Effect of an mHealth intervention for persons with type 2 diabetes and their acceptability of the device

results from the Norwegian randomised controlled study in RENEWING HeALTH

PhD thesis

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Takk

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Abbreviations

CES-D	Center for Epidemiologic Studies Depression Scale
eHealth	electronic health
heiQ	The Health Education Impact Questionnaire
RENEWING HeALTH	The REgioNs of Europe WorkINg toGether for HEALTH
MAST	Model for ASsessment of Telemedicine
HbA_{1c}	Glycated hemoglobin
mHealth	mobile health
PhD	Doctor of Philosophy
RCT	randomized controlled trial
SF-36	The Short Form Health Survey
SUTAQ	The Service User Technology Acceptability Questionnaire
WHO	World Health Organization

List of papers

Paper I

Torbjørnsen, A., Jenum, A. K., Småstuen, M. C., Årsand, E., Holmen, H., Wahl, A. K., & Ribu, L. (2014). A Low-Intensity Mobile Health Intervention With and Without Health Counseling for Persons With Type 2 Diabetes, Part 1: Baseline and Short-Term Results From a Randomized Controlled Trial in the Norwegian Part of RENEWING HEALTH. JMIR Mhealth Uhealth, 2(4), e52.

Paper II

Holmen, H., Torbjørnsen, A., Wahl, A. K., Jenum, A. K., Smastuen, M. C., Årsand, E., & Ribu, L. (2014). 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, 2(4), e57.

Paper III

Torbjørnsen, A., Småstuen, M. C., Jenum, A. K., Årsand, E., & Ribu, L. (2018). The Service User Technology Acceptability Questionnaire: Psychometric Evaluation of the Norwegian Version. JMIR Hum Factors, 5(4), e10255. doi:10.2196/10255

Paper IV

Torbjørnsen, A., Småstuen, C. M., Jenum, K. A., Årsand, E., & Ribu, L. (2018). Acceptability of an mHealth App Intervention for Persons With Type 2 Diabetes and its Associations With Initial Self-Management: Randomized Controlled Trial. JMIR Mhealth Uhealth, 6(5), e125.

Paper V

Torbjørnsen, A., Ribu, L. Rønnevig, M., Grøttland, A., & Helseth, S. (submitted). Users' acceptability of a mobile application for persons with type 2 diabetes: a qualitative study

Summary

Introduction: The prevalence of type 2 diabetes is rising in Norway, and multifactorial treatment for addressing risk factors has proven to reduce complications and increase life span. The use of diabetes education and support through health technology is currently under development.

Aim: The aim was to investigate the effects of a three-armed randomised controlled trial of a self-management mobile health solution for persons with type 2 diabetes using a diabetes diary app, with or without health counselling for 4 months, and the participants' acceptability of the device.

Methods: The Norwegian randomised controlled study for RENEWING HeALTH was part of a European collaboration. The study had three arms: a control group (n=50) and two intervention groups (n=51+50), both receiving the diabetes diary app for 1 year, where one of the groups received health counselling for the first 4 months. Inclusion criteria: type 2 diabetes, ≥ 18 years, HbA_{1c} ≥ 7.1% (54.1 mmol/mol). Primary outcome was HbA_{1c}, and secondary outcomes included health-related quality of life (SF-36), self-management (heiQ), depression (CES-D), lifestyle characteristics, and acceptability (SUTAQ). A psychometric evaluation of SUTAQ was performed. We conducted in-depth interviews after 1 year (n=24), exploring the participants' acceptability of the intervention.

Results: The intervention had no effect when compared with the control group at the 4-month or 1-year follow-up. We did not find the acceptability questionnaire to be a valid instrument. We did find an associations between the acceptability domain *perceived benefit* at 1 year and baseline self-management. These associations did not withstand multiple linear regression analysis. Frequency of use of the app was the strongest predictor of perceived benefit. The qualitative evaluation revealed possibilities for learning to manage type 2 diabetes by using a diabetes diary app with some support from health care personnel, but the app could lead to digital and clinical distress in the participants, due to the technology and clinical measures in the app.

Conclusion: The diabetes diary app and health technology intervention had no effect. Frequency of use of the app was the strongest predictor of participants' perceived benefit, although the participants reported some distress due to the intervention.

Contents

1.0 Introduction

Type 2 diabetes and its complications constitute a major personal, social, and financial burden worldwide. The International Diabetes Federation (IDF) has estimated a prevalence of diagnosed diabetes in the adult population in Europe of 6 – 7%. Europe has the second highest healthcare expenditures related to diabetes in the world, after the North American and the Caribbean regions [1]. Approximately 87 – 91% of people with diabetes have type 2 diabetes [2]. In Norway, the prevalence of type 2 diabetes increased from 4.9% to 6.1% in the 30 – 89 age group between 2009 and 2014. Of these, 23.6% did not receive glucose lowering medication treatment [3].

Intensified multifactorial treatment addressing all risk factors has been found to reduce complications and increase lifespan [4,5]. There is therefore a need for initiatives that can limit the economic and not least, the personal burden this poses [1].

Clinical guidelines for diabetes care have increased the emphasis on patient-centred and practical strategies for health care in order to support behavioural change, and tailor interventions to individual needs [6,7]. The American Diabetes Association has now included a recommendation for the use of technology in health care self-management education and support in their standards of medical care for diabetes [6]. The 2019 version of the "Standards of Medical Care in Diabetes" has a separate section dedicated to diabetes technology, although this is mostly related to glucose monitoring for type 1 diabetes. The awareness and use of technology-enabled diabetes education are expected to rise [8]. In the Norwegian clinical guidelines for diabetes, mobile apps for people with type 2 diabetes are recommended primarily to measure physical activity and its influence on blood glucose with the use of mobile apps as a means of motivation for increased physical activity [7]. *Mobile applications*, or the preferred abbreviation *apps* [9], can be defined as "software systems operating on mobile devices" [10].

A recent systematic review claims that mobile health could ease the burden for persons with type 2 diabetes through easier access to personalised health education and medical resources at home [11]. One of the first self-management apps for persons with diabetes on a smartphone was developed and evaluated by Eirik Årsand, Professor of eHealth and informatics at the UiT The Arctic University of Norway, in his PhD in 2009 [12]. Nevertheless, we are still in the early stages of the development, use and integration of digital health in diabetes care [13,14].

Furthermore, digital health has the potential to become a useful supplement to clinical care. However, to enhance clinical outcomes and reduce both personal and provider burdens, digital health technology must become better integrated with health care systems [13].

User perspectives are important, and it is essential to determine whether users will accept the digital solutions and feel comfortable with the use of mobile apps as a part of health care services. Furthermore, knowledge about whether the provided technology has the potential to reach all individuals in need of care, and at the same time seem personalised, reliable, secure and effective is urgently needed [13]. The use of apps can change both patient and personnel attitudes toward health care and shared decision-making, with consequences for both groups and their interactions. The quality of the apps and the context of use are also important. There are no official standards or mandatory procedures for scientifically testing apps before their launch, as there are for other medical technical equipment. There are also different requirements for quality, with partly unregulated market for apps on the one hand, and the standards of care of the health systems on the other [15]. Digital interventions in health care may cause unintended harm should they replace usual care [16]. Furthermore, digital interventions may cause confusion and distress in vulnerable persons [17].

This thesis is based on a randomised controlled trial under the umbrella of a larger European Union study: the REgioNs of Europe WorkINg toGether for HEALTH (RENEWING HeALTH), with studies from nine regions in Europe, including our Norwegian study. The RENEWING HeALTH collaboration used the Model for ASsessment of Telemedicine (MAST) applications as a guide for conducting a broad evaluation of the studies in the project [18]. The European Commission started the process in 2009 with workshops and a literature review to develop a framework to assess telemedicine apps and enable decision makers to choose an appropriate evaluation methodology. The overall objective of RENEWING HeALTH was to produce evidence and decision support for European health policies regarding the future implementation of telemedicine services with the potential to improve self-care at a reduced cost [19]. In the Norwegian pilot in RENEWING HeALTH, we evaluated whether the introduction of a personalised and technology supported self-management app, with or without health counselling, had produced benefits in terms of improved clinical outcomes and self-management in persons with type 2 diabetes. First, the two intervention groups and the control group received usual care. The two intervention

arms included a mobile phone with a diabetes diary app for one year. In addition, one intervention group received health counselling from a diabetes specialist nurse for the first four months of the study.

The users' engagement with a diabetes mobile app might have the potential to improve clinical outcomes, and various factors could affect this engagement in different directions, towards either more or less use [20]. Furthermore, an understanding of the individuals' acceptability of the technology could further increase the potential effectiveness [14,21]. This thesis investigates both the effect of the intervention, and the participants' acceptability of a diabetes mobile app.

1.1 Background and recent evidence

1.1.1 Type 2 diabetes

Type 2 diabetes is a condition that involves both insulin resistance and an absolute or relative reduction in the secretion of insulin from the pancreas [22]. The relative contribution of insulin resistance and reduced secretion may differ between individuals, but the result is increased plasma glucose, usually both in the fasting and postprandial state. Type 2 diabetes is caused by gene-environment interactions [23,24]. Obesity is the main risk factor for developing type 2 diabetes, often in combination with physical inactivity [25-29]. Disease-specific microvascular complications and macrovascular complications are associated with hyperglycaemia in type 2 diabetes. Microvascular complications present as neuropathy, nephropathy, and retinopathy, while macrovascular complications present as cardiovascular diseases, cerebrovascular (stroke) and peripheral vascular diseases which can lead to severe peripheral wounds and possibly to amputations [30,31].

According to the Norwegian clinical guidelines for diabetes, general practitioners, possibly also the primary health care team, including nurses and other health care personnel, have the primary responsibility for the diagnosis, treatment and follow-up of persons with type 2 diabetes. To reduce the risk of complications, treatment targets for persons with diabetes are included in the diabetes guidelines. Glycated haemoglobin (HbA_{1c}) is used as a reliable measure for average blood glucose,

and indicates the risk for complications related to poor metabolic control. Normal HbA_{1c} is considered to be 6% (42 mmol/mol) or less. When our study began in 2011, treatment targets according to the Norwegian clinical guidelines were [32]:

- Physical activity, a daily minimum of 30 minutes of walking or equivalent moderate activity
- No smoking
- $HbA_{1c} \leq 7{,}0$ % (53 mmol/mol)
- Fasting plasma glucose 4 – 6 mmol/l
- Non-fasting plasma glucose 4 -10 mmol/l
- Blood pressure < 135/80 mmHg
- LDL-cholesterol ≤ 2,5 (1,8) mmol/l

The Norwegian National Diabetes Plan 2017 – 2021 [33] emphasises that self-management is essential in patient education and diabetes care. Patient involvement, tailored care and close collaboration between the person with type 2 diabetes and health care personnel is usually necessary for self-management and for achieving the treatment target. Involvement of health personnel other than the general practitioner, and possibly the additional use of digital services might also be important. For most people who are diagnosed with diabetes, moderate changes in lifestyle, particularly in terms of diet, increased physical activity, and, if relevant, smoking cessation and weight reduction are fundamental in type 2 diabetes care [33]. A modified diet, and regular physical activity can improve metabolic control and have a positive effect on lipid levels and blood pressure [34-36]. The Norwegian clinical diabetes guidelines recommends a largely plant-based diet, including fibre, unsaturated fat and a reduced amount of processed foods, salt and sugar [7,32]. Several alternative diets can be used, depending on individual preferences, but the Norwegian diabetes guidelines recommends a Mediterranean diet, a moderately reduced carbohydrate intake, or a diet with low glycaemic index and moderate to intense physical activity, including endurance and strength, for at least 150 minutes a week [32]. The recent Norwegian clinical guidelines from 2016 [7] are similar to the guidelines from 2009 [32] based on diet and physical activity recommendations. Only a few details differ, such as the additional diets in the 2016 guidelines. The guidelines from 2016 have also added a chapter on

communication, management and motivation, and tailoring treatment targets to the patients' situation.

The burden of living with diabetes is related to maladjustments to diet, exercise, medication, fear of future complications, guilt and shame of unhealthy lifestyle and obesity. These are all factors that could lead to diabetes-specific emotional distress (diabetes distress). Perrin et al. found through meta-analyses that diabetes distress had an overall prevalence of 36%, measured by the Problem Areas in Diabetes (PAID) scale and the Diabetes Distress Scale (DDS) [37-39]. Furthermore, living with diabetes affects a person's health-related quality of life [40]. Other psychological comorbidities such as depression is also common among persons with type 2 diabetes. Depression could contribute to a reduced capacity for self-care. Health care personnel must therefore be aware of potential depression, and diagnose and treat this condition based on the needs of their patients [41].

In Norway, persons diagnosed with type 2 diabetes should be offered Start Courses in Diabetes in order to provide education and support self-management together with their families [7,42]. In some, but not all municipalities, general practitioners may refer persons with diabetes to Healthy Life Centres [Frisklivssentraler] [43]. These centres offer individual and group-based support aimed at changing dietary habits and increasing physical activity, although usually for a maximum of three months.

Findings from the ROSA4 study indicate that there have been some improvements in general practitioners' control of risk factors for type 2 diabetes over the past decade in Norway [44]. The use of a structured electronic form in the follow-up enhances the possibility of complying with the guidelines, although general practitioners' screening of microvascular complications could be considerably improved [45].

1.1.2 Diabetes self-management

Lorig and Holman studied and conceptualised self-management, and found that Thomas Creer was one of the first to use the concept self-management in 1976. He and his colleagues introduced self-management during the 1960s in the rehabilitation of children with chronic diseases. The term self-management means that the patient is active in her/his own treatment. Living with a chronic disease (like diabetes) requires

daily attention for the rest of the patient's life, and health care personnel should educate such patients for this task. In contrast with the principle of self-management, treatment was previously standardised by health care personnel, and interventions focused on enhancing the patients' adherence or compliance to standard goals. These interventions were less likely to succeed than self-management, where the goal is to self-tailor treatment [46]. Funnell et al. defined self-management for diabetes to mean that a person not only takes physical factors related to the disease into account, but also psychological factors such as culture, lifestyle, goals, priorities and personal values [47]. According to Lorig and Holman, there are five core self-management skills. These include problem-solving, decision-making, resource utilisation, the formation of partnerships with health care providers and using them as partners and supervisors, and taking action to change behaviour [46].

The American Diabetes Association standards on medical care for diabetes lists self-management, education and support as fundamental for lifestyle management. Diabetes self-management education aims to improve knowledge, and ability for self-care and diabetes self-management support to assist in both implementing and sustaining skills and actual behavioural changes [6].

1.1.3 Mobile health

The use of mobile technology to support diabetes self-management has expanded with increased availability. Enhanced benefits arise [48] as technology improves. This is consistent with a summary of reviews, which concludes that this technology is promising for persons with type 2 diabetes [49].

The field of health technology is multidisciplinary, with the cooperation of several different health professions, behavioural professions and technology professions [50]. Developments in the health care field, with an increasing awareness of patient centred care and self-management, aim to provide people with greater control over their own health and care, and the opportunity to make their own decisions [51]. The development in technology towards smaller devices, mobile phones and wearables [52], improves the person's ability to store and make use of larger amounts of data and of short- and longer-term trends in their glucose levels associated with diet and physical activity in daily life. The ability to share more data through faster and safer networks in

health care services is important for patients and for their interaction with their health care providers [53].

Several terms describe the concept of communication technology use in health care. In the RENEWING HeALTH project, the term *telemedicine* was used as a key concept. Kidholm et al. defines telemedicine as:

> "The delivery of healthcare services through the use of information and communication technologies in a situation where the actors are at different locations. The term *telemedicine app* refers to the overall intervention or service and not just to the telemedicine device used as part of the service." [54 p.44]

The term *eHealth* (electronic health) was employed from around the year 2000, as an umbrella term, which is difficult to define [55]. According to Oh et al. [55], researchers often cite Eysenbachs definition:

> *"E-health* is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology." [56 p.1].

Under the eHealth umbrella, the World Health Organization (WHO) defined *mHealth* (mobile health) as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" [57 p.6].

In our randomised controlled trial (RCT), with a self-management mobile phone app, we have primarily used *mHealth*, and the WHO definition fits our perspective.

Mobile apps contain either single or multiple features within one app, for instance, in diabetes apps, features about medication, exercise, diet and glucose monitoring [11]. In addition, the apps may contain educational items, coaching and offer motivational support [13].

Ever since smartphones with apps, and particularly health apps, became available, a large number of studies have been performed worldwide. The earliest

reviews of diabetes mobile apps concluded with promising, but inconclusive results on biological outcomes such as blood glucose control, but with a lack of findings on cognitive, behavioural, and emotional outcomes, and user friendliness has varied [58-61]. Recent research has found that use of mobile apps might contribute to a reduction in HbA_{1c} [14,62-70]. However, for other relevant clinical measures, such as blood pressure, lipids and weight, no evidence of effects have been reported, and further studies are needed [63,65,68]. Recently, evidence has emerged to indicate that when using diabetes mobile apps, the feedback, particularly real time feedback, tailored to needs of the user appears to be important, and might have an effect on HbA_{1c} [20,68,71,72].

There are more studies on diabetes mobile apps than on apps for other chronic diseases [73,74]. However, a report from The Agency for Healthcare Research and Quality found that few self-management diabetes apps were evaluated on their effect on health outcomes [68]. Nevertheless, this is considered a promising field in need of further development as room for improvement has been identified [13,75,76]. Although information technology in general may contribute to improved HbA_{1c}, little is known about how, why or when it could be of benefit [62].

