. Thus, the methodological strategies must keep their scientific standards, aiming for an unbiased evidence base.

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ERRATA

Page	Line	Original text	Correct text
31	1, Figure text	The RCT study process	Self-management with the FTA supported by health counselling.
31	Figure 3	The figure contains the wrong text within the figure with color codes: Green color=patient's situation. Blue color= intermediary organization research server.	Remove the color codes. "This study" on the left, "In the future" on the right. See attached correct figure, and page 5 in paper 1.
55	11 or table 13	The between groups effect size on change in HbA1c was 0.19, which was (…).	The between groups effect size on change in HbA1c was 0.12, which was (…).
57	5	For both change in physical activity and dietary habits, there were more persons in the action stage compared to the pre-action stage (Table 4).	For both change in physical activity and dietary habits, there were more persons in the pre-action stage compared to the action stage (Table 4).
96	36	World Health Organization. Constitution of the World Health Organization http://www.who.int/governance/eb/who_constitution_en.pdf2006 [	World Health Organization. Constitution of the World Health Organization. Basic Documents, Forty-fifth edition, Supplement, October 2006. [Available from: http://www.who.int/governance/eb/who_constitution_en.pdf]

Corrected attachments

Figure 3. Self-management with the FTA supported by health counselling.

Appendix

Forespørsel om deltakelse i forskningsprosjektet

Egenbehandling med mobiltelefon og helseveiledning via sms for personer med type 2 diabetes

Bakgrunn og hensikt
Dette er en forespørsel til deg om å delta i en forskningsstudie for å undersøke effekten av bruk av Diabetesdagbok på mobiltelefon i egenbehandlingen av type 2 diabetes, samt å undersøke effekten av helseveiledning fra diabetessykepleier via mobiltelefon og SMS. Antall personer med type 2 diabetes er i sterk økning i Norge og over hele verden. Mange av de som lever med diabetes type 2 synes det er vanskelig å følge anbefalinger om medisinering, kost og fysisk aktivitet. Hensikten med studien er å utvikle et tilbud til personer med type 2 diabetes for å øke den enkeltes mestring av sykdommen og for å kunne klare å gjennomføre eventuelle endringer i livsstil.

Selv om du får en mobiltelefon med en diabetesdagbok og veiledning fra diabetessykepleier, er det viktig at du gjennom hele studien opprettholder kontakten med din fastlege, og med annet helsepersonell (for eksempel diabetessykepleier eller legesekretær) som du jevnlig konsulterer. Ansvarlige virksomheter for studien er Høgskolen i Oslo og Akershus, og Nasjonalt Senter for Samhandling og Telemedisin. Prosjektet er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk.

Hva innebærer studien?
Dersom du kan tenke deg å delta i studien, vil vi invitere deg til et oppstartmøte der du vil få god informasjon om studien og mobiltelefonen med diabetesdagbok som dere vil få utdelt ved oppstart av prosjektet.

Personene som deltar vil tilfeldig fordeles i 3 grupper. Alle gruppene vil motta standard diabetesbehandling hos fastlegen slik de pleier:
Gruppe1 fortsetter med ordinær oppfølging av fastlegen.
Gruppe 2 vil i tillegg få en mobiltelefon med en selvhjelpsapplikasjon med fem tilgjengelige elementer der en kan registrere matvaner, fysisk aktivitet, personlige mål og å få faktainformasjon om diabetes. Dine blodsukkerdata vil automatisk bli overført fra blodsukkerapparatet ditt til telefonen, mens de øvrige data registreres av deg selv. Systemet er enkelt i bruk og du vil få god opplæring i å bruke det. Du vil kunne følge dine egne registreringer på mobiltelefonen, og kunne bruke denne som Diabetesdagbok. Dersom du gjennomfører studien vil du få beholde telefonen. Du kan bruke ditt vanlige mobiltelefonnummer.
Gruppe 3 vil i tillegg til Diabetesdagboka på mobiltelefon, få helseveiledning av diabetessykepleier basert på dine spørsmål og initiativ via sms. Tilbakemeldingene gis i form av

skriftlige tilbakemeldinger på mobiltelefonen. Tilbakemeldingene har som mål å støtte deg i å utføre det som blir anbefalt av fastlegen. Tilbakemeldingene innholder informasjon, råd, motiverende ord og spørsmål til å reflektere rundt med formål om å forbedre livsstil. Tilbakemeldingene skrives av en diabetessykepleier. Diabetessykepleieren vil i tillegg kontakte deg telefonisk for en samtale fire ganger i løpet av studien der du står fritt til å ta opp det du ønsker relatert til sykdommen din.

Den tilfeldige fordelingen i grupper vil gi oss muligheten til å sammenlikne resultatene mellom de tre ulike gruppene. Kontrollgruppen (Gruppe 1) vil følge sitt vanlige opplegg, mens formålet med gruppe 2 er å undersøke effekten av dagbokutfylling, mens formålet med gruppe 3 er å undersøke effekten av både dagbokutfylling og helseveiledning.

I tillegg vil alle personer som deltar (dvs fra alle 3 gruppene) fylle ut en del spørreskjema omhandlende livskvalitet, depresjon, mestring, kosthold og fysisk aktivitet, medisiner du bruker og bruk av helsetjenester ved oppstart av studien, etter 4 måneder, 1 år og 2 år. Vi kan komme til å be om å få anledning til å kontakte deg også på et senere tidspunkt med forespørsel om deltakelse i en oppfølgingsstudie. Du vil ved de samme tidspunkt måle din HbA1c, fastende blodsukker, lipider, vekt og høyde, mikroalbumineri/proteinuri, midtlivsmål og blodtrykk hos fastlegen din.