With respect to the health counselling part of our RCT, research has shown that personal health counselling as part of a mobile intervention for persons with type 2 diabetes with 4-6 months duration appears to be more effective than duration, either shorter or longer [77]. However, there are few studies with digital health communication where the methods are of sufficient quality [78], and the optimal intensity and mode of delivery of health counselling as a part of a mobile intervention is not known [67,77].

Finally, despite the possibility of an improved diabetes self-management [48], the health care system has still not fully integrated mobile apps, since many barriers still exist, including legislation, security, and privacy of health data [79]. We also need better methods to assess both the quality and the effect of mobile apps on changing health behaviour [80].

1.1.4 Acceptability of mobile health information technology

Several alternative and more or less related concepts are used in the evaluation of how patients experience the use of information technology in health care. In the

RENEWING HeALTH collaboration, *patient perceptions* were used as an umbrella term for several concepts, such as *patient satisfaction* and *acceptability* [18].

In the present thesis, I will use the term *acceptability*, defined by Nielsen as "whether the system is good enough to satisfy the needs and requirements of the users" [81 p.24]. Acceptability is hereby described as a broader concept than *usability* of the technology, with an additional awareness of social, organisational, and financial aspects [82]. Notably, we measured acceptability, in retrospect, in contrast with the dominant theory, referred to as The Technology Acceptance Model (TAM) [83,84], where the aim is to predict user acceptance – adoption and use. According to Kidholm et al. [85], when reviewing previous research, *user satisfaction* and *acceptability* have been regarded as synonymous concepts that to some extent overlap in the literature. Researchers have made attempts to combine the two concepts of *user satisfaction* and *technology acceptance* to give a more complete understanding of how system features both influence and predict use and the implementation of health technology [86,87]. However, *overall satisfaction* with the provided health technology as a narrower concept could be one aspect of *acceptability*, and as such constitute one domain in the acceptability concept, as in the questionnaire [21] used in the present thesis. The concept of *usability*, or how easy it is to use the device, has been defined by Nielsen as a subcomponent of acceptability [81].

In the recent research on acceptability, the automatic entry of data, reliable systems, graphical display with immediate feedback, and support were all factors that enabled the use of the information technology [88]. Alvarado et al. have identified system barriers of remote health management, and found that patient engagement must be addressed, including health and technology illiteracy, low perceived effectiveness and lack of confidence with remote health management in the future development of systems [11].

In their summary of reviews, Greenwood et al. concluded that more knowledge is needed about how persons with diabetes can integrate technology into their daily lives [48]. In a review of studies using the MAST framework, Kidholm et al. concluded that there was limited knowledge about the acceptability of telemedicine [89]. McMillan et al. found that limited knowledge exists about the users' acceptability, and how diabetes apps might support behavioural change, and stimulate an active lifestyle for persons with type 2 diabetes [90]. Furthermore, it has been concluded that different features in the apps would be necessary to support self-management, but more studies are needed

to explore how different features can motivate self-management [71], and find a balance as more complex features affect usability in a negative direction [75]. Chatterjee et al. concluded that educational innovation is necessary to explore the active ingredients that could lead to better outcomes in diabetes self-management [91].

1.2 The RENEWING HeALTH collaboration

The Norwegian study, on which this thesis builds, was planned under the umbrella of the European study REgioNs of Europe WorkINg toGether for HEALTH - RENEWING HeALTH European union collaboration. The Norwegian research team regularly attended meetings with the RENEWING HEALTH collaboration group in Europe prior to, during, and after the study to coordinate the intervention and its evaluation with the ongoing work in other regions.

In RENEWING HeALTH, the Model for ASsessment of Telemedicine (MAST) applications was used as a guide for evaluating the studies. This model has three elements: 1) preceding considerations of the relevance of performing an assessment, 2) performing a multidisciplinary assessment, and 3) assessing the transferability of the results [18]. MAST contains seven domains of what a multidisciplinary assessment should include:

1. a definition of the health problem and characteristics of the app
2. the safety of the app
3. clinical effectiveness
4. patient perspectives
5. economic aspects
6. organisational aspects
7. socio-cultural, ethical and legal aspects [18].

Evaluating telemedicine interventions is therefore a comprehensive piece of work, and this thesis addresses two of the domains: 3) clinical effectiveness and 4) patient perspectives. Clinical effectiveness refers to the app's effect on patients' health outcomes, including health-related quality of life and behavioural outcomes. The patient perspective refers to the perception of the involved stakeholders, i.e. patients, their relatives and healthcare professionals.

MAST does not recommend specific research designs or methods for evaluation of patient perspectives, but suggests that different approaches should be considered according to prevailing practice to achieve valid results [18]. Our research team used both quantitative and qualitative methods when addressing our research questions related to clinical effect and patient perspectives (Papers I-V, [92]).

As a part of RENEWING HeALTH, Kidholm et al. [85] performed a comprehensive review in order to plan the assessment of the patient perspective to be included in a common minimum dataset, but did not find valid questionnaires for this purpose. When planning RENEWING HeALTH, the Whole System Demonstrator study was one of the largest telehealth/telecare studies globally [93], and the research team in the study developed a relevant questionnaire, The Service User Technology Acceptability Questionnaire (SUTAQ). A collaboration between researchers in the RENEWING HeALTH and the Whole System Demonstrator study made it possible to translate and validate SUTAQ in the languages used in the regions of RENEWING HeALTH. This collaboration of researchers aimed to establish an *acceptability questionnaire* for future use in Europe, [54,85], and the SUTAQ questionnaire was therefore included in RENEWING HeALTHs Minimum Dataset. Hirani et al. later published a paper describing the validation process of SUTAQ from the Whole System Demonstrator study [21].

The research team in the Norwegian study

The Norwegian study had two study sites. One was in Tromsø at the Norwegian Centre for E-health Research (previously Norwegian Centre for Integrated Care and Telemedicine) and one in Oslo at Oslo Metropolitan University – OsloMet (earlier Oslo and Akershus University College of Applied Sciences). The two sites will be hereafter referred to as the Norwegian Centre for E-health Research and OsloMet.

The study was led from the Norwegian Centre for E-health Research by Project Manager Astrid Grøttland (Chief Advisor NSE), and Professor of eHealth and informatics Eirik Årsand (PhD) as responsible for the research together with Lis Ribu (PhD) at OsloMet. Two PhD students were engaged at the study site at OsloMet, Heidi Holmen and myself. We also collaborated with technicians and medical personnel at both sites.

During my doctoral studies, I participated in the European meetings for the RENEWING HeALTH collaboration, and was a part of the network, the collaboration

process and learned about the multiple interventions and the different evaluation methods. At the same time, I participated in the development of the Norwegian RCT, and was part of the research team that performed the intervention and supported the participants, and was involved in data collection. I coordinated the consecutive and daily collection of incoming data, the cleaning of data, and the reminders submitted to the participants at both study sites.

1.3 Aims

The overall goals for this thesis were to investigate the effects of a three-armed RCT of a self-management mobile health solution for persons with type 2 diabetes using the Few Touch Application (FTA) diabetes diary, with or without health counselling for four months, as well as the participants' acceptability of the device.

The specific aims were to:

- evaluate short term effects after 4 months on glycated haemoglobin (HbA_{1c}) levels, self-management, behavioural change, and health-related quality of life compared with usual care (Paper I)
- evaluate long term effects after 1 year on HbA_{1c} levels, self-management, and health-related quality of life compared with usual care (Paper II)
- assess the validity of the Norwegian version of the Service User Technology Acceptability Questionnaire (SUTAQ) (Paper III)
- explore associations between self-management at baseline and the level of acceptability of the device (Paper IV)
- obtain an understanding of the users' acceptability with a mobile app for diabetes self-management, and their communication with health care personnel with respect to the app (Paper V)

2.0 Methods

2.1 Study designs

1. For paper I and II, we used the gold standard method to evaluate the potential effects of the intervention and performed an RCT with evaluations at two points in time; 4 months (Paper I) and 1 year (Paper II) of the self-management mobile app for type 2 diabetes which had been developed and pilot-tested in Norway [94]. The trial had three arms; two intervention groups and one control group.
2. For Paper III, we translated and validated the Service User Technology Acceptability Questionnaire (SUTAQ) (psychometrics)
3. For Paper IV, we performed a quantitative study with an observational (descriptive) design to investigate participants acceptability of the mobile device with SUTAQ
4. For Paper V, we performed a qualitative explorative study design with in-depth interviews to further study participants' acceptability of the mobile device

An overview over the papers is presented in Figure 2.

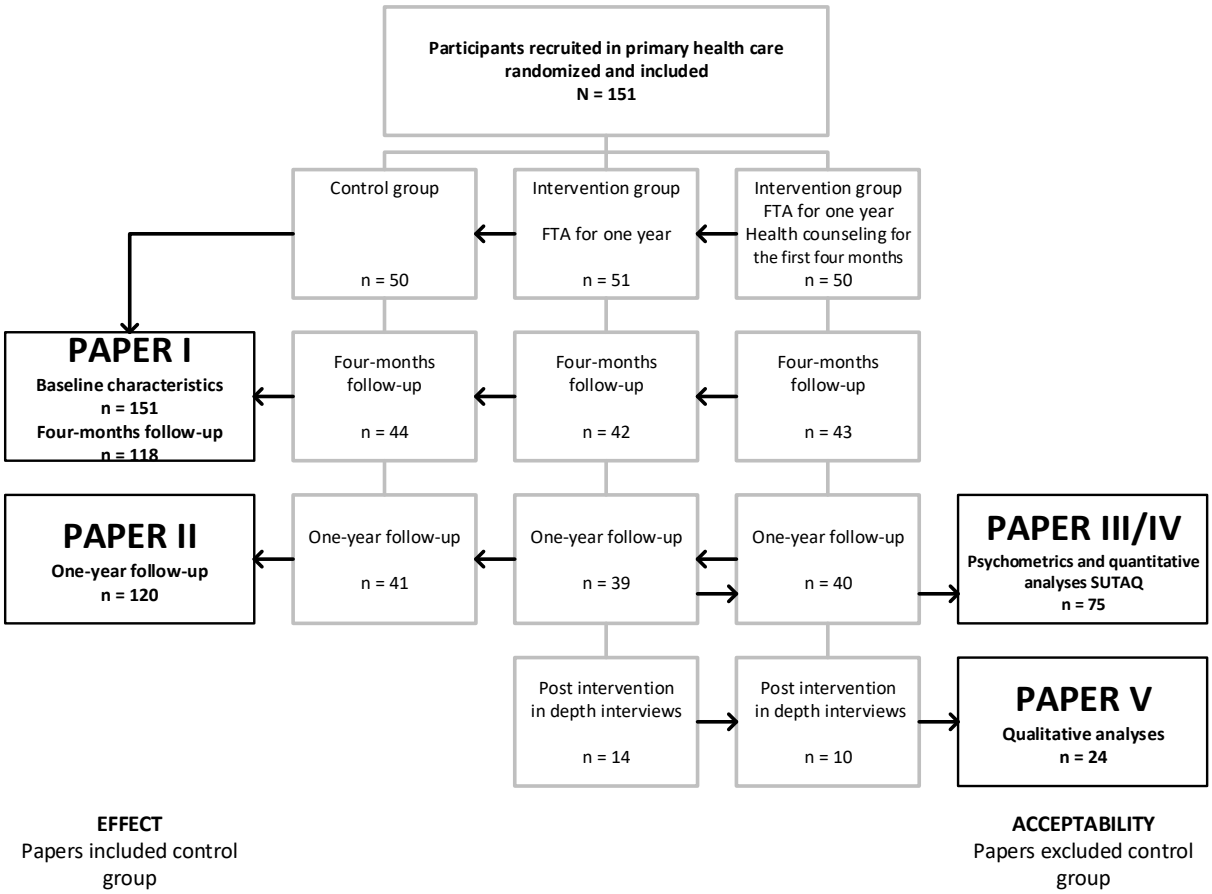

Figure 2. Flow chart of participants in the Norwegian RENEWING HeALTH study and overview of samples for Papers I-V

2.2 Inclusion and exclusion criteria

The inclusion criteria for the RCT were:

- adults ≥ 18 years old
- type 2 diabetes for three months or more
- HbA_{1c} ≥ 7.1 % (treatment target according to the Norwegian clinical guidelines [32])
- ability to use the app and fill out questionnaires in Norwegian.

Exclusion criteria were mental and physical conditions that could be an obstacle to accomplish the study as intended.

2.3 The control group and the intervention groups

In Norway, persons with type 2 diabetes are usually followed up by their general practitioners. Participants in all three groups received the usual care from their general practitioners. Both intervention groups received a diabetes diary app, and one group in addition received health counselling.

The control group – usual care

According to the National clinical guidelines for diabetes from 2009 (later revised in 2016), a consultation every 2 to 6 month is recommended to assess the person's self-management, with measurements of fasting glucose, HbA_{1c}, blood pressure, weight, as well as a discussion on treatment targets and how to achieve them. Once a year, a more thorough consultation was recommended, with additional screening for diabetes complications (electrocardiography, microalbuminuria, lipids, foot examination, and referral for eye examination/fundoscopy) and emotional stress/mental health [32].

The intervention group with the app only

Both intervention groups received a smartphone (HTC HD Mini, based on the Windows Mobile 6.5 operating system) with an app, a digital diabetes diary called "Few Touch application" (Figure 1) [95]. This app had previously been developed and tested in persons with type 2 diabetes as a part of a PhD study [12,94]. In addition, participants were provided with a blood glucose meter (OneTouch Ultra Easy from LifeScan Inc. West Chester, PA, USA), which they could connect to the app by Bluetooth (Polytel GMA from Polymap Wireless). The blood glucose meter sent data to the app that visualised the blood glucose levels using lists and graphs. The participants were able to manually register their daily diet and exercise and set their own goals. The app visualised the diet and exercise results and gave positive feedback (smilies) when the participants achieved their goals. Relevant examples of how to use the app were made available, in addition to an extended look-up system with general diabetes information from an endocrinologist with diabetes expertise.

Before the start of the study, the research team revised the examples in the app in cooperation with a diabetes specialist nurse and a clinical nutritionist. The app did not transfer data to electronic health records, however the participants were encouraged to use the app to share their data in consultations with health care personnel, such as their general practitioners or their diabetes specialist nurses. The Norwegian Centre for E-health Research continuously developed the app further, based on our experiences with the tool, and from other parallel studies.

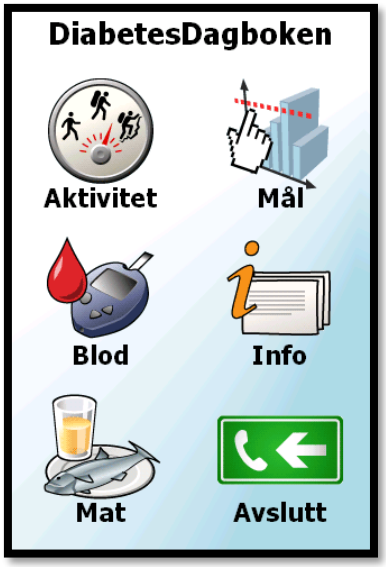

Figure 1. The display of the app, containing the features; physical activity registration, blood glucose measurements, diet registration, goal setting, and information.

Photo: Eirik Årsand

The intervention group with additional health counselling

One of the intervention groups received health counselling for the first four months of the study in addition to the app. A team composed of a diabetes specialist, a diabetes specialist nurse with previous training and education in motivational interviewing, a clinical nutritionist and PhD students developed the health counselling program which built on elements from a program developed in United Kingdom, with a low intensity interventions based on cognitive behaviour theory and a problem-solving model [96]. We designed the intervention using principles from motivational interviewing [97] and The Transtheoretical model by Prochasca [98].

The team developed five modules comprised of the following themes: introduction, living with diabetes, goal setting, diet and physical activity, looking back and continuing forward [95]. The diabetes specialist nurse made five telephone calls (one call per module) to the participants during the first four months of the study. Participants could discuss any problem with the use of the app during their phone calls with the diabetes specialist nurse. The diabetes specialist nurse also actively supported the participants in taking advantage of the different elements in the app to self-manage their diabetes. Prior to each module, the diabetes specialist nurse sent text messages to the participants through a secured text messaging system [Sikker dialog] on their smart phones to initiate the module theme. The participants could contact the diabetes specialist nurse through the same system during the health counselling intervention period.

At the beginning of the study, a clinical nutritionist trained the diabetes specialist nurse in how to respond to diet issues. Initially, a clinical psychologist, along with the research team, supervised the diabetes specialist nurse. The group discussed anonymised cases and how the diabetes nurse and the nutritionist could cope with the various participant issues.

2.4 Recruitment strategies

Researchers and technicians from both study sites recruited participants in primary care settings from both the north and in the south of Norway. Before the start of the recruitment process in March 2011, the two research groups had several meetings at the Norwegian Centre for E-health Research to plan recruitment and information to potential participants regarding the use of the equipment.

2.4.1 Recruitment strategies to the RCT

Our primary strategy was to invite general practitioners to recruit adult patients with type 2 diabetes living at home and receiving standard diabetes care according to the national guidelines [32]. The general practitioners recruited their eligible patients

based on the inclusion criteria of the study (n = 87, 57.6%). However, as the recruitment of patients was too slow, the research teams also collaborated with Akershus University Hospital (near Oslo) and the University Hospital of Northern Norway, which recruited through their Diabetes Start courses (n = 10, 6.6%) for persons newly diagnosed with type 2 diabetes living at home [7]. Additionally, we recruited from four different Healthy Life Centres [Frisklivssentraler] [43] in the municipalities (n = 25, 16.6%), from media advertisements (n = 13, 8.6%), and from local organisations of the Norwegian Diabetes Association (n = 16, 10.6%).

Randomisation

Once they provided written consent and completed the questionnaires at baseline, the participants were randomly assigned to one of three groups using a block randomisation approach. Information about the participant's initials and year of birth was first entered into a web-based solution designed by the Norwegian University of Science and Technology (NTNU, Norway). The web solution immediately generated an identification number and the allocation group, and an e-mail receipt was sent to the persons responsible for the research study in Tromsø and Oslo. Later, during data collection and analyses, this identification number was used to link the data to each participant.

Blinding

Blinding of the participants was not possible, as the features of the intervention had to be revealed to the participants at the start of the study. Healthcare providers, and researchers involved in recruitment, data collection and analyses were unblinded as well, as there were limited resources and personnel available to perform the study. However, the statistician who supervised the analyses of the quantitative data was not involved in data collection.

2.4.2 Recruitment strategies to the qualitative study

Once they were included in the study, the participants gave their consent to be contacted for qualitative interviews at the end of the study. All participants with completed follow-up data from the RCT were invited, apart from participants who were considered too ill to participate further and those who spontaneously expressed that they did not wish to be contacted for an individual interview. When participants expressed willingness to participate, one of the two interviewing researchers contacted them to make an appointment to perform an in-depth interview. These two researchers had no contact with the participants they interviewed during the RCT, before the interviews were scheduled.

2.5 Training and support

At the start-up meetings, the participants received verbal information and training on how to use the mobile phone and the app from the researchers. Technicians and researchers from Norwegian Centre for E-health Research had also developed information for equipment use, both in printed and digital versions.

All participants received a phone call within 14 days after the study started, and asked whether they had experienced any problems using the smartphone and the app. The Norwegian Centre for E-health Research provided phone support to all participants during the day, as part of an ongoing collaboration between the researchers in the project team and the technical support team. When the researchers revealed a technical problem, the support team contacted participants who had consented to being contacted. If the problem could not be solved by phone, the technical support team or researchers arranged additional personal meetings with the participants to replace or repair the equipment or to give additional training for use.

2.6 Data collection

We arranged meetings close to both study sites, located either in-house or at health care localities, depending of the participants' preferences and suitable localities. As potential participants were successively invited, the number of participants at each meeting differed from one to ten. They received thorough verbal and written information about the study before providing their informed written consent.

At the 4-month and 1-year follow-up, we individualised the data collection procedures. For some participants, it was suitable to set a physical meeting, while for others it was more convenient to send the questionnaires by post. If we did not receive an answer or completed questionnaires within 14 days, a reminder was sent by mail and later by telephone.

Regarding clinical variables from medical records, both the participants and the general practitioners were sent a study journal with a prepaid return envelope by post. We used the same procedures as for self-reported data, sending reminders by mail and later by telephone.

2.7 Evaluation of the intervention

Firstly, a quantitative approach was used to analyse the effect of the trial on the primary and secondary outcomes, and on the psychometric properties of the SUTAQ as well as the participants' acceptability of the app. Secondly, a qualitative evaluation was conducted after the end of the trial to obtain a broader understanding for the participants' subjective evaluation of the acceptability of the app.

2.7.1 Outcome measures

Table 1 presents an overview over measurements used in the respective papers.

Primary and secondary outcome measures of the effect of the intervention

The primary outcome was HbA_{1c}. We obtained the values from printouts from the general practitioners' medical records. For those who did not have measurements from their general practitioners, we measured HbA_{1c} in venous/capillary blood sample

with a DCA Vantage Analyzer, borrowed from Siemens. The DCA Vantage Analyzer was certified by the National Glycohemoglobin Standardization Program [99] and used equally in all randomised groups. We calibrated the Analyzer based on the procedure from Siemens. At baseline, we used HbA_{1c} levels measured within 14 days before or after the participants began the study. We had the same procedure at the 4-month and 1-year follow-up.

The secondary outcomes included health-related quality of life (SF-36) [100], depressive symptoms (CES-D) [101], self-management (heiQ) [102], physical activity [103,104], nutritional habits [105] and acceptability of the app (SUTAQ) [21], described in the protocol [95] and in paper I.

Table 1. Variables used in Papers I – IV

Variables		Variable source[a]	Paper I	Paper II	Paper III	Paper IV
Sociodemographic characteristics						
	Age	SR	X	X	X	X
	Gender	SR	X	X	X	X
	Education	SR	X	X	X	X
	Employment status	SR		X		
	Cohabitation status	SR		X		
	Technology knowledge	SR				X
Clinical characteristics						
	HbA_{1c}	MR	X[b]	X[b]		X
	Duration of diabetes	SR	X	X		X
	Height	MR	X	X		
	Weight	MR	X	X		
	Blood pressure	MR	X	X		
	Comorbidities	MR/SR	X	X		X
	Eye complication	SR		X		
	Foot ulcer complication	SR		X		
	Hypoglycaemia	SR		X		
Treatment variables						
	Glucose lowering medication	MR	X	X		
	Self-monitoring blood glucose	SR	X	X		
Patient perception - questionnaires						
	SF-36v2	SR	X	X		
	CES-D	SR	X	X		
	heiQ	SR	X	X		X
Lifestyle characteristics						
	Smoking	SR	X	X		
	Physical activity	SR	X	X		
	Diet characteristics	SR		X		
Acceptability data						
	Log data	SS	X	X		X
	SUTAQ	SR			X	X

[a] Self-reported (SR), general practitioners medical records (MR), data from secured server (SS)

[b] Primary outcome

Sociodemographic characteristics

At baseline age, gender, education, employment status, cohabitation status, technology knowledge, employment and cohabitation status were collected from self-reports and categorised as described in detail in the included papers.

Clinical characteristics

The clinical characteristics and outcomes were collected from the general practitioners' medical records such as HbA_{1c} (baseline, 4-months and 1-year), height, weight and blood pressure (baseline, 1-year). Information about comorbidities were obtained from medical records or self-reported (baseline). The general practitioners documented cardiovascular diseases such as atrial fibrillation, intermittent claudication, cerebrovascular diseases, coronary diseases and heart failure. Further, the participants self-reported at baseline whether they now or previously, had experienced chronic diseases such as heart disease, chronic obstructive pulmonary disease, rheumatism, kidney failure, cancer, if they received eye treatment or had foot ulcer complications (all the variables from the Minimal Dataset from the MAST framework in RENEWING HeALTH). The duration of diabetes was calculated based on self-reported information about the year the diabetes was diagnosed. The participants were asked at all the three time points whether they experienced hypoglycaemia, and if so, how often during the previous week.

Treatment variables

Self-reported treatment variables at baseline included whether they self-monitored blood glucose, and if so how often they usually monitored this during the day or week. The general practitioners reported all medication used at the 1-year follow-up. Glucose lowering medication were reported from the general practitioners at baseline and after 1 year and change in medication at 4 months and one year.

Patient perception - questionnaires

The Short Form Health Survey (SF-36) measures health-related quality of life and has 36 items with Likert scales from 1 – 3, 1 – 4, 1 – 5 or 1 – 6 that assesses eight health domains and mental and physical health summary scores [100]. The health domains *physical functioning, role-physical functioning, bodily pain* and *general health* represent the summary score *physical component summaries*. The health domains *vitality, social functioning, role-emotional functioning* and *mental health* represent the summary score *mental component summaries*. The Norwegian questionnaire has been translated and validated [106].

The Center for Epidemiologic Studies Depression Scale (CES-D) measures symptoms associated with depression. This questionnaire has 20 items with a 1 – 4 Likert scale from "rarely or none of the time" to "most or almost all the time". The questionnaire is not a diagnostic tool, but rather estimates a score indicating a higher number of depressive symptoms, and a cut-off of ≥16 represents a risk of clinical depression [101]. The measure has been translated and used in Norwegian settings, however, the psychometric assessments have not been published. Cronbach's alpha coefficient computed for all 20 CES-D items at baseline had a satisfactory internal consistency with an alpha of 0.771. A good internal consistency according to Polit is 0.80 or higher [107]

The Health Education Impact Questionnaire (heiQ), which measures self-management, was not a part of the RENEWING HEALTH minimum dataset, but instead supplemented the questionnaires in the Norwegian study. The heiQ questionnaire has 40 items. The participants filled out a Likert scale with scoring 1 – 4 from "strongly disagree" to "strongly agree" to rate the level of statement agreement. The eight domains included *positive & active engagement in life, health directed behaviour, skill and technique acquisition, constructive attitudes and approaches, self-monitoring and insight, health service navigation, social integration and support,* and *emotional distress* (well-being). Higher scores reflect higher self-management in all domains except for the domain Emotional distress [102]. The questionnaire has been validated in a Norwegian context for persons with chronic conditions, including diabetes [108].

Lifestyle characteristics

Lifestyle characteristics were self-reported. At baseline and 1 year the participants were asked whether they were daily smokers.

Physical activity was assessed by questions from the HUNT study [103,104] regarding the frequency, intensity and duration of physical activity in addition to daily physical activity and sedentary time. We combined frequency, intensity and duration [109] to a dichotomised variable of active and inactive subjects.

Information about diet was collected with questions from the NORCAPP study, based on traditional Norwegian food and recommendations. Questions regarding the

frequency of consumed fruits and vegetables (merged variable), poultry, meat and fish [110] are presented by number and percent.

Data about the Acceptability of the app

The Service User Technology Acceptability Questionnaire (SUTAQ) measures the patients' acceptability of the use of telemedicine/telehealth equipment. The SUTAQ questionnaire has 22 items with both positive and negative statements with values from 1 to 6 on a Likert scale to rate the level of agreement with the statement. The items are divided into five domains [21];

- *perceived benefit*
- *privacy and discomfort*
- *care personnel concerns*
- *kit as substitution*
- *satisfaction*

High scores reflect a high degree of agreement with the statements. In two of the domains, *privacy and discomfort* and *care personnel concerns*, the statements are negative [21]. The questionnaire was translated for our study, and the translation process and validation in the Norwegian context were described in Paper III.

App log data for use of the app was sent from the study telephone and stored in a secure server at the Norwegian Centre for eHealth Research in Tromsø. We calculated the measurements of blood glucose and other keystrokes in the app and defined high frequency of use as ≥ 5 measurements of blood glucose per month and ≥ 50 keystrokes for at least 6 months of the study period of 1-year.

2.7.2 Qualitative post-intervention evaluation

We performed a qualitative evaluation after the trial in accordance with the study protocol [95], with the aim to explore the participants' acceptability of the provided technology. We developed a semi-structured interview guide with open-ended questions about their use of the technology, the use of the app, their interaction with the app and their interaction with the general practitioners. The themes in the interview guide are presented in Paper V.

2.8 Analyses

In this thesis, several statistical methods were applied in the different Papers I-V (Table 2).

Table 2. Analyses and tools

Analyses and tools		**Papers**				
		Effect		Acceptability		
		I	**II**	**III**	**IV**	**V**
Descriptive statistics						
	counts with percentages for categorical variables	X	X	X	X	X
	means and SDs for continuous variables	X	X			
	median and range for continuous variables			X	X	
Bi-variate analyses						
	Kruskal-Wallis (between group differences continuous variables)	X				
	Chi-square (between group differences categorical variables)		X			
	One way analyses of variance (ANOVA) (between group change)	X				
	Students *t*-test (within group change continuous variables)		X			
Regression analyses						
	univariate linear regression (between group change)	X	X			
	univariate linear regression (testing associations)				X	
	univariate logistic regression (subgroup analyses)		X			
	multivariate linear regression (between group change, adjusted)	X	X			
	multivariate linear regression (testing associations, adjusted)				X	
	multivariate logistic regression (subgroup analyses, adjusted)		X			
Questionnaire validation						
	Cronbach's alpha			X		
	Confirmatory factor analysis using principal component approach (PCA), confirmation of the original factors			X		
Tools for analyses						
	SPSS version 21 (IBM Corp, Armonk, NY, USA)	X	X			
	SPSS version 23			X	X	
	Nvivo 11 pro (QSR International)					X
Qualitative analysis						
	qualitative content analysis					X

2.8.1 Statistical analyses

Statistical analyses Paper I and II

We performed one-way analyses of variance (ANOVA) to assess between group changes in the three groups in papers I and II, to compare each of the randomised groups [111]. The assumptions to perform the analysis were fulfilled as the change (delta) variables were normally distributed in all three groups. In addition, we modelled associations between the three groups and the secondary outcome using both univariate linear regression and multiple regression after inclusion of possible confounders.

Statistical analyses Paper III

In paper III, we considered our sample size to be too small for exploratory factor analysis to explore how the SUTAQ questionnaire performed in the present context. However, we performed confirmatory factor analyses to confirm or reject the original construct of the SUTAQ questionnaire.

Statistical analyses Paper IV

In paper IV, we modelled associations with univariate and multiple linear regression analyses with the aim to explore acceptability of the app. Consequently, only the intervention groups were analysed. These were combined, as we found no differences between the two groups concerning background variables. We explored associations between acceptability (dependent variable) and baseline self-management.

All statistical analyses were performed with a statistical computer package, SPSS version 21 and 23. Table 2 provides an overview and further details concerning the statistical analyses and tools used in each of the papers.

Power calculations

Power calculations were performed prior to recruitment, giving an estimate of the minimum sample size needed, based on the anticipated and clinically relevant change in HbA_{1c} which was used as the primary outcome. Given an anticipated

difference of 0.30 for HbA_{1c}, a standard deviation of the outcome variable of 0.5, power of 0.80, significance level of 5% 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+50 (intervention groups), and 50 in the control group, i.e. N=150.

2.8.2 Qualitative analyses

Two health researchers conducted the interviews. We used the qualitative content analysis method described by Schreier [112] to analyse the individual interviews. When working with analyses in the early phase, the group of co-authors in paper V met regularly to discuss the progression and to reach a common understanding. The focus of our research was to explore the acceptability of the app and how the participants related to health care personnel using their app.

Preparation for coding

First, I read all the transcriptions and summarised the content in each interview, emphasising the use of the device. We discussed the summarised form of each interview, to reach an agreement on a shared understanding of the core meaning. This was important, since as a researcher I had only read the transcriptions from the interviews, while two of the other researchers were more familiar with the material due to their roles as interviewers.

Segmentation and analyses

As suggested by Schreier [112], we first selected units of text, which answered our question of acceptability. We then pilot-coded the first 12 interviews and developed a code frame, before examining the rest of the interviews based on the frame. Our development of the code frame was data driven. At first, the codes were narrow, multiple and presented more as a map than performed hierarchically. Based on the early coding, the group agreed on the patterns and developed the themes. We went back and forth between full interviews to text segments to ensure that the given meaning of each theme made sense. We then developed a theme table as a matrix, with both horizontal and vertical associations according to one main theme and three subthemes. Examples

of the path from text extractions to themes are described in Table 3. In order to present quotes representing the themes, we removed names, places and accents.

Analysing findings based on an acceptability model

Initially, our general understanding of the acceptability concept was the experience of the use of the app, and we developed our themes from this perspective. A theoretical understanding of acceptability did not guide the development of codes and themes at this early stage of analysis. As reflected in the discussion part of Paper V, the next step was to interpret the identified themes, according to Nielsen's model of acceptability [81], and other relevant research. The use of an acceptability model in our interpretations led to an extended understanding of our themes in relation to the concepts of Nielsen's acceptability model, and the significant relevance to the use of apps in health care. The reason we chose this particular model was that it made it possible to explore the nature of acceptability with the use of an app, as Nielsen emphasises an evaluation within a lifecycle of the technology, towards both users and the environment [81].

Use of software in the qualitative research

We used nVivo to store the full transcript interviews, to mark the sequences of text to code, to keep track of the coding frame and to analyse the relationships between the major themes. For instance, we found usability issues to be a common theme in almost all the interviews. A related question was whether usability issues were a main explanatory factor of acceptability. We used the nVivo to discover possible patterns between usability issues and use of the app, which turned out to be random.

Table 3. Examples from the path between units of text and the theme

Extracts from the selected units of text	I've used it when going for walks. I sometimes take a walk when I come home from work. Then I measure the walk. When I eat things like fish or other things, I also write that down and see how many times a week I eat fish or other things. (P4)	The diabetes journal has actually been very good - as an aid, so that I can see how my blood sugar reacts to certain types of food I've eaten, and to the way I exercise. I can follow it and make sure my blood sugar stays fairly steady. (P6)	I think it was great. I could take it along to the doctor and to the diabetes nurse and she checked it. (P18)
Sub-theme	Inspiration: To establish or keep up routines	Understanding the test results: The app identifies healthy lifestyle patterns	Decision support: Confirmation of the decision from health-care personnel
Theme	Meaningful routines	Meaningful overview	Meaningful interactions

2.9 Ethical issues

The study was designed in accordance with the ethical principles of the Helsinki declaration and the Norwegian Act on Medical and Health Research. The Regional Committees for Medical and Health Research Ethics (REC) granted approval for the ethical aspects of the study (REC no 2010/427).

In the written informed consent in the Norwegian study, we informed that participation was voluntary and that it was possible to withdraw from the study at any time (Appendix I). In addition, the informed consent described potential harm and discomfort. This was mainly related to the intervention group, either indirectly caused by app use such as possible hypoglycaemia, or directly as potential increased expenses.