Mulige fordeler og ulemper
Noen kan oppleve det som belastende å ha med seg telefonen og motta meldinger på tidspunkter som kan være ubeleilige. Det krever litt tid hver dag å fylle ut dagbøkene (ca 5 minutter) og gjøre de oppgavene som foreslås. Dersom du lykkes i å endre din livsstil kan du komme til å oppleve økt forekomst av hypoglykemiepisoder (føling).
Videre vil noen kunne oppleve det som tidkrevende å fylle ut spørreskjema ved oppstart og oppfølgingene. Det tar ca 25-30 minutter å fylle ut skjemapakken hver gang.
På den annen side vil du få tett oppfølging gjennom studien, og du som skal være i en av intervensjonsgruppene vil få en mobiltelefon med en spesialtilpasset diabetesapplikasjon i form av en diabetesdagebok. Dersom vi får kjenneskap til alvorlig sykdom vil vi henvise til ordinært hjelpapparat. Ved hyppige hypoglykemiepisoder må du ta kontakt med fastlegen for å justere medikamentdose. Videre vil du bli oppfordret til å foreta egenkontroll av blodsukker daglig som en del av utfyllingen av dagboken.
Tidligere forskning har vist at en bedre mestring av sykdommen vil medføre en bedre helsetilstand og økt livskvalitet, og det er også vist at denne type veiledning kan være effektiv i forhold til å endre livsstil. Bruk av Diabetesdagboka vil medføre at registrerte data sendes til en server over en sikker forbindelse på Internett, og kostnaden (som er veldig liten: ca. 100-200 kroner årlig) må dekkes av deltageren.

Hva skjer med prøvene og informasjonen om deg?
Prøvene tatt av deg og informasjonen som registreres om deg skal kun brukes i forbindelse med denne studien. Registreringene du gjør på telefonen blir lagret i en lukket database på en sikker server bak en brannmur. Innholdet i databasen, samt alle andre data, opplysninger og prøver vil bli lagret og behandlet uten navn, fødselsnummer eller andre direkte gjenkjennende opplysninger. Det vil kun være en kode som knytter deg til dine opplysninger og prøver, og det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. All informasjon som samles vil bli anonymisert og personidentifiserbare data vil bli slettet i 2020.

Frivillig deltakelse
Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke for å delta i studien. Dette vil ikke få konsekvenser for din videre behandling eller kontakt med helsevesenet. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte stipendiat Astrid Torbjørnsen på telefon 92633075 eller prosjektleder Lis Ribu på telefon 922 06 229.

Ytterligere informasjon om studien finnes i kapittel *A* – *utdypende forklaring av hva studien innebærer.*

Ytterligere informasjon om personvern og forsikring finnes i kapittel B – *Personvern, økonomi og forsikring.*

Samtykkeerklæring følger etter kapittel B.

Med vennlig hilsen

Lis Ribu, PhD

Forskningsansvarlig, førsteamanuensis

Høgskolen i Oslo og Akershus

Astrid Grøttland

Prosjektleder

Nasjonalt senter for samhandling og telemedisin

Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse
1. Alder > 18
2. Diagnostisert diabetes type 2 i mer enn tre måneder
3. Forstå og kunne gjøre seg forstått på norsk både muntlig og skriftelig
4. Kunne benytte mobiltelefon til å gi tilbakemelding til prosjektet via SMS
5. HbA1c > 7. HbA1c er en markør for nivået av glukose i blodet (blodsukkeret). Nivået av HbA1c utrykker den gjennomsnittlige konsentrasjon av blodsukkeret i en periode fra fire uker til tre måneder.

Bakgrunnsinformasjon om studien
Antall personer med type 2 diabetes er i sterk økning i Norge og over hele verden. Økningen er tydelig og dramatisk og knyttes til endringen av matvaner og fysisk aktivitet. Livsstilsrelatert sykdom kan føre til dårligere livskvalitet for den enkelte, og til store kostnader for helsetjenesten, og det er viktig å utvikle effektive livsstilstiltak. Det er vist at omlegging av kosthold og mosjonsvaner har hatt god effekt. Forskningen har vist en korttidseffekt på forbedret blodsukkerkontroll, men det er behov for å utvikle tiltak som viser at denne effekten kan vedvare.

Hensikten med denne studien er å prøve ut en intensiv mobiltelefonbasert livsstilsintervensjon. Pasientene vil foreta dagbokregistreringer på mobiltelefonen og noen vil i tillegg kommunisere via sms med diabetessykepleier Begge er tiltak som vil kunne fremme pasientenes egenbehandling. Metoden vil baseres på kognitive adferdsterapeutiske prinsippers. Tidligere forskning har vist at bedre mestring av sykdommen vil medføre en bedre helsetilstand og økt livskvalitet, og det er også vist at veiledning basert på kognitiv atferdsterapeutiske prinsipper kan være effektive. Ved å oppnå de ønskelige resultater med studiens formål vil dette også bidra til redusering av diabetes komplikasjoner som følge av dårlig kontroll av blodsukkernivået.

Alternativ behandling pasienten dersom du velger å ikke delta i studien
Dersom du velger å ikke delta i studien påvirker det på ingen måte din pågående behandling hos din fastlege.

Undersøkelser, blodprøver og annet deltager må gjennom
Vi vil veie og måle alle som deltar i studien, videre vil vi måle HbA1c og fastlegen vil foreta en del blodprøver (fastende blodsukker, kolesterol, HDL-kolesterol og triglycerider), måle mikroalbumineri / proteinuri, måle vekt, midtlivsmål og blodtrykk når du inkluderes i studien, etter 4 måneder, og 1 år og 2 år.
Du vil videre fylle ut spørreskjema omhandlende livskvalitet, diabetesrelatert stress, kosthold og fysisk aktivitet, og bruk av medisiner ved de samme tidspunkt.
Medisinsk informasjon som tilleggsdiagnose(r) og blodprøvesvar vil bli innhentet fra fastlegen.