Kidholm et al. emphasises that both the app itself and consequences of the use of the app could involve concerns about ethical issues such as equality of access, dignity related to monitoring, and the right to refuse [18]. In the MAST evaluation, one of the domains describes ethical issues [18], and guidance on how to conduct the study, with respect to autonomy, privacy and benefit for the users. In the final report of the RENEWING HeALTH project, the lack of national and international guidelines and laws to ensure legal issues and ethical assessments were discussed. Ethical and legal

issues such as confidentiality, protection of the data, liability and product safety were raised and discussed in the report [19].

As this was a mobile health intervention, and confidentiality was a particularly important issue, the participants were registered with id numbers, and we locked the alignment between the numbers and the identification in a safe that was only available to the researchers. In addition, the researchers had access to personal health data in the app stored in a secure server. Both Norwegian Centre for E-health Research, which hosted the secure server for personal health data, and OsloMet performed risk analyses prior to the study to detect any potential leak of sensitive data.

The in-depth interviews provided the participants with more detailed written and verbal information about the qualitative part of the study, even though they had signed the informed consent and given their written permission for approval for interviews once the study was completed. They were also given an additional opportunity to confirm their participation in interviews verbally before participation.

We stored signed written informed consents, the list with id numbers, along with the audiotaped interviews in a locked safe at OsloMet to keep the identification of the participants unrevealed.

There is a risk of revealing confidentiality when publishing qualitative results using quotes. However, the quotes presented in Paper V were general and characteristic of several of the participants.

3.0 Results

3.1 The results from the studies of effect

3.1.1 Paper I: Effect of the intervention after 4 months

In the first paper, we explored the short-term effect of the intervention at the 4-month follow-up. We analysed data from 124 individuals (attrition rate of 17.9%). Firstly, we found no significant differences in HbA_{1c} between the three groups when adjusted for age, gender and education, however, HbA_{1c} declined in the two intervention groups as well as in the usual care group. Secondly, the heiQ score, improved and reached the level of statistical significance in the domain *health service navigation* in the intervention group receiving only the app when compared to the control group (estimated β = –0.23, 95% CI = –0.41 to –0.05, p = 0.01). The intervention group receiving both the app and health counselling improved within the same domain when compared with both other groups (estimated β = –0.19, 95% CI = –0.37 to –0.01, p = 0.04). In the heiQ domain *skill and technique acquisition*, the group receiving the app reported a statistically significant larger decline compared to the control group (estimated β = –0.22, 95% CI = –0.40 to –0.03, p = 0.02). We found no statistically significant changes in quality of life (SF-36), diet or physical activity for any of the groups.

3.1.2 Paper II: Effect of the intervention after 1 year

In this paper, we explored the long-term effects of the intervention after 1 year. We analysed data from 120 participants (attrition rate of 20.5 %) with data from the baseline and 1-year follow-up. We found no statistically significant differences in HbA_{1c} between the groups. However, we did find a decline in HbA_{1c} in all three groups. We found a statistical significance between group differences in the heiQ domain *skill and technique acquisition* where the intervention group that received both app and health counselling had enhanced scores compared to the other two groups (Estimated β = 0.21, 95% CI = [0.01 to 0.40], p = 0.04). We analysed data from the app log using binary

logistic regression and found a statistically significant association regarding age and use of the app, where participants aged ≥ 63 years were almost three times more likely to use the app compared to participants who were younger (OR 2.7, 95% CI [1.02 to 7.12] p = 0.045). We found no statistically significant changes in quality of life (SF-36), diet or physical activity for any of the included groups.

3.2 The results from the studies of acceptability

3.2.1 Paper III: Psychometrics of the SUTAQ

When assessing the validity of our translated acceptability questionnaire, the Service User Technology Acceptability Questionnaire (SUTAQ), we analysed 75 cases (attrition rate of 25.7%) among those who had completed the study. We used confirmatory factor analysis, and confirmed only two of the original five factors of the SUTAQ in this study, *perceived benefit* and *care personnel concerns*. Cronbach's alpha coefficient computed for all 22 items was 0.851, which is a good internal consistency according to Polit et al. [107]. We used only these two confirmed factors in our models in paper IV.

3.2.2 Paper IV: Associations between acceptability and self-management

When exploring associations between the level of acceptability of a mobile diabetes app after the 1-year follow-up, and the initial ability of self-management (at baseline), we analysed data from 75 cases (attrition rate of 25.7%). We found statistically significant associations between five of the eight self-management domains and *perceived benefit*, one of the SUTAQ factors confirmed in paper III. However, when using multiple linear regression analyses adjusted for age, gender and frequency

of use, only one domain, *skill and technique acquisition*, remained significantly associated with *perceived benefit* (estimated β = 0.60, 95%CI = [0.03 to 1.17], p = 0.04). Frequency of use of the app was the strongest predictor in adjusted analyses of the acceptability domain *perceived benefit*. We found no associations between the SUTAQ domain *care personnel concerns* and initial self-management.

3.2.3 Paper V: Users acceptability of the app, qualitative analysis

When exploring the users' acceptability of the app through in-depth interviews, using qualitative content analyses, we found that the users' acceptability of the app varied. Overall, the responses indicated that the use of a digital diabetes diary was hard work, but could also ease the efforts to achieve a lifestyle change and improved glucose control. Crucial to this acceptability was the establishment of use as a routine incorporated into daily life, which could give an overview of diabetes registrations and new insights into self-management. In addition, the participants stated that support from health care personnel with diabetes knowledge was essential, either for confirming their decisions to use the app, or to get additional self-management support. We interpreted the findings within the frame of Nielsen's acceptability model of practical and social acceptability [81].There were gradual transitions between practical and social acceptability, where the utility of the app seemed to be necessary for both practical and social acceptability. Lack of acceptability could lead to both digital and clinical distress. We concluded that both practical and social acceptability were important at different levels. If the users found the utility of the app to be acceptable, they were able to tolerate some lack of usability. Awareness of both digital and clinical distress for app users appears to be necessary when diabetes apps are included in health care.

4.0 Discussion

4.1 Methodological considerations

The study design of randomisation and control of the experimental situation is the gold standard method for experiments, when evaluating the effect of a new treatment, given good internal validity [107]. Throughout the study, we experienced a number of unpredicted issues concerning methodology, and have discussed several of these in the papers, such as blinding (Paper I), design (Paper I), outcome measures (Paper I and II), intervention (Paper I and II), intervention intensity (Paper I and II), and outdated technology (Paper I and II).

In the following, I will primarily discuss what I consider to be the main methodological concerns related to the RCT, which may have influenced our findings of no effect of the intervention on the primary outcome HbA_{1c} after 4 months and 1 year, as all groups showed a similar decrease. We found no consistent effect of secondary outcomes such as health-related quality of life (SF-36) and self-management (heiQ). However, we did find some improvement in the intervention groups in the heiQ domains *health service navigation* and *skill and technique acquisition* at 4 months. These findings were not consistent at the 1-year follow up. Issues related to the content of the app might have been relevant to discuss in a methodological section, as these comprised a major part of the intervention. However, the app was developed prior to the RCT [12], and from the perspective of technology at that time, the app represented new technology. I will discuss the content of the app in the general discussion on future research related to technology (chapter 4.4).

4.1.1 Randomisation and lack of blinding

Blinding of the participants is often impossible in mHealth studies when comparing use to non-use of mHealth devices as blinding requires an option of placebo [54,113]. We discussed the option of giving all the participants a smartphone. However,

we found this to be too expensive, and we would still not have been able to blind the participants, as we did not have an alternative app for the control group. Lack of blinding of the participants, such as in our study, could give performance bias as the attention from researchers and health care personnel, and use of time in the consultation, may differ between the groups, or the participants could change their behaviour or reporting based on whether they were in the intervention or control group [114]. Lack of blinding therefore threatens validity, particularly in a study that examines the effect of the intervention, since non-blinded participants could report their symptoms differently. Self-reported subjective outcomes could be especially biased [115]. This may not affect the HbA_{1c} findings directly as it is an objective outcome, but there is a risk for co-interventions [115]. Multiple factors could influence on HbA_{1c} and act as co-interventions. We registered some of the most important factors that could mediate an effect at the 1-year follow-up (Paper II), such as change in diabetes medication, participation in courses aimed at changing diet or physical activity, and the use of other diabetes apps. We included these variables in our first analysis, but found that these factors did not alter our results. When the study ended, smartphones and apps were still not in widespread use, and none of the participants reported to have found other apps to support diabetes self-management.

Lack of blinding could increase the risk of attrition in the control group [115]. However, we found an even attrition between the three groups in our study (flowcharts Paper I and II). We registered that some of the participants spontaneously mentioned that the group allocation was their given reason for dropping out of the study. These were participants from the control group that had preferred to receive the intervention, and participants from the intervention groups who experienced the intervention as too demanding. As such, we found attrition to have different causes, none of which involved any particular group.

4.1.2 Attrition

According to Altman, the dropout rate from a study is a major issue for statistical interference and generalisability of the results, as there may be differences between the participants that dropped out and those who completed the study. Dropouts could be random, such as participants moving out of the country, or dropouts for no reason. A dropout may be linked to the intervention itself, eventually due to adverse

events or subjective side effects [111]. A similar health technology study in RENEWING HeALTH described a higher dropout rate in the intervention group, and analyses revealed that the participants who dropped out were less familiar with using a computer [116]. Such an unequal attrition would most likely be treatment-related [111]. However, our study had even attrition in all three groups, and we found no differences between the participants that dropped out and those who remained (Paper I and II). As such, the internal validity could be considered good in terms of attrition [107]. The attrition rate was as anticipated in similar studies, with an approximate 20% attrition both at the 4-month and 1-year follow-up. We still had enough power to analyse HbA_{1c}-data, based on pre-study power calculations indicating a minimum of 34 cases in each group.

4.1.3 Intention to treat and per protocol analyses – use of app log data

We used intention to treat analysis to detect between-group differences in accordance with the gold standard method to identify the true effect of an intervention [107] as an alternative to per protocol analyses of effect (see below).

We expected the participants in the intervention groups to use the app, but found a large variation in use. Our pre-study expectations of the involvement and use of the app among participants in the intervention group was probably too optimistic, and findings from the qualitative study confirmed that some of the participants were distressed (Paper V). We asked the participants to use the app according to their individual needs, which likely contributed to the observation of large variations in use as documented in the log data.

Per protocol analyses might have given us more answers to our question of true effect of the app as such. However, our aim was to analyse the effect of introducing an app to persons with diabetes in real life, where it is likely that many who are offered an app will not use it. Thus, the intention-to-treat analyses is always the preferred method of analysing RCT data. In paper II and IV, we defined active users based on log data, as we found it relevant to identify those who actually received the intervention. We named the variable *substantial use* in Paper II, but changed the name to *high frequency of use* in Paper IV. We searched the literature, but found no standards for defining a non-

complier. Persons with type 2 diabetes have individual needs for treatment due to differences in disease burden, age and medication. This makes it difficult to identify a standard cut score for effective use of an app.

For instance, one of our older participants spontaneously described her benefit of the app. She had recently begun insulin treatment, and measured her blood glucose carefully and regularly, following her new routines. Although she was committed to achieving the treatment goals, she found it difficult. She was randomised to the health counselling intervention group. As she made registrations in the app and discussed the results with the diabetes specialist nurse, the nurse discovered that her breakfast yoghurt was the most important source of high glucose levels. Once she solved her problem, she found no further need of app use. This is a simple example we could characterise as "lesson learned", however it does illustrate the differences included in beneficial use. The app and health counselling was beneficial for the participant even though her log data did not indicate her app use as active within the definition we have established as *high frequency of use* (Paper IV) or *substantial use* (Paper II).

Generally, per protocol analysis may lead to unreliable results due to small group size and lack of power, and since there will always be non-responders, the effect could be overestimated, which would weaken the internal validity.

Årsand's research team at the Norwegian Centre for E-health Research has explored and analysed patterns in the user log and indicated the potential in analysing such log data to better understand the participants' engagement in telemedicine studies. They found a decrease in HbA_{1c} with long-term use [117].

4.1.4 Measuring acceptability

It has previously been noted that health technology studies measuring acceptability are often characterised by a lack of common outcomes [78,118]. According to MAST and the evaluation of the patient perspective, the Service User Technology Acceptability Questionnaire (SUTAQ) was chosen in the larger project as part of the minimum dataset for the last assessment point when the participants were completing the study [19]. As noted earlier, we were not able to find a validated and general (not disease specific) questionnaire, that specifically included features of telemedicine. The idea of translating and validating SUTAQ within the RENEWING HeALTH network was to develop a questionnaire to evaluate patient perceptions in

future telemedicine studies in Europe. The guidelines of the framework mentioned additional qualitative studies as an alternative for acceptability evaluation [54], as we did, but only a few of the other pilots in RENEWING HeALTH chose to add qualitative studies [19].

The researchers that developed the SUTAQ questionnaire did so based on a literature review and on qualitative interviews with persons included in the Whole System Demonstrator study [21]. The questionnaire was designed to be general, due to the differences in diagnoses, health care settings and chosen devices. As European researchers have translated the questionnaire into several languages [119-121], SUTAQ has proven to be a potentially useful generic questionnaire. However, apart from our study (Paper III) very few of the studies have published psychometrics regarding possible validity in the translations beyond the original study. Measuring psychometrics is time consuming, and future studies could build on our findings and establish SUTAQ in the event that monitoring becomes a part of future health care.

Although the lack of confirmed factors in our study might be due to a low number of cases and lack of statistical power (Paper III), we could ask whether the constructs are concurrent with the other studies. Both the interventions and the persons receiving the intervention differed between the Whole System Demonstrator (WSD) study in United Kingdom and the Norwegian RENEWING HeALTH. The Whole System Demonstrator interventions included monitoring [93,122], while our study was a self-management intervention. The persons included in the Whole System Demonstrator study had to some extent a greater need for health care [93,122]. However, one obstacle for establishing an acceptability questionnaire could be the acceptability concept itself, as there is a constant evolvement of the concept, and it is an umbrella concept with several sub-dimensions. This lack of homogeneity in the use of a concept could make it difficult to develop reliable instruments, as described earlier by Tractinsky, who criticised the usability concept [123].

4.1.5 Adding a qualitative study

The most common qualitative contribution to RCTs is the in-depth interview [124]. Before the study began, we planned that the qualitative study would take place after the RCT was completed, in order to better understand the findings, the

accessibility and the process of the intervention (Paper V) [95]. There are several reasons for using qualitative research along with a RCT. However, it is common to explore the acceptability of the intervention with qualitative methods, either initially together with feasibility, or later in evaluation of the trial [124]. I will discuss issues tied to qualitative research in general and in particular related to an RCT.

A qualitative study can be performed at different stages of the RCT. The most commonly used model, the Technology Acceptance Model [83,84] suggests measuring acceptability prior to a technical intervention. We could have performed the qualitative study prior to, or early in the intervention [124]. However, in our study with substantial technical support, we continuously evaluated the intervention and problems that were identified, such as the Bluetooth connections that frustrated many of the participants. Furthermore, some of the participants spontaneously expressed their opinions about the provided app at the 4-month follow-up. In addition, previous earlier studies using the same app included qualitative methods [12], and had already concluded that the app could be used in other studies.

In retrospect, we could probably have detected some of the findings earlier, such as clinical and digital distress, which was a burden for some of the participants, and which lasted too long. However, we were interested in the participants' experiences when using the app, and changing the app intervention was not an option. We therefore performed 24 interviews shortly after the participants left the study, out of the 75 participants who went through with the intervention. It would not necessarily have been a problem if we had performed a single one-hour interview after the 4-month assessment point. However, it has been discussed whether contamination of quantitative data could be an issue in this matter [124]. Another point is that had we performed the qualitative study earlier, it would be difficult to know whether our findings regarding educational or supportive use (Paper V) might have been masked, as those experiences need some time for maturation. However, the recall bias after one-year may be considerable, threatening the dependability of the data, and as such, its credibility, as stability of the qualitative data over time [107] could be questioned. For instance, we found that the interviews described almost nothing from the health counselling part of the intervention, which half of the participants received during the first four months. We could ask whether this was because they did not remember the health counselling or if the health counselling was without value. In addition, we could have used other qualitative methods such as direct observation, which is more common in usability

studies. It might have been interesting to use additional pen and paper or digital diaries to identify thoughts on the perception of use. Again, this is a discussion on intervention contamination and added burden to participants in an already time-consuming intervention study.

We did not include participants that dropped out in our qualitative study, as the Whole System Demonstrator study did [125]. They included persons that declined to participate and those who withdrew from the study, which provided knowledge about barriers and concerns regarding adoption of the intervention, in addition to the participants' fear of change in health care [125]. They were able to use their findings to improve their recruitment procedures. Our focus was to explore in greater depth the relationship between the app and the user, something the persons who declined the study would not have been able to answer. Had we included individuals from the control group, we could have gathered knowledge about usual care, and elaborated our findings on relationships between health care providers, but this was not the focus of our qualitative study.

Initially, when we analysed the data, coded and developed themes, we only had a general understanding of the concept of acceptability as described in a report from RENEWING HeALTH, i.e. as subjective preferences for use [85]. Nielsen's acceptability model [81], which we used in the discussion of Paper V, is an early model that specifies acceptability, from technologically oriented literature. Alternative theories or models, including psychological, motivational, relational or other theories, might have supplied a more in-depth understanding of the mechanisms affecting or developing the acceptability. The Technology Acceptance Model (TAM) is widely used [126]. However, this model primarily emphasises acceptability prior to use, and is not necessarily suitable for our long-term evaluation. The utilisation of Nielsen's model gave us a better understanding of how both practical and social acceptability affected use of the app and for some of the participants, important emotional and clinical factors.