Tidsskjema – hva skjer og når skjer det?
Hvis du ønsker å delta så signerer du på dette skrivet. Videre blir det trukket lodd om hvilken gruppe du skal høre til (Gruppe1, 2 eller 3). En datamaskin avgjør ved "loddtrekning" (randomisering) hvilken behandling du skal få. Dette gjøres på en maskin ved Enhet for anvendt klinisk forskning, Det medisinske fakultet, NTNU. I denne databasen får du et tilfeldig nummer som lagres sammen med dine initialer og ditt fødselsår og bare forskeren kjenner koblingen mellom din behandling og din identitet. Gruppene får ulike tilbud.

<u>Hvis du blir inkludert i gruppe 1:</u>
Du vil ta HbA1c og blodprøver (se ovenfor) hos fastlegen før oppstart. Videre vil du ta blodprøver og fylle ut spørreskjemaer om sykdommen, mestring og livskvalitet som beskrevet ovenfor. Dersom du ikke sender inn skjema som avtalt vil vi purre to ganger (en gang med brev og en gang per telefon).

Hvis du blir inkludert i gruppe 2:
Du får samme tilbud som gruppe 1. Du får i tillegg en mobiltelefon med en Diabetesdagbok og får god opplæring i hvordan den brukes. Diabetesdagboka er en selvhjelpsapplikasjon med fem tilgjengelige elementer der en kan registrere matvaner, fysisk aktivitet, personlige mål og få fakta informasjon om diabetes. Dine blodsukkerdata vil automatisk bli overført fra blodsukkerapparatet ditt til telefonen, mens de øvrige data registreres av deg selv. Systemet er enkelt i bruk. Du får beholde telefonen dersom du gjennomfører studien etter ett år, og kan bruke ditt vanlige mobiltelefonnummer. Alle opplysninger vil bli behandlet konfidensielt .

Hvis du blir inkludert i gruppe 3:
Du får samme tilbud som gruppe 1 og 2. I tillegg får du en veiledningsperiode på tre måneder. Den starter med en samtale med en veileder (diabetes sykepleier). Sammen kartlegger dere kort hvordan sykdommen påvirker livet ditt og hva du ønsker støtte til og hvilken nytte du kan ha av denne veiledningen i tiden fremover. I veiledningsperiode vil du få den samme type mobiltelefon og diabetesdagbok som beskrevet for Gruppe 2, og du vil også bruke denne til å kommunisere skriftlig via sms med veilederen. Du kan sende spørsmål til diabetessykepleier, og vil du motta skriftlig tilbakemelding via sms fra sykepleieren i samarbeide med ernæringsfysiolog med ulik informasjon, råd, motiverende ord og spørsmål til å reflektere rundt. Tilbakemeldinger gis i 4 måneder og er basert på det du tar opp med sykepleier. Det er med andre ord du som styrer om du vil ha veiledning og hva du ønsker å få veiledning på relatert til din sykdom.
Noen vil senere få forespørsel om å delta i et intervju med en av forskerne for å snakke om hvordan du har opplevd veiledningen (ca en time). Alle opplysninger vil bli behandlet konfidensielt .

Mulige fordeler
Alle pasienter vil få en tettere oppfølging av sin diabetes og sin generelle helse i den perioden studien varer, og pasientene vil behandles i henhold til nasjonale retningslinjer for personer med diabetes. Pasientene i intervensjonsgruppene (dvs. gruppe 2 og 3) vil få et ekstraordinært tilbud med mobiltelefon med en applikasjon rettet mot livsstilsendring, og noen vil også få tett oppfølging tilpasset den enkelte. Pasientene vil få en mulighet til å lære noe nytt angående mestring og egenkontroll, og motiveres til endring av livsstil.

Mulige bivirkninger
Det er ingen kjente bivirkninger.

Mulige ubehag/ulemper
Noen kan oppleve det som belastende å ha med seg telefonen store deler av døgnet. Det tar litt tid å foreta registreringene, og kommunisere med diabetessykepleier via sms. Dersom tiltaket er effektivt kan du oppleve økt antall hypoglykemier (følinger). Dette vil du få hjelp av fastlegen din til å behandle (med justering av diabetes medisiner).

Pasientens/studiedeltakerens ansvar
Deltagere kan når som helst trekke seg fra studien uten å oppgi grunn til det.

At deltakeren vil bli orientert så raskt som mulig dersom ny informasjon blir tilgjengelig som kan påvirke deltakerens villighet til å delta i studien
Du vil bli orientert så raskt som mulig hvis ny informasjon blir tilgjengelig som kan påvirke villigheten din til deltagelse.

At studiedeltakeren skal opplyses om mulige beslutninger/situasjoner som gjør at deres deltagelse i studien kan bli avsluttet tidligere enn planlagt

Hvis du ikke bruker Diabetesdagboka på mobiltelefonen over en periode på tre uker vil forsker ta kontakt med deg og høre om du ønsker å avslutte behandlingen.

Kompensasjon til og dekning av utgifter for deltakere
Deltagelse skal ikke medføre betydelige utgifter for deg utover ca. 100-200 kroner i datatrafikk. For å unngå at du får ekstra kostnader ved datatrafikk i utlandet er det viktig at du husker å skru av datatrafikk på telefonen, eller unngår å bruke systemet i denne perioden. Detaljer om dette finnes i bruksanvisningen som du får utdelt.
Ekstra utgifter hos lege knyttet til prosjektet refunderes av prosjektledelsen.

Kapittel B - Personvern, økonomi og forsikring

Personvern
Opplysninger som registreres om deg er navn og personnummer samt informasjon om medisinske diagnoser, blodprøver og medisiner som innhentes fra fastlegen din. Disse opplysningene blir oppbevart i et sikkert registrer hos prosjektleder. De personidentifiserende opplysningene blir holdt adskilt fra annen registrert informasjon, for eksempel spørreskjemaer og den daglige registrerte dataen. Alle som får innsyn har taushetsplikt.

Høgskolen i Oslo og Akershus, ved avdelingsdirektør Lars Albertsen er databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre
Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at avidentifiserte opplysninger fra spørreskjemaene utleveres til internasjonale samarbeidende partnere i EU-prosjektet ”RENEWING HEALTH”. Opplysningene utleveres for å kunne sammenligne resultatene med forskning på lignende telemedisinske løsninger utført i EU prosjektet. Alle som får tilgang til disse data har taushetsplikt.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi
Prosjektet er finansiert av Norges Forskningsråd og EU-kommisjonen, samt HelseNord, Nasjonalt senter for Telemedisin og Høgskolen i Oslo og Akershus, samt har mottatt noen midler fra Høgskolen i Oslo og Akershus, Akershus Universitetssykehus og Norges Diabetesforbund.

Forsikring
Alle deltagere vil forsikres i følge regler om pasientskadeerstatning.

Informasjon om utfallet av studien
Du har rett til å få informasjon om prosjektets resultater. Resultatene vil bli publiserte i norske og internasjonale tidskrifter.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Adresse

Telefon

Fødselsår

Fastlege

Prosjektledelsen fyller ut:
ID_____
GRUPPE_____

Spørreskjema Test 1 nr.

Livsstilsstudien

"Renewing Health"

Informasjon om utfylling av spørreskjemaet

Dette er et hefte med en del spørreskjema som er stiftet sammen og som vi vil be deg om å fylle ut så godt du kan. Noen deler av skjemabunken stiller direkte spørsmål om hvordan det er å leve med diabetes type 2, om mestring av sykdommen, og om endring av livsstil. Andre deler av skjemabunken har standardiserte spørsmål som er brukt overfor ulike grupper, både friske og syke.

Les introduksjonen til hver del nøye og vurder spørsmålene i den rekkefølge de er nedskrevet. Når det gjelder hvilket svar du gir på de ulike spørsmålene er den første innskytelsen som regel best.

Selv om enkelte spørsmål kan se like ut eller er på siden av din situasjon er det viktig at du svarer på alle spørsmålene. Det finnes ingen riktige eller gale svar.

Dersom du synes det er slitsom å svare på alle spørsmålene, kan du ta deg en kort pause og fortsette etterpå.

Det er viktig at det er din oppfatning av å leve med og mestre din diabetes som kommer frem.

Har du noen spørsmål eller noe du lurer på i forbindelse med utfylling av dette spørreskjemaet, vær vennlig å ta kontakt med Lis Ribu på mobil 922 06 229 eller med en av de som deltar i oppstartmøtene.

Dag Måned År

Dato for utfylling: □□ □□ 20□□

BAKGRUNNSOPPLYSNINGER

PERSONLIGE OPPLYSNINGER

1. Fødselsdato Dag Måned År

□□ □□ 1□□□

2. Kjønn
   - ☐ Mann
   - ☐ Kvinne

3. Sivilstand *(her kan det settes flere kryss)*
   - ☐ Ugift
   - ☐ Gift/registrert partner
   - ☐ Skilt
   - ☐ Separert
   - ☐ Enke/enkemann
   - ☐ Bor sammen med noen

4. Hvor mange personer >18 år, inkludert deg selv, er i din husstand (sett antall):…….

5. Hvilken er den høyeste utdanning du har fullført*? (sett et kryss)*
   - ☐ Grunnskole
   - ☐ Real - eller middelskole, framhaldsskole, yrkesskole
   - ☐ Ett- eller toårig videregående skole
   - ☐ Artium, økonomisk gymnas eller allmennfaglig (studiekompetanse)
   - ☐ Høgskole eller universitet
   - ☐ Høgskole eller universitet mer enn fire år (for eksempel doktorgrad)

6. Hva slags arbeidsituasjon hadde du før du fikk diabetes? *(Sett et kryss)*

- ☐ Kommune- /statsansatt
- ☐ Ikke-kommune-/statsansatt
- ☐ Selvstendig næringsdrivende
- ☐ Deltid: hvis deltid, hvor stor %:…….
- ☐ Ikke-betalt arbeid
- ☐ Student, militærtjeneste
- ☐ Heltids husarbeid
- ☐ Arbeidsledig, permittert
- ☐ Pensjon
- ☐ Uføretrygd

7. Hva kan best beskrive din arbeidssituasjon de siste 12 måneder? *(Sett ett kryss)*

- ☐ Kommune-/ statsansatt
- ☐ Ikke-kommune-/ statsansatt
- ☐ Selvstendig næringsdrivende
- ☐ Deltid: hvis deltid, hvor stor %:…….
- ☐ Ikke-betalt arbeid
- ☐ Student, militærtjeneste
- ☐ Heltids husarbeid
- ☐ Arbeidsledig, permittert
- ☐ Pensjon
- ☐ Uføretrygd

8. Sett et kryss hvis du den senere tiden (de siste fire uker) har opplevd noen av følgende hendelser:

- ☐ Giftet deg/flyttet sammen med samboer
- ☐ Fått barn
- ☐ Dødsfall familie/nære venner
- ☐ Alvorlige bomessige eller økonomiske problemer
- ☐ Andre betydelige livshendelser

9. Er du kjent med bruk av datamaskin?

- ☐ Ja
- ☐ Nei

10. Er du kjent med bruk av mobiltelefon?

- ☐ Ja
- ☐ Nei

SYKDOMSSPESIFIKKE DATA

Spørsmålene videre handler om diabetes, vi ber deg å svare så godt du kan på disse.

Vær vennlig og sett ett kryss i den boksen som passer best.