As mentioned earlier, I only read the transcriptions and did not perform the interviews. This could have reduced my understanding of the underlying meaning of the participants' explanations. However, the co-authors, qualitative health researchers and technology professionals, adhered to a stringent analysing process, which enhanced its credibility and confirmability. Two of the co-authors conducted the interviews, and all the authors participated in extensive discussions regarding the interpretation of some of the statements, where we had different interpretations of the text.

When adding a qualitative component to an RCT, researchers often have high expectations of the findings [124]. We knew from the quantitative analysis that the intervention had no effect on primary outcomes and no consistent effect on any secondary outcomes when we started the analysis (Paper I and II). This may have made us eager to find constructive qualitative findings. However, through technical support and collection of data, we knew that many of the participants experienced frustration associated with usability. In retrospect, we acknowledge that findings from the qualitative study may have contributed to the development of an intervention with potentially greater effect, and as such it might have provided a more throughout insight into acceptability before measuring effect. As we learned from later studies, the key to effect might be the amount of follow-up and interactive support from health care personnel [14,48,68,72], and a qualitative study (e.g. pre-test or feasibility study) could have revealed the need for a more well-designed app and more intensive health counselling.

4.2 General discussion of results

4.2.1 The lack of effect of the intervention

The RCT failed to show that the intervention had any effect on HbA_{1c}, or on health-related quality of life, diet, physical activity and only non-consistent findings in change of self-management.

At the 4-month follow up, we found a decrease in HbA_{1c} for all groups. Within the groups, changes were greater than the power we set at 0.3% (chapter 2.9.1), both in the health counselling group (mean change in HbA_{1c} -0.41), and in the control group (mean change in HbA_{1c} -0.39) (Paper I). As we discussed in Paper I, this could be explained by a Hawthorne effect rather than the intervention as a cause of the effect. Notably, there is not necessarily a one-to-one association between statistical significance and clinical importance [111]. Based on between-group changes, the change in HbA_{1c}, estimated β adjusted for age, gender and education, were respectively 0.03 between the two intervention groups and 0.16 between the group receiving health counselling and the control group at 4 months (Paper I) and this difference was even

less at 1 year (Paper II). With a larger number of participants, the precision of our estimates might be greater (reduced the standard errors) and thus the results (differences) could have achieved the level of statistical significance [111]. However, the between-group differences would have little clinical relevance, as the decline should be at least 0.3% to 0.5% to be considered clinically relevant [77] with a latitude of 0.2%, as stated by the Norwegian health authorities [127]. HbA_{1c} was measured with different devices during the study, as the participants were included at multiple sites. In addition, HbA_{1c} could be affected by conditions such as anaemia and severe kidney disease, but is in general a reliable measure [7]. However, if this did cause differences between participants, they were equally distributed between groups with respect to randomisation.

As mentioned earlier, later research indicates that tailored interaction between patients and health care providers in the use of apps could be of benefit for clinical effect [14,48,68,72], and there may be a need for further research on user engagement [14]. Further, the use of artificial intelligence in apps could enhance the utilisation of complexity in decision-making, support and treatment [128,129].

More specifically, when evaluating telemedicine interventions, the MAST framework defines a broad evaluation, as telemedicine interventions are complex and involve a range of stakeholders. Safety, economical, organisational and socio-cultural aspects are of importance along with clinical effectiveness and the patient perspectives [18]. Furthermore, obtaining the acceptability of an app would be fundamental for the effective implementation of app use in the health care system [18,130].

The app intervention used in our RCT had been thoroughly tested in previous studies [12,94] while health counselling by phone was not, although it was performed by an experienced diabetes specialist nurse in our project. In retrospect, before testing the intervention, both the app and the health counselling should to a greater extent have been feasibility-tested beforehand in daily life in order to capture factors contributing to acceptability of use and effect. We could then have adjusted and improved the intervention and thereby the effect of the RCT.

In addition, the psychometric evaluation of the acceptability questionnaire SUTAQ should ideally have included additional participants and further tests (e.g. test-retest). As Klonoff points out, a more pragmatic and observational study of the intervention prior to an RCT would involve lower cost and the opportunity to test out the robustness of the intervention in a real-world setting [131]. Due to our cooperation

in the EU-project, we had little time and resources to conduct such tests before starting the study.

Despite the lack of statistically significant changes in HbA_{1c}, the papers from our study, both individually and combined, have provided an important contribution to the still very limited amount of available knowledge about scientific diabetes app evaluations. Our study has been included in numerous systematic reviews [14,69,70,72,77,90,132-137, and others].

The important issue of integration of apps in health care has still not been resolved. According to recent systematic reviews evaluating diabetes technology in health care, the concept of education could have been better developed [48,70]. A more planned use of education could be a key to the implementation of technology. Recent research has found that one factor of success is two-way feedback between health care personnel and the person using the diabetes app [48]. As such, future apps planned for a reciprocal communication from health care personnel would require experienced health scientists to assure the professional quality of the feedback, whether it is given automatically or in person.

4.2.2 Qualitative findings and ethical concerns regarding self-management technology

In the psychometric evaluation of the acceptability questionnaire, we failed to confirm three of the original factors (Paper III). These factors consisted of highly relevant themes regarding privacy and discomfort with the app, in addition to the app as a substitution to usual care with face-to-face consultations and overall satisfaction. The qualitative part of the study found these issues to be challenging for some of the participants as the use of the app could cause distress and the expressed need for additional health care support (Paper V). As such, it is of interest to discuss ethical issues further regarding the content and the delivery of the intervention.

MAST advises researchers to investigate ethical issues related to the app, or consequences of implementing the app [18]. Prior to the study, we did our best based on available knowledge at that time, to clarify the potential risks associated with the use of the app and health counselling in the information letter that composed part of the informed consent. The app itself was well-tested and several skilled technologists made

sure the equipment was reliable and safe. We performed a separate risk evaluation of the app and its security to avoid errors at both research institutions, based on recommendations.

However, health care devices are neither neutral nor innocent, and can affect the person using it, as well as their health, relationships, the health care system and policies [138], and the devices themselves have no capacity for moral judgement [139]. Technology is modern and progressive and at the same time demanding and involves routine work [140]. Today, an app intervention could easily be downloaded to the participants' own preferred smartphone. This could possibly reduce usability issues, though it would still have been necessary to study the potential barriers for app use.

Polit et al. describe how harm and discomfort for participants in nursing interventions can be physical, emotional, social or financial [107]. In line with this, we did find some reported emotional harm, such as stress. Therefore, in retrospect, the informed consent should also have described possible emotional harm, as some stress will be unavoidable, in addition to physical and financial harm.

Taking steps to avoid ethical concerns is not sufficient. We know that multiple factors influence both personal and environmental satisfaction, [141] and some forms of harm are difficult to predict. Both researchers and health care personnel have less knowledge about how a relationship develops between the user and the device, whether it becomes beneficial for the user or if they will experience unforeseen harm. Psychosocial consequences are difficult to detect in contrast with physical, unintended consequences [107]. We described a potential physical risk in the informed consent, which was a possible drop in blood glucose levels caused by the interventions provided due to increased physical activity or a more healthy diet. During the study, we measured blood glucose levels using both log data from the app and HbA_{1c} from medical records. This potential risk related to biomedical measures was easy to predict and to measure. However, it was far more complex to predict the extent of app-related emotional distress than the qualitative interviews revealed. We could have measured the level of diabetes distress using a scale, such as Problem Areas In Diabetes scale (PAID) or the Diabetes Distress Scale (DDS) [38,39,142], however the use of digital tools may lead to concerns related to both disease and health care [17]. The SUTAQ has one item that addresses whether the app made the participants feel physically or emotionally uncomfortable [21]. Emotional issues might to a larger extent be included in acceptability questionnaires to better address emotional harm in mHealth studies.

If we take a step back and take a closer look at our intention, we presented the app as a self-management tool, so that the users could manage their diabetes in a self-management oriented health care system. It was up to the users to decide if they wanted to share their data with health care personnel. In this manner, the app was an individualised tool. Multiple contextual and sociocultural factors can influence the chance to succeed in diabetes self-management. If a person fails to manage the provided technology, this type of individualised approach could lead to a sense of personal failure, self-blame and lack of desired behaviour [143]. When a person with type 2 diabetes views the treatment to be beyond their control and responsibility, the goal of improved self-management could be experienced as a burden [144]. However, part of the self-management task is to learn to manage the emotions related to the disease [46], and emotional intelligence and diabetes-related distress are associated with self-management behaviour. A better understanding of, and management of emotions may be beneficial for diabetes distress and self-management skills [145], and the user might be better able to manage the app when it reminds them of unhealthy health behaviour. As we detected some experiences of distress both digitally, clinically and in combination, the app, rather than being a benefit, could potentially become a burden on the user, if they are not able to self-manage. It could serve as a reminder of their lack of success, despite use of the tool. Shared decision-making is important for persons with type 2 diabetes in the health care sector, and this perspective must be considered when developing an app [132]. In a discussion on MAST, Kidholm et al. mentioned the awareness of patient dignity when they are constantly being monitored in their environment [18]. In this manner, the model initiated a fundamental basis for the intervention and potential ethical issues. Our findings emphasise the need for a broad ethical reflection when conducting research using diabetes apps in health care. It is important for researchers to be aware of both the expectations and experiences of this use [146] and to understand the balance between the apps' benefit and burden, researcher influence and user reactions.

Although our RCT did not find an effect of the intervention, our exploration of the acceptability of the app, through both quantitative and qualitative studies has provided contributions to future studies, for both implementation and evaluation, guided by user experiences, the participation of health scientists in multidisciplinary research teams, and by the use of further developed technology and its new and yet unknown opportunities.

4.3 Summary of the main findings

- We found no effect of the diabetes self-management mobile health intervention, either with or without health counselling as compared with usual care, at the 4-month or 1-year follow-up. There were no effects on the primary outcome HbA_{1c}, or secondary outcome as self-management, behavioural change and health-related quality of life
- The acceptability questionnaire did not prove to be a valid instrument, however the domain *perceived benefit* and *care personnel concerns* are domains of interest as they were the only domains that were confirmed.
- We found an associations between the acceptability domain *perceived benefit* at 1-year and baseline self-management. However, these associations did not withstand multiple linear regression analyses. Frequency of use of the app was the strongest predictor of perceived benefit.
- The qualitative evaluation revealed findings that suggested the potential for learning to manage type 2 diabetes by using the app. However, the users needed health care personnel to confirm their self-management decisions. In addition, the qualitative study revealed distress regarding both the digital use of the app and the clinical measures revealed by the app.

4.4 Future perspectives

In the future, qualitative studies and feasibility studies should precede well-planned RCTs to direct more attention to the acceptability of the intervention before measuring effect. Initial studies should address acceptability in a broader sense and perhaps for a selected group of participants at this stage of development. Furthermore, acceptability should be monitored during the conduction of the RCT to prevent unintended harm.

When evaluating mHealth interventions, better measurements are needed to evaluate acceptability of the interventions [11,78,88,89]. However, in the crossroads

between technical, clinical and care perspectives of an intervention with broad exposure, engagement from health scientists is required for the successful integration of health technology into clinical practice, in active dialogue with patients using the app.

This technology is continuously and rapidly developing, along with the possibility of automatic entry, complex features and advanced graphics. We can compare with the type 1 diabetes technology with closed loop, which automatizes blood glucose monitoring and adjusts medication [14,147]. Technology still has the potential to make diabetes self-management easier for people with type 2 diabetes and with less hands-on blood glucose control. Bioinformatics has the potential to utilise complex data analysis from diverse sources to assess dietary intake and provide individualised feedback adjusted to the diets that influence blood glucose and target behavioural change [148] or digital characters providing empathetic feedback [149]. Advanced technology could make feedback both automatic and individualised at another level and has the potential to give advice that is far more precise on how to successfully reduce HbA_{1c}. In addition, extensive analyses of app log data, both individual data and big data, offer endless opportunities.

Utilising these technological possibilities and balancing them with demanding self-management for persons with type 2 diabetes would require well-planned research and close interdisciplinary collaboration that focuses on both effect and acceptability.

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Appendix

Appendix 1 Informed consent

Appendix 2 Baseline questionnaires

Appendix 3 SUTAQ questionnaire, 1-year follow-up

Appendix 4 Information letter given the participants attending qualitative interviews

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.
Dersom det påløper ekstra utgifter til egenandel ved én eller flere av de tre konsultasjoner som er påkrevet i prosjektet, kan det søkes refusjon for det beløpet. Til dette må det benyttes et eget skjema som fås utlevert fra prosjektadministrasjonen.

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

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

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?

- ☐ 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?

- ☐ 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
- ☐ Aldri
- ☐ Vet ikke

ANDRE SYKDOMMER OG PLAGER

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

- ☐ Hjertesykdom
- ☐ Hjernesykdom
- ☐ 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!

Veiledning:
Nedenfor finner du en liste med utsagn som viser til det utstyr (telemedisinsk utstyr) du har fått utdelt som støtte til din behandling. Vær vennlig å angi i hvilken grad du er enig i hvert utsagn ved å **KRYSSE** av i den boksen som passer best for deg.

1. Utstyret har gjort at jeg har spart tid i og med at jeg ikke har hatt behov for å besøke min fastlege eller andre behandlere like ofte som ellers.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

2. Utstyret jeg har mottatt har forstyrret mine daglige gjøremål.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

3. Utstyret jeg har mottatt har gitt meg økt tilgang til behandling (hos helsepersonell og/eller sosiale tjenester).

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

4. Utstyret jeg har mottatt har hjulpet meg til å forbedre min helse.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

5. Utstyret jeg har mottatt har grepet inn i mitt privatliv.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

6. Jeg har fått tilstrekkelig veiledning i bruk av utstyret.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

7. Man kan stole på at utstyret virker hensiktsmessig.

☐	☐	☐	☐	☐	☐
Svært Enig	Nokså Enig	Litt Enig	Litt uenig	Nokså Uenig	Svært uenig

8. Utstyret har fått meg til å føle meg utilpass, f.eks. fysisk eller følelsesmessig.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

9. Jeg er bekymret for om de som følger med på min helse via utstyret har tilstrekkelig ekspertise.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

10. Utstyret har gjort at jeg er mindre bekymret for min helse og/eller helseoppfølging.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

11. Utstyret har gjort meg mer aktivt engasjert i min helse.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

12. Jeg er bekymret for konfidensialiteten av den private informasjon som sendes via utstyret.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

13. Utstyret gjør det mulig å følge bedre med på min tilstand for de som passer på meg.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

14. Jeg er fornøyd med utstyret jeg har mottatt.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

15. Utstyret kan/bør anbefales til andre personer med en liknende tilstand som min.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

16. Utstyret kan være en erstatning for min vanlige helseoppfølging.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

17. Utstyret kan helt sikkert være et godt supplement til min vanlige oppfølging i helsevesenet.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

18. Utstyret er ikke så velegnet som ansikt til ansikt konsultasjoner med de som følger meg opp.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

19. Utstyret har gjort det lettere for meg å komme i kontakt med behandlere i helsevesenet.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

20. Utstyret forstyrrer kontinuiteten i behandlingen jeg mottar (f.eks. at jeg ikke ser de samme behandlerne hver gang).

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

21. Jeg er bekymret for at den personen som følger opp min helsestatus gjennom utstyret ikke kjenner min personlige syke- og oppfølgingshistorie.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

22. Utstyret har gjort det mulig for meg å være mindre bekymret for min helsetilstand.

☐	☐	☐	☐	☐	☐
Svært enig	Nokså enig	Litt enig	Litt uenig	Nokså uenig	Svært uenig

Takk for dine svar.
Vær så snill å kontrollere at du har besvart alle spørsmålene.
Dine svar vil bli behandlet fortrolig.

UTDYPENDE INFORMASJON OM PERSONLIG INTERVJU VEDRØRENDE OPPLEVELSER KNYTTET TIL EGENBEHANDLING MED DIABETESDAGBOK PÅ MOBILTELEFON OG HELSEVEILEDNING

I det informerte samtykkeskrivet som du underskrev da du ble inkludert i studien - «Forespørsel om deltakelse i forskningsprosjektet *Egenbehandling med mobiltelefon og helseveiledning via SMS for personer med type 2 diabetes*» ble det opplyst i «Kapittel A – utdypende forklaring av hva studien innebærer» at noen vil få forespørsel senere om å delta i et intervju med en av forskerne for å snakke om hvordan de har opplevd tiltaket. Vi intervjuer nå alle etter hvert som de avslutter studien.

Siden du nå har avsluttet studien og har bekreftet at du kan tenke deg at vi tar kontakt med deg for et slikt intervju om dine erfaringer, ønsker jeg å gi deg litt mer informasjon om intervjuet. Videre ønsker jeg å lage en avtale for gjennomføringen av intervjuet, så fremt du fortsatt er interessert.

Intervjuet vil kunne foretas i ditt eget hjem, på mitt kontor, eller på samme sted som du har vært på møter i studien tidligere.

Dersom du deltar i dette intervjuet så er det en samtale hvor du med egne ord vil si noe om hvordan du har opplevd å bruke den elektroniske Diabetesdagboken og hvordan du har opplevd helseveiledningen. Intervjuet vil vare ca. 1,5 time. En slik samtale hvor man kan snakke om sine tanker i ro og fred vil for mange kjennes godt. Samtalen vil bli tatt opp på lydbånd som slettes når analysen er ferdig. Analysearbeidet vil skje i samarbeide med med-forskere i prosjektet. Etter at analysearbeidet er avsluttet vil alle data bli anonymisert. Dette innebærer at de opplysningene jeg får av deg blir behandlet konfidensielt, lagret avidentifisert og blir publisert på en slik måte at din anonymitet er sikret.