DIAGNOSE

1. Hvordan ble din diabetes oppdaget?
   - ☐ Jeg søkte lege pga. symptomer
   - ☐ Ble oppdaget uten at jeg hadde symptomer (*ved legeattest, bedriftshelsekontroll, undersøkelse for annen sykdom eller lignende)*

2. Hvilket årstall ble din diabetes oppdaget?

BLODSUKKERKONTROLL

3. Måler du noen ganger hjemme hvor mye sukker (glukose) du har i blodet (blodsukker)? (*Svar "Ja" også om noen hjelper deg eller gjør det for deg)*
   - ☐ Ja
   - ☐ Nei

4. Omtrent hvor mange ganger måler du blodsukker i løpet av en vanlig dag/uke?

_____ ganger per dag
_____ ganger per uke

5. Hvordan opplever du stort sett at det er å kontrollere blodsukkeret ditt?
   - ☐ Svært vanskelig
   - ☐ Vanskelig
   - ☐ Både/og
   - ☐ Lett
   - ☐ Svært lett

6. Har du noen ganger hatt for lavt blodsukker?
   - ☐ Ja
   - ☐ Nei

7. Hvis ja, hvor mange ganger har du hatt det i den siste uka?

SYN

8. Har du hatt problemer med synet som lege har sagt skyldes din diabetes?
   - ☐ Ja
   - ☐ Nei

9. Går du til regelmessig øyeundersøkelse (av netthinna/ øyebunnen) på grunn av din diabetes?
   - ☐ Ja
   - ☐ Nei

10. Har du fått laserbehandling av øynene pga. øyebunns - forandringer som skyldes din diabetes?
   - ☐ Ja
   - ☐ Nei

FOTPROBLEMER

11. Har du hatt sår på føttene som har brukt over tre uker på å gro?
   - ☐ Ja
   - ☐ Nei

12. Har du fått amputert (skjært bort) en del av ett eller begge bein svarende til: *(Skriv årstall til høyre)*
   - ☐ Tær/fot? _____ Årstall
   - ☐ Legg/kne? _____ Årstall
   - ☐ Lår? _____ Årstall

TOBAKK OG ALKOHOL

13. Røyker du tobakk daglig?
   - ☐ Ja
   - ☐ Nei

14. Bruker du, eller har du brukt, snus?
   - ☐ Ja
   - ☐ Nei

15. Forsøk å anslå hvor ofte har du drukket minst ett glass alkohol de siste 12 måneder?

- ☐ Daglig
- ☐ 5-6 dager i uken
- ☐ 1-4 dager i uken
- ☐ 1-3 dager i måneden
- ☐ Mindre enn en dag i måneden
- ☐ Vet ikke

ANDRE SYKDOMMER OG PLAGER

16. Har du, eller har du noen gang hatt, noen av disse sykdommene/plagene

- ☐ Hjertesykdom
- ☐ Hjernesykdom
- ☐ Demens
- ☐ Kronisk obstruktiv lungsykdom (KOLS)
- ☐ Bindevevssykdom eller revmatisme
- ☐ Mavesår
- ☐ Mave-tarm sykdom
- ☐ Leversykdom
- ☐ Hjerneslag (halvsidig lammelse)
- ☐ Nyresvikt
- ☐ Kreft
- ☐ AIDS
- ☐ Psykisk lidelse
- ☐ Andre sykdommer
- ☐ Vet ikke

45555

SF-36 SPØRRESKJEMA OM HELSE

Pasnr: ☐☐☐

Dato(dd.mm.åå) ☐☐.☐☐.☐☐

INTRODUKSJON: Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å sette et kryss (X) i den boksen som passer best for deg. Hvis du er usikker på hva du vil svare, vennligst svar så godt du kan.

---

1. Stort sett, vil du si at din helse er

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

2. Sammenlignet med for ett år siden, hvordan vil du si at din helse stort sett er nå ?

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

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye?

	Ja, begrenser meg mye	Ja, begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a. Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	☐	☐	☐
b. Moderate aktiviteter som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid	☐	☐	☐
c. Løfte eller bære en handlekurv	☐	☐	☐
d. Gå opp trappen flere etasjer	☐	☐	☐
e. Gå opp trappen en etasje	☐	☐	☐
f. Bøye deg eller sitte på huk	☐	☐	☐
g. Gå mer enn to kilometer	☐	☐	☐
h. Gå noen hundre meter	☐	☐	☐
i. Gå hundre meter	☐	☐	☐
j. Vaske eller kle på deg	☐	☐	☐

4. I løpet av de siste 4 ukene, hvor ofte har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	☐	☐	☐	☐	☐
b. Du har **utrettet mindre** enn du hadde ønsket	☐	☐	☐	☐	☐
c. Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål	☐	☐	☐	☐	☐
d. Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (for eksempel fordi det krevde ekstra anstrengelser)	☐	☐	☐	☐	☐

5. I løpet av de 4 siste ukene, hvor ofte har du hatt noen av de følgende problemer i ditt arbeid eller andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som for eksempel å være deprimert eller engstelig) l?

	Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	☐	☐	☐	☐	☐
b. Du har **utrettet mindre** enn du hadde ønsket	☐	☐	☐	☐	☐
c. Du har utført arbeidet eller andre gjøremål mindre **grundig** enn vanlig	☐	☐	☐	☐	☐

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

Ikke i det hele tatt	Litt	En del	Mye	Svært mye
☐	☐	☐	☐	☐

7. Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene?

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

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt vanlige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt	Litt	En del	Mye	Svært mye
☐	☐	☐	☐	☐

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

	Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Følt deg full av liv?	☐	☐	☐	☐	☐
b. Følt deg veldig nervøs?	☐	☐	☐	☐	☐
c. Vært så langt nede at ingenting har kunnet muntre deg opp?	☐	☐	☐	☐	☐
d. Følt deg rolig og harmonisk?	☐	☐	☐	☐	☐
e. Hatt mye overskudd?	☐	☐	☐	☐	☐
f. Følt deg nedfor og deprimert?	☐	☐	☐	☐	☐
g. Følt deg sliten?	☐	☐	☐	☐	☐
h. Følt deg glad?	☐	☐	☐	☐	☐
i. Følt deg trett?	☐	☐	☐	☐	☐

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følesesmessige problemer påvirket din sosiale omgang (som det å besøke venner, slektninger osv.) ?

Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
☐	☐	☐	☐	☐

11. Hvor RIKTIG eller GAL er hver av de følgende påstander for deg ?

	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a. Det virker som om jeg blir syk litt lettere enn andre	☐	☐	☐	☐	☐
b. Jeg er like frisk som de fleste jeg kjenner	☐	☐	☐	☐	☐
c. Jeg tror at helsen min vil forverres	☐	☐	☐	☐	☐
d. Jeg har utmerket helse	☐	☐	☐	☐	☐

Vennligst kontroller at du har besvart alle spørsmålene

Senter for epidemiologiske studiers depresjonsskala
(Norwegian version of CES-D, NIMH)

Nedenfor er det en liste med måter du kan ha følt deg eller oppført deg på. Vennligst si meg hvor ofte du har følt deg slik i løpet av den siste uka.

	I løpet av siste uke			
	Sjelden eller aldri (mindre enn 1 dag)	En del eller litt av tiden (1-2 dager)	En moderat del av tiden eller ganske ofte (3-4 dager)	Mesteparten av eller hele tiden (5-7 dager)
1. Jeg ble plaget av ting som vanligvis ikke plager meg.	☐	☐	☐	☐
2. Jeg hadde ikke lyst til å spise; jeg hadde dårlig appetitt	☐	☐	☐	☐
3. Jeg følte at jeg ikke klarte å slutte å føle meg nedfor, selv med hjelp fra familie eller venner.	☐	☐	☐	☐
4. Jeg følte at jeg var like verdifull som andre folk.	☐	☐	☐	☐
5. Jeg hadde vansker med å konsentrere meg om det jeg holdt på med.	☐	☐	☐	☐
6. Jeg følte meg deprimert.	☐	☐	☐	☐
7. Jeg følte at alt jeg gjorde var en anstrengelse.	☐	☐	☐	☐
8. Jeg følte meg optimistisk når det gjaldt fremtiden.	☐	☐	☐	☐
9. Jeg tenkte at livet mitt hadde vært mislykket.	☐	☐	☐	☐
10. Jeg følte meg redd.	☐	☐	☐	☐
11. Søvnen min var urolig.	☐	☐	☐	☐
12. Jeg var glad og lykkelig.	☐	☐	☐	☐

	I løpet av siste uke			
	Sjelden eller aldri (mindre enn 1 dag)	En del eller litt av tiden (1-2 dager)	En moderat del av tiden eller ganske ofte (3-4 dager)	Mesteparten av eller hele tiden (5-7 dager)
13. Jeg snakket mindre enn vanlig.	☐	☐	☐	☐
14. Jeg følte meg ensom.	☐	☐	☐	☐
15. Folk var uvennlige.	☐	☐	☐	☐
16. Jeg gledet meg over livet.	☐	☐	☐	☐
17. Jeg hadde gråteanfall.	☐	☐	☐	☐
18. Jeg følte meg trist.	☐	☐	☐	☐
19. Jeg følte at folk mislikte meg.	☐	☐	☐	☐
20. Jeg kunne ikke “komme i gang”.	☐	☐	☐	☐

hei **Q**

health education impact questionnaire

Versjon 2.0

Instruksjoner

Angi hvor enig eller uenig du er i de følgende påstandene ved å krysse av for det svaret som best beskriver deg nå.

Eksempel
Kari Nordmann har besvart undersøkelsen på følgende måte:

Merk av i en rute ved å sette ett kryss:
☐☐☐☒

	Akkurat <u>nå</u>			
Påstand:	veldig uenig	uenig	enig	veldig enig
1. Jeg holder på med noen av mine hobbyer	☐	☐	☒	☐
2. Jeg planlegger å utføre en fysisk aktivitet	☐	☒	☐	☐

På spørsmål 1 viser Karis svar at hun akkurat nå er <u>enig</u> i at hun i det siste har holdt på med noen av sine hobbyer.

På spørsmål 2 er Kari <u>uenig</u> i påstanden om at hun akkurat nå planlegger å utføre en fysisk aktivitet.

Vennligst svar på følgende spørsmål:

Merk av i en rute ved å sette ett kryss:

☐☐☐☒

Akkurat <u>nå</u>

	veldig uenig	uenig	enig	veldig enig
1. De fleste dagene i uken utfører jeg minst én aktivitet for å bedre helsen min (f.eks. gå tur, slappe av, trene)	☐	☐	☐	☐
2. De fleste dagene gjør jeg noen av tingene jeg virkelig liker	☐	☐	☐	☐
3. I tillegg til legebesøk følger jeg regelmessig med på endringer i helsen min	☐	☐	☐	☐
4. Jeg bekymrer meg ofte for helsen min	☐	☐	☐	☐
5. Jeg prøver å få mest mulig ut av livet	☐	☐	☐	☐
6. Jeg vet hva som kan utløse helseproblemene mine og gjøre dem verre	☐	☐	☐	☐
7. Helseproblemene mine gjør meg svært misfornøyd med livet	☐	☐	☐	☐
8. Jeg gjør interessante ting i livet mitt	☐	☐	☐	☐
9. Jeg utfører minst én fysisk aktivitet hver dag i minst 30 minutter (f.eks. gå tur, hagearbeid, husarbeid, dans, svømming)	☐	☐	☐	☐
10. Jeg har planer om å gjøre ting jeg liker i løpet av de neste dagene	☐	☐	☐	☐
11. Jeg har svært god forståelse av når og hvorfor jeg skal ta medisinene mine	☐	☐	☐	☐
12. Jeg føler meg ofte sint når jeg tenker på helsen min	☐	☐	☐	☐
13. De fleste dagene i uken setter jeg av tid til helsebringende aktiviteter (f.eks. gå tur, slappe av, trene)	☐	☐	☐	☐
14. Jeg føler håpløshet på grunn av helseproblemene mine	☐	☐	☐	☐