Jeg ber samtidig om å få ringe deg etter intervjuet dersom jeg skulle bli usikker på om jeg har forstått deg rett.

Deltagelsen er frivillig og du kan trekke deg fra undersøkelsen på et hvilket som helst tidspunkt uten å angi årsak og uten at det får personlige konsekvenser for deg av noe slag.

Hvis det er noe du lurer på kan du kontakte Marit Rønnevig. Min postadresse er Høgskolen i Oslo og Akershus, Fakultet for Helsefag, Institutt for Sykepleie, Postboks 4, St.Olavs Plass, 0130 OSLO, Epost: Marit.Ronnevig@hioa.no, Tlf: 67 23 61 77, mobil 911 61 731.

Du kan også kontakte forskningsansvarlig Lis Ribu, Høgskolen i Oslo og Akershus, Fakultet for Helsefag, Institutt for Sykepleie, tlf 922 06 229.

Med vennlig hilsen

Marit Rønnevig

Paper I – V

I

Original Paper

A Low-Intensity Mobile Health Intervention With and Without Health Counseling for Persons With Type 2 Diabetes, Part 1: Baseline and Short-Term Results From a Randomized Controlled Trial in the Norwegian Part of RENEWING HEALTH

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Related Article:

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Abstract

Background: Self-management support for people with type 2 diabetes is essential in diabetes care. Thus, mobile health technology with or without low-intensity theory-based health counseling could become an important tool for promoting self-management.

Objectives: The aim was to evaluate whether the introduction of technology-supported self-management using the Few Touch Application (FTA) diabetes diary with or without health counseling improved glycated hemoglobin (HbA_{1c}) levels, self-management, behavioral change, and health-related quality of life, and to describe the sociodemographic, clinical, and lifestyle characteristics of the participants after 4 months.

Methods: A 3-armed randomized controlled trial was conducted in Norway during 2011-2013. In the 2 intervention groups, participants were given a mobile phone for 1 year, which provided access to the FTA diary, a self-help tool that recorded 5 elements: blood glucose, food habits, physical activity, personal goal setting, and a look-up system for diabetes information. One of the intervention groups was also offered theory-based health counseling with a specialist diabetes nurse by telephone for 4 months from baseline. Both intervention groups and the control group were provided usual care according to the national guidelines. Adults with type 2 diabetes and HbA_{1c} ≥7.1% were included (N=151). There were 3 assessment points: baseline, 4 months, and 1 year. We report the short-term findings after 4 months. HbA_{1c} was the primary outcome and the secondary outcomes were self-management (Health Education Impact Questionnaire, heiQ), behavioral change (diet and physical activity), and health-related

quality of life (SF-36 questionnaire). The data were analyzed using univariate methods (ANOVA), multivariate linear, and logistic regression.

Results: Data were analyzed from 124 individuals (attrition rate was 18%). The groups were well balanced at baseline. There were no differences in HbA_{1c} between groups after 4 months, but there was a decline in all groups. There were changes in self-management measured using the health service navigation item in the heiQ, with improvements in the FTA group compared to the control group (*P*=.01) and in the FTA with health counseling group compared with both other groups (*P*=.04). This may indicate an improvement in the ability of patients to communicate health needs to their health care providers. Furthermore, the FTA group reported higher scores for skill and technique acquisition at relieving symptoms compared to the control group (*P*=.02). There were no significant changes in any of the domains of the SF-36.

Conclusions: The primary outcome, HbA_{1c}, did not differ between groups after 4 months. Both of the intervention groups had significantly better scores than the control group for health service navigation and the FTA group also exhibited improved skill and technique acquisition.

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KEYWORDS

self-care; quality of life; diabetes mellitus, type 2; randomized controlled trials; telemedicine; mHealth; mobile apps; counseling; complex intervention; life style

Introduction

People with type 2 diabetes have an increased risk of cardiovascular morbidity and mortality, but the multifactorial risk can be reduced by changes in diet, exercise, and education often combined with antihypertensives, statins, and oral glucose-lowering agents or insulin-lowering drugs [1-3]. However, type 2 diabetes is a complex disease for the individual and clinicians [4]. Furthermore, severe comorbidity may decrease the capacity for self-management and patients with a macrovascular comorbidity, such as heart failure, or other diseases not related to the diabetes (eg, depression and chronic pain) may place a lower priority on their diabetes treatment [5]. Moreover, the co-occurrence of multiple diseases is associated with obesity [6] and weight loss through behavioral change may be an essential part of the treatment [7], although findings regarding the benefits of weight loss are inconclusive [8,9].

Intensive long-term interventions related to lifestyle and obesity in patients with type 2 diabetes have achieved some effects on weight loss and improved glycemic control, but these were not enduring [10]. The treatment is also more complex when type 2 diabetes is of longer duration. Due to costly treatment, it may become necessary to differentiate between those in need of a low- or high-intensity intervention, thereby offering the patients the lowest level of effective management [11] and reducing the costs. This approach is in accordance with the Norwegian Coordination Reform, which aims to transfer treatment services from hospitals to local centers in the municipalities [12]. At present, most patients with chronic diseases are treated in primary care where they are educated to improve their self-management, which is an important activity for the successful attainment of personal health goals, and to communicate with health professionals [13]. Furthermore, the development of self-management support is recommended by international guidelines because it has also been shown to have an effect on glycemic control [14,15].

Computer-based solutions may support self-management in everyday life and research shows that mobile health tools in particular may improve glycemic control, although the findings are inconclusive [16-18]. Furthermore, few telemedicine studies have detected effects on cognitive, behavioral, or emotional outcomes [17], and few studies have measured self-management using appropriate questionnaires. Some interventions combine self-monitoring with professional support, which is based primarily on the monitoring of results by health care providers, with subsequent counseling and advice [18-22]. More research is needed in this area to determine the effects on both clinical outcomes and self-management, and to assess the benefit of providing health counseling to support patients in the implementation and maintenance of the necessary behaviors required to manage their diabetes [15].

The European Union collaborative project REgioNs of Europe WorkING together for HEALTH (RENEWING HEALTH) was set up to evaluate innovative telemedicine tools on a large scale using a specially designed framework, the Model for the Assessment of Telemedicine (MAST) [23]. The present study is from the Norwegian part of the RENEWING HEALTH network. Results from the 4-month intensified part of a 1-year intervention are presented in the present paper.

The primary aim of this paper was to assess whether the use of a mobile health self-management intervention, the Few Touch Application (FTA) diabetes diary [24], with and without a theory-based health counseling intervention, was superior to usual care in terms of glycated hemoglobin A_{1c} (HbA_{1c}) levels, self-management, behavioral change (diet and physical activity), and health-related quality of life after 4 months. Further, the secondary aim was to describe sociodemographic, clinical, and lifestyle characteristics of persons volunteering to participate in such a lifestyle intervention.

Methods

Study Design

This study was a block randomized controlled trial (RCT) [25] with 3 parallel groups: 1 control group and 2 intervention groups using the FTA diary during the 1-year study in which 1 of the

2 groups received a strengthened intervention with health counseling. The groups are described in detail in the study protocol [26]. We had a longitudinal design with 3 assessment points: baseline, after 4 months, and after 1-year follow-up. Further, the patients' registrations in the FTA diary were recorded continuously and transferred securely to a server for research purposes.

Participants

We used broad eligibility criteria: age ≥18 years, diagnosed with type 2 diabetes a minimum of 3 months before inclusion, HbA_{1c} ≥7.1%, able to use the FTA system, and capable of understanding and completing the questionnaires. The exclusion criteria were mental or physical conditions that interfered with the protocol [26]. HbA_{1c} measurements needed to be available to the researchers within a 1-month window (ie, 2 weeks before or after randomization) to control the eligibility criteria [27]. Participants were recruited to the study by several routes. Firstly, through general practitioners who accepted an invitation by letter after being supplied with standard information about the protocol. Secondly, at educational "diabetes start courses" which were arranged by the health care specialist for patients newly diagnosed with diabetes, and from local public health clinics in the municipalities. Finally, a few participants were recruited through media advertising. People who stated their willingness to participate were given a letter that contained a brief summary of the study and an invitation to obtain more in-depth information at start-up group meetings arranged by the research team, each of which included a maximum of 10 participants. The participants were also allowed one-to-one meetings if group meetings were not feasible for practical reasons. The participants were randomized after they signed the informed consent form.

Study Setting and Data Collection

Participants were from the Northern and Southeastern part of Norway because the project originated from research teams in these regions and the inclusion of participants was conducted in local start-up group meetings in the regions.

The recruitment period lasted from March 2011 to October 2012. The measurement points were at baseline, after 4 months, and after 1 year. The short-term follow-up was performed between August 2011 and January 2013.

After 4 months, all the participants were invited to attend the first follow-up meeting to complete the questionnaires. They were also asked to visit their general practitioner for measurement of their HbA_{1c} levels and collection of data from their medical records. Preferably, the general practitioners completed the patients' case record form at the same time as the questionnaires (±14 days) and returned them to the researchers in a prepaid addressed envelope. Participants who could not attend the follow-up meeting were sent the questionnaires by mail to their postal address with a prepaid addressed envelope to return them to the study center.

Randomization

We used a computer-generated block randomization system, which was developed and administered by the Unit of Applied Clinical Research, Institute of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway, to ensure a good balance between the numbers and confounding factors in each of the 3 groups. The blocks were small and their sizes varied. The procedure is described in detail elsewhere [26].

Power

Power analyses were performed before recruitment to estimate the sample size required based on the HbA_{1c} level as the primary outcome. The sample size was estimated to be 34 individuals in each group with a decrease in the HbA_{1c} level of 0.35%, a significance level of 5%, a standard deviation (SD) in the outcome variable of 0.5, statistical power of 80%, and a 2-tailed significance test. To compensate for dropouts, the sample size was set to 50 in both intervention groups and 50 in the control group (total=150).

Control Group

The control group received usual care according to the Norwegian clinical guidelines [28]; patients with type 2 diabetes are recommended to consult their general practitioner every 2-6 months and to have a more thorough consultation once a year with measurements of their blood pressure, serum lipids, glucose, HbA_{1c}, weight, body mass index (BMI), etc. The treatment target for HbA_{1c} in Norway is ≤7.0% [28].

Intervention

In addition to the usual care provided by their general practitioners, the participants randomized to the intervention arms received either the FTA diary only or the FTA diary and health counseling, which are described subsequently and in more detail in the published protocol [26].

Few Touch Application Intervention

Both intervention groups were given a smartphone with the FTA diary for type 2 diabetes system installed. The participants were generally not able to use the app on their own smartphone because it required a specific phone model to operate properly. They were encouraged to replace their current mobile phone with the smartphone provided for the study and use it in everyday life as an ordinary mobile phone and as a diabetes diary. The smartphone provided was a HTC HD Mini based on the Windows Mobile 6.5 operating system, and the blood glucose meter was the OneTouch Ultra Easy from LifeScan. The phone and the blood glucose meter were linked using Bluetooth wireless communication so that glucose measurements were automatically transferred to the diabetes diary part of the FTA on the phone. The FTA and smartphone intervention lasted for 1 year. The FTA is a self-management tool that comprises 5 main elements accessible to the user: (1) the blood glucose data management system, (2) food habits data management system, (3) physical activity data management system, (4) personal goal-setting system, and (5) general diabetes information look-up system [24]. The blood glucose results were transferred directly from the blood glucose monitoring system to the app via Bluetooth. The diet and physical activity systems enabled an easy way of entering such data manually into the diabetes diary by the user.

Few Touch Application With Health Counseling Intervention

In addition to the FTA intervention described previously, the participants in this group were offered health counseling with a diabetes specialist nurse for 4 months from baseline. The health counseling was based on motivational interviewing [29], the transtheoretical model [30], and a problem-solving model [11]. The nurse also supported the participants in their use of the FTA, specifically the various elements of the tool and how to take advantage of the app. The participants received 5 telephone calls from the nurse during the first 4 months, each of which lasted for an average of 20 minutes. A schedule for each conversation was developed before the study by an interdisciplinary research team [26]. In addition, the participants could contact the diabetes specialist nurse via a secured text messaging system using their smartphones when necessary [31]. The nurse responded to the messages at least twice each week. The monitoring of the sessions showed that 38 of 50 participants (76%) completed the whole program (all 5 modules), whereas 12 participants conducted 4 modules or less. Of these, 4 participants completed 4 of 5 health counseling sessions, 2 completed 3 of 5 sessions, 4 completed 2 of 5 sessions, and 2 completed 1 of 5 sessions.

Training

Both the FTA group and the FTA with health counseling group were trained to use the mobile phone-based system at the start-up meetings, which included a demonstration of the diabetes diary [26]. They were also provided with a manual that contained instructions on the use of the smartphone, whereas the instructions for the FTA were supplied in the form of a paper-based handbook and on a universal serial bus (USB) memory stick. In addition, the consent form informed the participants about the diary and its specific procedures. A telephone support service was available to answer questions and to help the participants with technical aspects during weekdays from 9:00 to 15:00. The participants in the FTA with health counseling group were given additional training about how to send and receive secure messages to the diabetes specialist nurse.

Measures

We used a broad evaluation based on a complex intervention framework [32] and MAST [23]. The Consolidated Standards of Reporting Trials (CONSORT) statement for reporting of RCTs [33], CONSORT for pragmatic trials [25], and the eHealth checklist [34] were used. The primary and secondary outcomes are described in Table 1, as well as the time points for the assessments. RENEWING HEALTH established a common minimum dataset of sociodemographic and clinical characteristics for all regions in the project (Table 1). Depressive symptoms were defined based on a total Center for Epidemiologic Studies Depression Scale (CES-D) score ≥16 [35]. Behavior change was measured with diet [36,37] and physical activity [38,39] questionnaires, and with the Health Education Impact Questionnaire (heiQ) [13]. Participants who reported a minimum of 60 minutes per week of moderate to vigorous activity were categorized as physically active. Detailed descriptions of the measures and the national and international validations of the measures are given in the published protocol [26]. The Diabetes Empowerment Short-Form scale [40] (described in the protocol) demonstrated a ceiling effect; thus, the data collected using this scale were not analyzed.

Table 1. Data collected at baseline and after 4- and 12-month follow-ups.

Measurements	Baseline	After 4 months	After 12 months
Sociodemographic variables			
Demographics, marital status, education, work situation[c]	X		
Clinical characteristics			
Related to disease, self-monitoring blood glucose, late complications (foot ulcer, eye)	X		
Comorbidity[c] (EU minimum dataset)	X		
Smoking and alcohol habits[c]	X		X
Self-reported questionnaires			
Health-related quality of life (SF-36) version 2.0 [41][b,c]	X	X	X
Depression (CES-D) [35]	X	X	X
Self-management (heiQ) [13][b]	X	X	X
Physical activity (from HUNT) [38] and motivation (transtheoretical model) [39][b]	X	X	X
Diet [36,37][b]	X	X	X
System Usability Scale [42][d]		X	
Service user technology acceptability (SUTAQ)[c,d]			X
Participation in other courses/programs during the study[e]			X
In-depth interviews			
Participants' perceptions of the intervention[d]			X
From general practitioners' medical records			
Diabetes medication	X		
Change in medication		X	X
Medication in general			X
Height[c]	X		
Weight, blood pressure, and waist circumference[c]	X		X
HbA_{1c}[a]	X	X	X
Lipids	X		X
Hypoglycemic events	X	X	X
Cardiovascular complications	X		
Use of health care, expenses[c]		X	X
General practitioners classification of diseases			X
Mobile user log			
Log data from FTA[d]	X	X	X

[a] Primary outcome.

[b] Secondary outcome.

[c] EU minimum dataset.

[d] Only the groups receiving a mobile phone (FTA and FTA with health counseling).

[e] Such as swimming, cooking, weight reduction.

Blood Samples and Clinical Data

Information about the HbA_{1c} level, weight, height, blood pressure, and medication were obtained from the medical records through the case record form. The HbA_{1c} level was also measured using a DCA Vantage Analyzer (Siemens) by the research team if the HbA_{1c} results were not provided by the general practitioner or were missing for other reasons (19/269,

7.1% of total cases). The blood pressure was measured according to the standardized instructions (ie, the clinicians used the correct cuff size and the patient was sitting for a 5-minute rest before 3 measurements were obtained with 1-minute intervals) and the mean of the last 2 measurements was recorded. The waist circumference was measured at the umbilical level.

Blinding

Blinding of participants was not possible because the participants were aware of their group allocations. The general practitioners were not blinded because the participants were encouraged to discuss the progression of their glucose measurements, diet records, and activity logs with them. The assessment of the participants' eligibility according to the inclusion criteria and the smartphone use training were performed by the research team. The researchers were part of the project team; thus, they also knew the groups to which the participants were allocated as did the technical support team.

Statistical Analysis

The baseline sociodemographic, clinical, treatment variables, and lifestyle characteristics were expressed as counts with percentages for categorical variables or means and SDs for continuous variables. The differences in mean change from baseline to 4-month follow-up between the groups were analyzed using 1-way analyses of variance (ANOVA) for both the primary outcome (HbA_{1c}) and the secondary outcomes (heiQ and SF-36). Further, change in both primary (HbA_{1c}) and secondary outcomes (heiQ and SF-36) were modeled with univariate linear regression models. To correct for possible confounding effects, we adjusted for age, gender, education, comorbidity, work situation, BMI, depression, and regions from different parts of Norway using multiple linear regression. For baseline measurements, all 3 groups were compared using the Kruskal-Wallis test.