☐☐☐☒

Akkurat nå

	veldig uenig	uenig	enig	veldig enig
15. Jeg er aktivt engasjert i livet	☐	☐	☐	☐
16. Når jeg har helseproblemer, har jeg en klar forståelse av hva jeg må gjøre for å holde dem i sjakk	☐	☐	☐	☐
17. Jeg passer nøye på helsen min og gjør det som er nødvendig for å holde meg så frisk som mulig	☐	☐	☐	☐
18. Jeg blir opprørt når jeg tenker på helsen min	☐	☐	☐	☐
19. Som trening spaserer jeg minst 15 minutter hver dag de fleste dagene i uken	☐	☐	☐	☐
20. Når jeg tar helsen min i betraktning, har jeg realistiske forventninger til hva jeg kan og ikke kan gjøre	☐	☐	☐	☐
21. Hvis jeg tenker på helsen min, blir jeg deprimert	☐	☐	☐	☐
22. Hvis jeg trenger hjelp, har jeg mange mennesker som jeg kan støtte meg til	☐	☐	☐	☐
23. Jeg har effektive måter å hindre at symptomene mine (f.eks. ubehag, smerte, stress) begrenser det jeg kan gjøre i livet	☐	☐	☐	☐
24. Jeg har et svært godt forhold til mitt helsepersonell	☐	☐	☐	☐
25. Jeg vet godt hvordan jeg kan håndtere helseproblemene mine	☐	☐	☐	☐
26. Når jeg har symptomer, har jeg ferdigheter som hjelper meg å mestre dem	☐	☐	☐	☐
27. Jeg prøver å ikke la helseproblemene hindre meg i å nyte livet	☐	☐	☐	☐
28. Jeg har nok venner som kan hjelpe meg med å mestre helseproblemene mine	☐	☐	☐	☐
29. Jeg kommuniserer godt og tillitsfullt med legen om de helsemessige behovene mine	☐	☐	☐	☐

☐☐☐☒

Akkurat <u>nå</u>

	veldig uenig	uenig	enig	veldig enig
30. Jeg har god kunnskap om hva slags hjelpemidler som kan gjøre livet mitt lettere	☐	☐	☐	☐
31. Når jeg føler meg syk, så forstår familien min og omsorgspersonell virkelig hva jeg går gjennom	☐	☐	☐	☐
32. Jeg gir tillitsfullt den informasjonen helsepersonell trenger for å hjelpe meg	☐	☐	☐	☐
33. Jeg får behovene mine dekket av tilgjengelige helseressurser (f.eks. leger, sykehus og offentlige tjenester)	☐	☐	☐	☐
34. Helseproblemene ødelegger ikke livet mitt	☐	☐	☐	☐
35. Generelt føler jeg at jeg blir tatt godt vare på av venner eller familie	☐	☐	☐	☐
36. Jeg føler at jeg har et meget godt liv, selv når jeg har helseproblemer	☐	☐	☐	☐
37. Jeg får nok muligheter til å snakke om helseproblemene mine med folk som forstår meg	☐	☐	☐	☐
38. Jeg jobber i et team sammen med leger og annet helsepersonell om mine helseproblemer	☐	☐	☐	☐
39. Jeg lar ikke helseproblemene mine styre livet mitt	☐	☐	☐	☐
40. Hvis andre kan mestre slike problemer som jeg har, kan jeg det også	☐	☐	☐	☐

Diabetes empowermentskala - kortform (DES-SF)

De åtte uttalelsene nedenfor utgjør DES-SF.

Kryss av i firkanten som passer best for deg.

Generelt sett tror jeg at jeg:

1. ...vet hvilke deler av egen diabetes behandling som jeg ikke er fornøyd med.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig
2. …kan få mine diabetesmål til å bli en gjennomførbar plan.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig
3. ...kan prøve ut forskjellige måter å overvinne hindringene for å nå mine diabetesmål.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig
4. ...kan finne måter å ha det **bedre på** med diabetes.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig

5. ...kjenner til de **positive** måter jeg kan mestre diabetes-relatert stress på.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig
6. ...kan ved behov be om støtte til å leve med og behandle min diabetes.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig
7. ...vet hva som motiverer meg i min egen behandling av diabetes.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig
8. ...vet nok om meg selv som person slik at jeg kan ta de valgene som er riktige for meg når det gjelder å behandle min diabetes.	☐1 Svært uenig	☐2 Litt uenig	☐3 Verken enig eller uenig	☐4 Litt enig	☐5 Svært enig

MOSJON/FYSISK AKTIVITET

Med mosjon mener vi at du for eksempel går tur, går på ski, dansing, svømming eller driver trening/idrett

1. Hvor ofte driver du med mosjon? *(Ta et gjennomsnitt)*
   - ☐ Aldri
   - ☐ Sjeldnere enn en gang i uka
   - ☐ En gang i uka
   - ☐ 2-3 ganger uka
   - ☐ Omtrent hver dag

2. Dersom du driver slik mosjon, så ofte som en eller flere ganger i uka; hvor hardt mosjonerer du? *(Ta et gjennomsnitt)*
   - ☐ Tar det rolig uten å bli andpusten eller svett
   - ☐ Tar det så hardt at jeg blir andpusten og svett
   - ☐ Tar meg nesten helt ut

3. Hvor lenge holder du på hver gang? *(Ta et gjennomsnitt)*
   - ☐ Mindre enn 15 minutter
   - ☐ 15-29 minutter
   - ☐ 30 minutter – 1time
   - ☐ Mer enn 1 time

4. Har du vanligvis minst 30 minutter fysisk aktivitet daglig på arbeid og/eller fritida?
   - ☐ Ja
   - ☐ Nei

5. Omtrent hvor mange timer sitter du i ro på en vanlig hverdag? (*Regn med både jobb og fritid*)

6. Følgende spørsmål handler om hvor motivert du er for fysisk aktivitet *(sett kun ett kryss)*

- ☐ For tiden er jeg ikke fysisk aktiv, og jeg har ingen planer om å bli fysisk aktiv i løpet av de neste 6 måneder
- ☐ For tiden er jeg ikke fysisk aktiv, men jeg tenker på å bli mer fysisk aktiv i løpet av de neste 6 måneder
- ☐ For tiden er jeg noe fysisk aktiv, men det er ikke regelmessig
- ☐ For tiden er jeg regelmessig fysisk aktiv, men det er først i løpet av de siste 6 månedene jeg har begynt med det
- ☐ For tiden er jeg fysisk aktiv, og jeg har vært det lengre enn de siste 6 måneder.

MAT OG DRIKKE

1. Hvor ofte spiser du disse matvarene? (g.=ganger)
(Sett ett kryss for hver linje)

	Sjelden/ aldri	1-3 g. per mnd	1-3.g per uke	4-6 g. per uke	1-2 g per dag	3 g. el mer
Frukt, bær	☐	☐	☐	☐	☐	☐
Rå grønnsaker, salat	☐	☐	☐	☐	☐	☐
Kokte grønnsaker	☐	☐	☐	☐	☐	☐
Kokte poteter	☐	☐	☐	☐	☐	☐
Egg	☐	☐	☐	☐	☐	☐
Ost (alle typer)	☐	☐	☐	☐	☐	☐
Fjørfe til middagsmat (f eks kylling)	☐	☐	☐	☐	☐	☐
Annet kjøtt til middagsmat	☐	☐	☐	☐	☐	☐
Fet fisk til middag eller pålegg	☐	☐	☐	☐	☐	☐
Sjokolade/smågodt	☐	☐	☐	☐	☐	☐
Chips, potetgull	☐	☐	☐	☐	☐	☐

2. Hvor mye drikker/spiser du vanligvis av følgende matvarer <u>per dag</u>?
(Sett ett kryss for hver linje)

		Antall per dag				
	Bruker ikke	Færre enn ett	1-2	3-4	5-6	7-8	9+
Helmelk (søt og sur), glass	☐	☐	☐	☐	☐	☐	☐
Lettmelk (søt og sur), glass	☐	☐	☐	☐	☐	☐	☐
Skummet melk (søt og sur), glass	☐	☐	☐	☐	☐	☐	☐
Brød (inkl. knekkebrød), skiver ...	☐	☐	☐	☐	☐	☐	☐

3. Hva slags fett bruker du oftest?
(Sett ett kryss for hver linje)

	Meieri-smør	Hard margarin	Myk/lett margarin	Oljer	Bruker ikke fett
På brødet	☐	☐	☐	☐	☐
I matlagingen	☐	☐	☐	☐	☐

4. Hvis du bruker smør eller margarin på brødet, hvor mange skiver rekker en liten porsjonspakning vanligvis til? *Vi tenker på en slik porsjonspakning som du får på kafé, fly o.l. (12 gram)*

En slik porsjonspakning rekker til ca. ☐☐ skiver

5. Har du endret kostvanene dine det siste året?

JA ☐ NEI ☐

Hvis "JA", vennligst spesifiser:…….....
……..
……..

6. Følgende spørsmål handler om hvor motivert du er for å spise slik som du er anbefalt når du lever med Type 2 diabetes *(sett kun ett kryss)*

☐ For tiden spiser jeg ikke som anbefalt, og jeg har ingen planer om å spise som anbefalt i løpet av de neste 6 måneder

☐ For tiden spiser jeg ikke som anbefalt, men jeg tenker på å spise som anbefalt i løpet av de neste 6 måneder

☐ For tiden spiser jeg som anbefalt, men jeg er ikke helt konsekvent

☐ For tiden spiser jeg som anbefalt, men det er først i løpet av de siste 6 månedene jeg har begynt med det

☐ For tiden spiser jeg som anbefalt, og jeg har spist som anbefalt de siste 6 måneder

Har du fylt ut hele skjema på egenhånd?

Ja ☐

Nei ☐

Takk for at du har tatt deg tid til å fylle ut denne pakken med skjema!

APPENDIX III. Interpretation of Risk of Bias domains and relevance for the current objective

Domain	Support for judgement
Selection bias	
Random sequence generation	Er det oppgitt tilstrekkelig informasjon vedrørende randomiseringsprosedyre/ allokerings sekvens (for eksempel blokk randomisering) slik at man med sikkerhet kan fastslå en tilfeldig fordeling av deltakere i gruppene, og at gruppene vil bli like.
Allocation concealment	Er det oppgitt tilstrekkelig informasjon slik at man med sikkerhet kan fastslå at det ikke vil være mulig å finne ut av gruppefordeling på forhånd? For eksempel ved bruk av fødselsdato kan man finne ut av på forhånd hvilken gruppe man kommer i og den som rekrutterer kan ta gjøre om på sin rekkefølge slik at «Hansen» kommer i ønsket gruppe. Dette vil være HIGH risk. Web-based etc. vil være low risk.
Performance bias	
Blinding of participants and personnel	Blinding er svært vanskelig av apper, men må også anta at det at deltakeren vet at de er i intervensjonsgruppen kan positivt forsterke bruk, og derfor vil manglende blinding gi HIGH risk. Dersom studien ikke har blinding som tema skal det settes UNCLEAR risk.
Detection bias	
Blinding of outcome assessment	Blinding av utfall er mulig selv i teknologiske studier, og bør diskuteres. Er det ikke blindet er det HIGH risk, er det ikke nevn er det unclear.
Attrition bias	
Incomplete outcome data	Frafall bør oppgis og årsak til dette, og frafallet bør være like stort i gruppene. Dersom frafall ikke er rapportert skal det og man ikke kan vurdere risiko for bias relatert til frafall skal det stå «unclear»
Reporting bias	
Selective reporting	Om det er tilgjengelig protokoll eller registrering i for eksempel clinicaltrials.gov slik at rapportert outcome kan etterprøves om er det outcome de har oppgitt å studere, eller dersom de oppgitte outcome ikke er fullstendig rapportert. Om man ikke kan kontrollere dette er high risk.
Other bias	
Other sources of bias	Er studien problematisk på andre vis, er det knyttet svindelsaker til den etc.

Paper I-III