Data that were not available were considered missing and the results were based on the intention-to-treat approach. The trend in the use of the app was described with number of glucose measurements and other keystrokes in the app. P values <.05 were considered statistically significant. All tests were 2-sided. The analyses were performed using SPSS version 21 (IBM Corp, Armonk, NY, USA).

Ethics and Safety

The study was approved by the Regional Committee for Medical and Health Research Ethics. All participants gave their written informed consent before study start. The ethical guidelines and rules were followed with the intention to do well and prevent harm or risks.

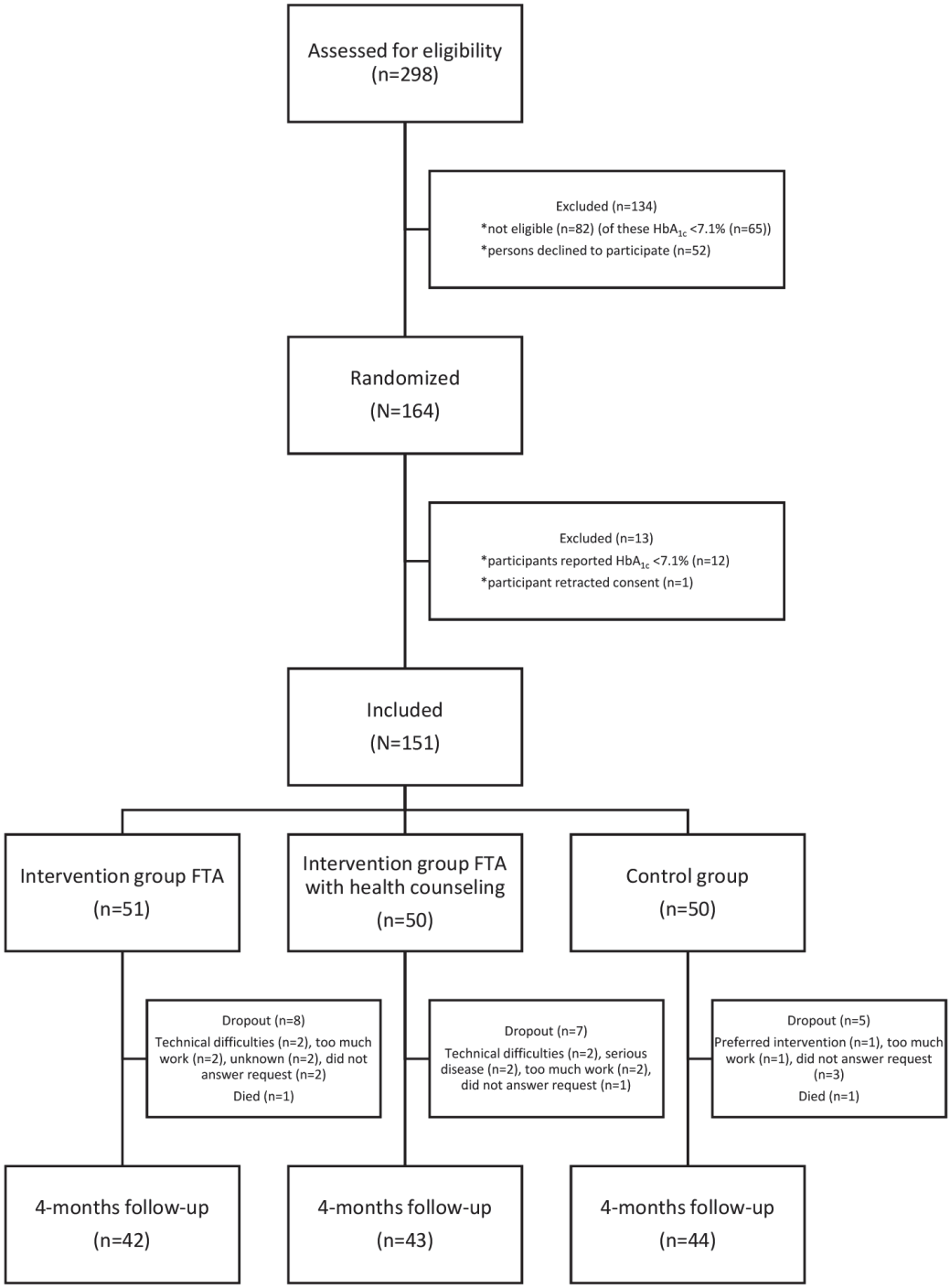
The participants' entries in the FTA diabetes diary app were recorded continuously and transferred to a secure server at 1 of the study sites (Tromsø). A comprehensive risk analysis of the technology was performed before the start of the study to ensure that privacy and security issues were addressed in an appropriate manner and the data were kept at the responsible research institutions [26]. Through the informed consent form, participants were made aware of the possibility of hypoglycemia related to behavioral change and they were informed to contact their general practitioner according to their instructions.

Results

Overview

In total, 298 individuals were assessed for eligibility (Figure 1), 65 of which were excluded because of HbA_{1c} levels <7.1%, 17 were not eligible due to other reasons, and 52 declined to participate. In total, 164 participants were randomized of which 151 were included in the study because 12 participants had HbA_{1c} <7.1% at the time of inclusion and 1 retracted consent.

Figure 1. Flow diagram showing the design of the study.



Baseline Characteristics of the Groups

There were no statistically significant differences between the groups in terms of the baseline variables, except for rheumatism and depressive symptoms (Table 2). Significantly more participants in the FTA group had rheumatism compared with both of the other groups (n=11, 4, and 3 in the FTA, FTA with health counseling, and control groups, respectively, *P*=.03). More individuals had depressive symptoms (a CES-D score ≥16) in the control group (n=17) compared with the FTA group (n=10) and the FTA with health counseling group (n=7, *P*=.045).

Of the 151 participants, the mean age was 57 years (SD 12), 62 (41.1%) of participants were women, and 83 (55.0%) had less than 12 years of education. The mean HbA_{1c} was 8.2% (SD 1.1) or 66 mmol/mol (SD 12), the mean BMI was 31.7 kg/m^2 (SD 6.0), and 58.1% (75/129) were obese [43]. Only 9 of 131 participants (6.9%) did not receive glucose-lowering medication. In total, almost half of the participants (72/151, 48%) reported 2 or more comorbidities and 36 of 151 (23.8%) reported heart disease.

Table 2. Baseline characteristics of the control group and the 2 intervention groups.

Variables	Intervention groups		Control group (n=50)
	FTA (n=51)	FTA with health counseling (n=50)	
Sociodemographic characteristics			
Age (years), mean (SD)	58.6 (11.8)	57.4 (12.1)	55.9 (12.2)
Gender (female), n (%)	17 (33)	25 (50)	20 (40)
Educational background <12 years, n (%)	26 (51)	26 (52)	31 (62)
Clinical characteristics			
HbA $_{1c}$ (%), mean (SD)	8.1 (1.1)	8.2 (1.1)	8.3 (1.2)
HbA_{1c} (%),median (range)	7.8 (7.1-12.4)	7.9 (7.1-11.3)	7.9 (7.1-11.6)
HbA_{1c} (mmol/mol), mean (SD)	65 (12.1)	66 (12.2)	67 (12.7)
Comorbidity (≥2), n (%)	28 (55)	22 (44)	22 (44)
BMI (kg/m^2), mean (SD)	32.4 (6.5)	30.7 (5.6)	32.0 (6.0)
BMI range, n (%)			
Normal (18.50-24.99)	2 (4)	7 (16)	4 (10)
Preobese (25.00-29.99)	17 (38)	13 (30)	11 (28)
Obese class I (30.00-34.99)	13 (29)	14 (32)	15 (38)
Obese class II (35.00-39.99)	8 (18)	6 (14)	6 (15)
Obese class III (≥40)	5 (11)	4 (9)	4 (10)
Missing data, n	6	6	10
Weight (kg), mean (SD)	98 (23)	91 (20)	96 (25)
Missing data, n	6	4	9
Height (cm), mean, (SD)	173 (10)	171 (10)	172 (11)
Missing data, n	6	6	10
Blood pressure (mm Hg), mean (SD)			
Systolic	136 (16.9)	132 (13.7)	134 (14.5)
Diastolic	81 (8.2)	79 (8.6)	82 (9.4)
Missing data, n	8	7	16
Duration of diabetes (years), mean (SD)	11.2 (7.3)	9.6 (8.4)	9.4 (5.5)
Missing data, n	3	5	5
Treatment variables			
Glucose-lowering medication, n (%)			
No medication	3 (7)	2 (4)	4 (11)
Only oral agents	20 (44)	27 (57)	16 (42)
Only injections	9 (20)	7 (15)	3 (8)
Combination oral/injections	14 (30)	11 (23)	15 (40)
Missing data, n	5	3	13
Self-monitoring blood glucose, n (%)	48 (94)	45 (90)	49 (98)
Lifestyle characteristics			
Smoking (yes), n (%)	5 (10)	12 (24)	7 (14)
Physical activity, n (%)			

Variables	Intervention groups		Control group (n=50)
	FTA (n=51)	FTA with health counseling (n=50)	
Little or not engaged in physical activity	31 (63)	34 (68)	33 (66)
Some to very engaged in physical activity	18 (37)	16 (32)	17 (34)
Missing data, n	2	0	0

Characteristics in Responders Versus Nonresponders

When comparing distribution of variables at baseline and at 4 months in responders versus nonresponders, there were no significant differences between the groups. Hence, our analyses of dropouts vs nondropouts indicated that attrition did not change the distribution between the groups at baseline (Table 3).

Table 3. Differences between responders and nonresponders at 4 months.

Variables	Responders at 4 months (n=118)	Nonresponders[a] at 4 months (n=33)	*P*
Age (years), mean (SD)	57.9 (10.7)	55.3 (15.9)	.52[b]
Gender (female), n (%)	47 (39.8)	15 (46)	.56[c]
Education <12 years, n (%)	68 (57.6)	15 (46)	.21[c]
HbA_{1c} (%), mean (SD)	8.2 (1.1)	8.2 (1.1)	.74[b]
BMI (kg/m^2), mean (SD)	31 (6.0)	34 (5.9)	.09[b]
Missing data (BMI), n	7	15	
Comorbidities ≥2, n (%)	58 (49.2)	14 (42)	.49[c]
Diabetes duration (years), mean (SD)	10 (7.0)	9 (7.8)	.20[b]
Missing data (diabetes duration), n	9	4	

[a] Nonresponders (those without HbA_{1c} at 4 months).

[b] Between-group differences tested with Mann-Whitney test.

[c] Between-group differences tested with chi-square test.

Primary Outcomes and Estimations

In total, 118/151 (78.2%) participants provided HbA_{1c} data at 4 months. There were no statistically significant differences in HbA_{1c} level changes from baseline between the 3 groups (*P*=.65) after 4 months (Table 4). Adjustments for age, gender, and education did not affect the estimates.

The mean HbA_{1c} level declined in all groups: –0.41 (95% CI –0.71 to –0.11) in the FTA with health counseling group, –0.23 (95% CI –0.47 to 0.01) in the FTA group, and –0.39 (95% CI –0.75 to –0.03) in the control group.

Table 4. Changes in HbA_{1c} between baseline and 4 months.

Groups	Baseline		4 months		Mean change	
Intervention	n	Mean (95% CI)	n	Mean (95% CI)	n	Mean (95% CI)
FTA	51	8.1 (7.8, 8.4)	40	7.8 (7.5, 8.0)	40	–0.23 (–0.47, 0.01)
FTA with health counseling	50	8.2 (7.9, 8.5)	39	7.8 (7.4, 8.2)	39	–0.41 (–0.71, –0.11)
Control	50	8.3 (8.0, 8.6)	39	8.0 (7.6, 8.4)	39	–0.39 (–0.75, –0.03)

Secondary Outcomes

We obtained data from 124/151 (82.1%) participants who provided self-reported data at 4 months. We found that there was significantly improved self-management between baseline and 4-month follow-up with respect to 2 heiQ domains for at least 1 intervention group compared to the control group (Table 5). The participants in the FTA group reported significantly higher scores than the control group (*P*=.01) for health service navigation indicating an improved ability to discuss their health

needs with their provider. Moreover, the FTA with health counseling group reported significantly higher scores than both the control group and the FTA group (*P*=.04) also after the scores were adjusted for age, gender, and education level to account for possible confounders (Table 6).

For the skill and technique acquisition domain, which indicates that the participants possess the skills and techniques required to relieve symptoms and manage health challenges, the FTA group reported significantly higher scores than the control group (*P*=.02) after adjusting for age, gender, and education level in the linear regression analyses. However, there were no differences between the FTA with health counseling group and the other 2 groups (*P*=.11). The difference between the FTA group and the control group was also found after adjusting for age, gender, and education level.

We fitted linear regression models for the health service navigation domain and the skill and technique acquisition domain and the following explanatory variables: duration of diabetes, comorbidity, work situation, BMI, depression, and regions from different parts of Norway. None of these explanatory variables were statistically significant.

There were no statistically significant differences in the changes between baseline and 4-month follow-up for health-related quality of life (SF-36) within or between the 3 groups or for changes in diet and physical activity (results not shown).

The trend in the use of the app was not particularly different between the 2 intervention groups regarding either the number of blood glucose measurements (Figure 2) or number of keystrokes (Figure 3). The degree of use was lowest during the first month; it increased slightly during the second month and remained at about the same level during the third and fourth months.

Table 5. Changes in 2 heiQ domains from baseline to 4 months.

Domain and group	Baseline		4 months		Mean change	
	n	Mean (95% CI)	n	Mean (95% CI)	n	Mean (95% CI)
Skills and technique acquisition						
FTA	51	2.95 (2.82, 3.07)	40	2.98 (2.81, 3.15)	40	0.02 (–0.12, 0.16)
FTA with health counseling	50	2.87 (2.75, 2.99)	41	3.04 (2.90, 3.19)	41	0.17 (0.04, 0.29)
Control	50	2.92 (2.83, 3.02)	43	2.92 (2.76, 3.07)	43	–0.04 (–0.18, 0.09)
Health service navigation						
FTA	51	3.14 (3.00, 3.28)	40	3.21 (3.04, 3.37)	40	0.02 (–0.10, 0.14)
FTA with health counseling	50	3.08 (2.95, 3.20)	41	3.27 (3.11, 3.42)	41	0.22 (0.07, 0.37)
Control	50	3.13 (2.98, 3.27)	43	3.20 (3.05, 3.35)	43	0.00 (–0.11, 0.12)

Table 6. Linear regression analysis with crude and adjusted values for HbA_{1c} and heiQ domains from baseline to 4-month follow-up.

Group	n	Unadjusted		Adjusted[a]	
		Estimated β (95% CI)	*P*	Estimated β (95% CI)	*P*
HbA 1c					
FTA	40	.02 (–.40, .44)	.91	.03 (–.40, .46)	.90
FTA with health counseling	39	.18 (–.24, .60)	.40	.16 (–.27, .58)	.47
Control (ref)	39				
heiQ domains					
Skills and technique acquisition					
FTA	40	–0.21 (–0.39, –0.03)	.02	–0.22 (–0.40, –0.03)	.02
FTA with health counseling	41	–0.14 (–0.33, 0.04)	.13	–0.15 (–0.34, 0.03)	.11
Control (ref)	43				
Health service navigation					
FTA	40	–0.21 (–0.39, –0.04)	.02	–0.23 (–0.41, –0.05)	.01
FTA with health counseling	41	–0.20 (–0.38, –0.02)	.03	–0.19 (–0.37, –0.01)	.04
Control (ref)	43				

[a] Adjusted for age, gender, and education.

Figure 2. Number of blood glucose measurements during the first 4 months for the 2 intervention groups: Few Touch Application (FTA) and FTA with health counseling (HC). Time 1 (baseline): n=90; time 2: n=83; time 3: n=80; and time 4: n=79.

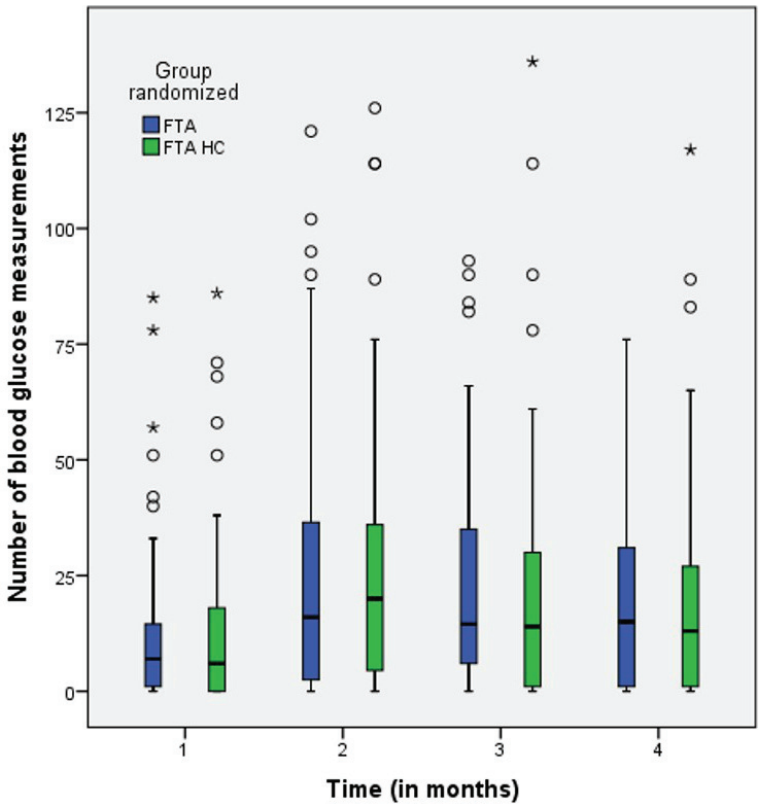
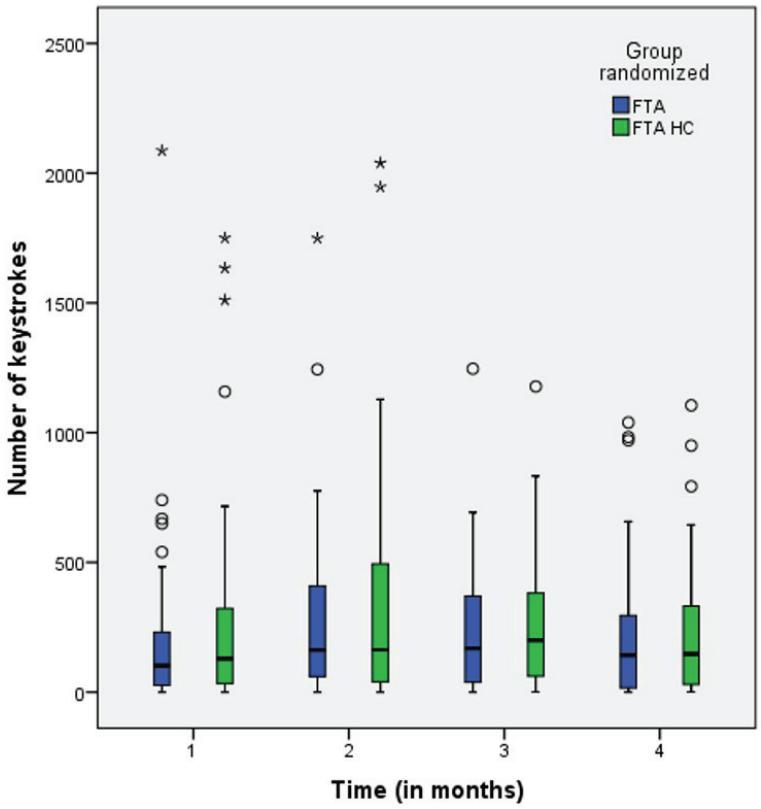


Figure 3. Number of keystrokes during the first 4 months for the 2 intervention groups: Few Touch Application (FTA) and FTA with health counseling (HC). Time 1 (baseline): n=90; time 2: n=83; time 3: n=80; and time 4: n=79.



Adverse Events

No adverse events or important unintended effects were reported. Two persons died during the study, but these events were not related to the intervention or the study overall.

Discussion

We found no significant changes between groups for the primary outcome measure HbA_{1c}, although there were declines in the control group and in the intervention groups from baseline to 4-month follow-up. However, to the best of our knowledge, this is the first study to describe an effect of an electronic diabetes diary (FTA) in persons with type 2 diabetes in terms of their self-management and confidence in their capacity for health service navigation which may indicate an improved understanding of how to access health care to meet their needs. In addition, we found that the participants developed skills and technique acquisition, indicating that they improved their skills in relieving symptoms and gaining better health (according to heiQ) [13]. The FTA with or without health counseling from the diabetes specialist nurse appears to be a supporting tool that improved perceived self-management and it may have mitigated the burden caused by the illness.

The reasons for the lack of effect on the primary outcome of HbA_{1c} between groups are not clear, but several explanations are possible.

First, the HbA_{1c} level declined in all groups, thus the FTA intervention with or without health counseling may not be sufficiently effective, at least in the short term, to encourage a sufficient change in lifestyle to cause a further decrease in HbA_{1c}. It is also reasonable to question what outcome measures could be used to better judge the effectiveness of self-management interventions and to evaluate behavior change [40,44]. The participants in our study had a mean diabetes duration of approximately 10 years and approximately 60% were obese, 50% reported 2 or more comorbidities, and only 7% did not receive glucose-lowering medication. In total, 31% of the participants were treated with both oral medication and injections, indicating that they had serious disease, which makes it difficult to reduce HbA_{1c} with a low-intensity lifestyle intervention. Thus, a higher intensity intervention may be required that considers the complexity of chronic conditions, whereas the low-intensity intervention used in our study provided less support and less frequent contacts with the health care providers [11,26]. However, after we adjusted for BMI, comorbidities, and medication, we found no indications that the effect differed between those with high and low BMI or disease burdens. Irrespective of these findings, one may nevertheless speculate whether a low-intensity intervention is appropriate for people who have been living with diabetes for a long time and if it is realistic to think that lifestyle changes can result in improved self-management and weight reduction. More recently, research has indicated that contact in clinical practice through telemedicine should be increased over time [18]. Many patients need closer support with structured interventions to help them attain the goals that they chose [15].

The FTA intervention could also have been too time-consuming because it required daily recordings of blood glucose, diet, and physical activity, and even more for the group that received additional health counseling. However, the app was accessed via the smartphone distributed in the project and it could be used as their own and when convenient. Another aspect of interest in this intervention is the health psychology models used in the health counseling and the proper use of theories in mHealth in general. Different directions within health psychology may also suit different people. More research within this area is needed. A transdisciplinary research approach is necessary in this matter and this is an area in which technology and psychology have to cooperate closer in the future.

Blinding of participants and health care personnel was not possible and the decline in the HbA_{1c} level in all groups, including the controls, may be attributed to the Hawthorne effect, particularly the attention the participants received when joining the study, which may have increased their self-confidence with respect to their diabetes management. They may also have received special attention from their general practitioners because "their patients" were included in a lifestyle intervention with modern technology [45]. Furthermore, according to the study design, a run-in period prior to randomization could have helped to stabilize the HbA_{1c} level before the study started, but we lacked the resources and the time for this additional process. However, a run-in period could also have led to increased dropouts, which in turn could have threatened the external validity if only participants that were highly motivated by a telemedicine intervention were randomized. In addition, expectations about the project and the possible intervention could have increased during a run-in period; thus, the participants who were disappointed about not receiving the expected intervention might have caused further dropouts and threatened a successful randomization due to dropouts from causes other than usual [46-49]. To address this challenge, a stepped wedge trial design, in which all participants received the intervention gradually could have compensated for the dilemma of withholding the intervention and the related Hawthorne effect. However, the design would then have been expensive because of the length of the intervention and the demands of collecting data [50]. More research is needed to optimize intervention-based research designs for patients with diabetes, as discussed previously [51].

It was also interesting that several participants wanted to attend the study although they were not eligible according to the eligibility criterion of HbA_{1c} ≥7.1%, as indicated in the flow diagram. This suggests that even though they were within their recommended treatment goals, they felt the need for professional support to facilitate a lifestyle change in addition to their use of medication. This should be taken into consideration when deciding the inclusion criteria and using HbA_{1c} as a primary outcome in future research.

With respect to the self-management measures, we found that the participants in both intervention groups reported significantly better scores for the heiQ health service navigation domain, whereas the intervention group that received FTA also reported significantly better scores in the skill and technique acquisition

domain. Increased skill and technique acquisition may indicate an increased ability to reduce symptoms and manage health challenges, including the use of management devices. Furthermore, the health service navigation domain indicates that communication with health personnel is improved and that the communication is more specific to the patient's own health needs [13]. It appears that the participants' self-management skills and ability to make contact with health personnel increased during the intervention, whereas typical well-being domains, such as emotional well-being, social integration and support, and positive and active engagement in life, remain unchanged after 4 months. These results extend the findings of Nolte [44] by confirming that self-management courses appear to improve these skills in patients with chronic diseases.

The strengths of this study are that it was an RCT with 3 arms of equal size and few differences between groups and equal dropouts. The control group provided an opportunity to compare the standard treatment with a mobile health intervention based on theory. According to the power calculation based on the HbA_{1c}, the sample size was acceptable and it provided sufficient support for the primary outcome, but the sample and subgroups were still small and they did not allow subgroup analysis as desired.

Another limitation is that the participants and their general practitioners were not blinded, indicating there was greater opportunity for the participants to influence the results. For example, the control group could have used similar apps. However, the app was meant to be shared with others, such as health care personnel, and the participants were expected to communicate and clarify their needs. This could have affected the intervention groups, but also the controls.

Finally, technology is developing rapidly. When the inclusion period was extended to recruit sufficient participants, the smartphone used was gradually lagging behind the latest smartphone software released onto the market. We found that an immediate transfer of the app to another mobile software system was too demanding, despite the risk of reduced interest in the app. The use of new software could have changed the intervention because the participants would also have been able to use the smartphone for calls and a more user-friendly phone could have changed perceptions of the app's accessibility and usability.

The significant differences between the randomized groups were slightly uneven with respect to the distribution of rheumatic diseases and depression. Both of these diseases and their treatments can affect self-management and influence the HbA_{1c} levels. However, the estimates did not change after adjusting for these variables. As mentioned earlier, the randomization procedure was generally successful with 3 equal groups at baseline and the dropouts were distributed almost equally among the groups.

The use of the FTA diabetes diary with or without additional health counseling improved self-management in terms of the ability to navigate health services and the skills required to reduce symptoms. The app and the health counseling did not help to reduce the HbA_{1c} levels of the participants in the intervention groups compared with those who received usual care.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
CIP: Competitiveness and Innovation Framework Programme
CONSORT: Consolidated Standards of Reporting Trials
FTA: Few Touch Application
HbA1c: glycated hemoglobin A1c
heiQ: Health Education Impact Questionnaire
MAST: Model for the Assessment of Telemedicine
RCT: randomized controlled trial
RENEWING HEALTH: REgioNs of Europe WorkING together for HEALTH
USB: universal serial bus

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II

Original Paper

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

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Abstract

Background: Self-management is crucial in the daily management of type 2 diabetes. It has been suggested that mHealth may be an important method for enhancing self-management when delivered in combination with health counseling.

Objective: The objective of this study was 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 A_{1c} (HbA_{1c}) level, self-management, and health-related quality of life compared with usual care.

Methods: We conducted a 3-arm prospective randomized controlled trial involving 2 intervention groups and 1 control group. Eligible participants were persons with type 2 diabetes with an HbA_{1c} level ≥7.1% (≥54.1 mmol/mol) and aged ≥18 years. Both intervention groups received the mobile phone–based self-management system Few Touch Application (FTA). The FTA consisted of a blood glucose–measuring system with automatic wireless data transfer, diet manual, physical activity registration, and management of personal goals, all recorded and operated using a diabetes diary app on the mobile phone. In addition, one intervention group received health counseling based on behavior change theory and delivered by a diabetes specialist nurse for the first 4 months after randomization. All groups received usual care by their general practitioner. The primary outcome was HbA_{1c} level. Secondary outcomes were self-management (heiQ), health-related quality of life (SF-36), depressive symptoms (CES-D), and lifestyle changes (dietary habits and physical activity). Data were analyzed using univariate methods (*t* test, ANOVA) and multivariate linear and logistic regression.

Results: A total of 151 participants were randomized: 51 to the FTA group, 50 to the FTA-health counseling (FTA-HC) group, and 50 to the control group. Follow-up data after 1 year were available for 120 participants (79%). HbA_{1c} level decreased in all groups, but did not differ between groups after 1 year. The mean change in the heiQ domain skills and technique acquisition was

significantly greater in the FTA-HC group after adjusting for age, gender, and education (*P*=.04). Other secondary outcomes did not differ between groups after 1 year. In the FTA group, 39% were substantial users of the app; 34% of the FTA-HC group were substantial users. Those aged ≥63 years used the app more than their younger counterparts did (OR 2.7; 95% CI 1.02-7.12; *P*=.045).

Conclusions: The change in HbA_{1c} level did not differ between groups after the 1-year intervention. Secondary outcomes did not differ between groups except for an increase in the self-management domain of skill and technique acquisition in the FTA-HC group. Older participants used the app more than the younger participants did.

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KEYWORDS

self-care; mobile applications; cellular phone; telemedicine; counseling; motivational interviewing; diabetes mellitus, type 2; hemoglobin A1c protein, human

Introduction

Type 2 diabetes is a complex disease [1,2] with an increasing prevalence worldwide [3,4]. Multifactorial treatment is necessary to improve long-term outcomes as stated in treatment guidelines [1,5,6]. Still, many do not meet the recommended goals for diabetes care [7-9]; in Norway, research has shown that only 20% attain the target for metabolic control for glycated hemoglobin A_{1c} (HbA_{1c}), blood pressure, and lipid level, although the quality of care has improved [8]. New treatments are evolving rapidly and self-management is crucial in daily disease management and to prevent macro- and microvascular complications [2,10,11].

The field of technology-supported health care is growing and offers new ways of self-management education and support. Mobile phones are essential in people's lives today and may serve as a platform for a variety of self-management tools, such as apps. However, the current reviews are inconclusive and the effects of mobile health (mHealth) remain unclear [12-16]. The studies included in these reviews are heterogeneous and have used different mobile phone-based interventions and lengths of follow-up, and people with type 1 and type 2 diabetes are often included in the same studies. In most interventions, patients are monitored by health care personnel in contrast to interventions in which self-management is based on self-monitoring and self-care [14,17]. Despite this, mHealth is recognized as a potential addition to usual care in that some studies have found positive short-term effects on glycemic control, although the effects of the intervention decreased with time [15]. mHealth apps have also been shown to be effective without support from health care personnel, which may reduce health care costs [14].

Apps for mHealth interventions are often combined with health counseling, but the research related to these complex interventions is inconclusive because of heterogeneity in the types of studies [17,18]. Earlier research has shown that phone counseling is feasible, convenient, low cost, and may be an alternative to frequent visits [17,18]. In countries such as Norway, people in rural areas may have less access to specialized health care. A recent Coordination Reform has reorganized the delivery of health care, with more responsibility transferred from specialist health care to primary health care services and with more emphasis on self-management. The application of innovative technologies may be a supplement to this reform [19].

Few studies have used the combination of a mobile phone app for self-management supported by health counseling via telephone. Studies often include monitoring with real-time feedback from health care personnel, which may lead to the investigation of dimensions other than self-management. However, an intervention based largely on the patient's initiative to self-manage at a frequency that does not interfere with daily life should be feasible in today's society [20].

Earlier reviews noted the lack of integration of behavior change theory into mHealth research and recommended that interventions should be theory-based [13,17]. Motivational interviewing is a technique in health counseling [21] and a well-known clinical method recommended for use in Norwegian guidelines for persons with diabetes [5]. Research has also indicated an effect of motivational interviewing on persons with type 2 diabetes trying to attain behavior change in lifestyle-related issues [22-24]. Further, some studies have tailored health counseling to the patient's stage of readiness to change according to the transtheoretical model of stages of change [25] and have demonstrated effects for persons with type 2 diabetes with the use of this model [26,27]. In the present study, both techniques were used in the health counseling.

The current study is the Norwegian part of the European Union collaboration study RENEWING HEALTH (REgioNs of Europe WorkING together for HEALTH), which comprises telehealth interventions in different health care and home settings [28]. The short-term findings after 4 months are described elsewhere [29].

The aim of this study was to determine if the use of a mobile phone–based self-management system for 1 year, with or without telephone health counseling by a diabetes specialist nurse for the first 4 months, could improve HbA_{1c} level, self-management, and health-related quality of life compared with usual care. The primary outcome was glycemic control, as assessed by the HbA_{1c} level. Secondary outcomes were self-management and health-related quality of life, depressive symptoms, and lifestyle changes (dietary habits and physical activity).

Methods

Trial Design

We conducted a 3-armed prospective randomized controlled trial (RCT) with a 1:1:1 allocation ratio using block randomization to 1 of 2 intervention groups or to a control group. The allocation has been described in detail elsewhere [30].

Participants

All participants lived in their homes and received usual care by their general practitioner (GP). They were eligible if they were aged ≥18 years, had an HbA_{1c} level ≥7.1% (54.1 mmol/mol), and were capable of completing questionnaires in the Norwegian language. They also had to be cognitively able to participate and to use the system and devices provided, although prior familiarity with mobile phones was not necessary. The majority of participants were recruited through 2 study centers in the southern and northern parts of Norway in collaboration with their GPs. Some participants were recruited from local public health clinics in the municipalities, through diabetes courses held by the specialist health providers for those newly diagnosed with type 2 diabetes, and through advertisement in The Norwegian Diabetes Association's media. The HbA_{1c} level was set to HbA_{1c} >7.0% (53 mmol/mol); that is, above the treatment target according to the Norwegian guidelines [5]. Written informed consent was obtained from participants after detailed information about the project was provided by the research team during the start-up meetings. Data collection was obtained through self-reported questionnaires and from medical records at the GPs' offices. Randomization was performed consecutively.

There were 3 assessment points: baseline (time of randomization) and at 4 and 12 months after randomization. For the follow-up assessment, participants were invited to meet with the research team for data collection (questionnaires). Those not able to attend the follow-up meetings were sent questionnaires and a prepaid envelope to be returned by mail to the study center. All patients were asked to visit their GP for measuring of their HbA_{1c} level and weight at the same time (±14 days) after they had filled in the questionnaires.

Interventions

Overview

The Norwegian study in RENEWING HEALTH was a 1-year intervention to increase self-management comprised of 3 intervention groups: the Few Touch Application (FTA) intervention group, the FTA with health counseling (FTA-HC) intervention group, and the control group [30].

All participants in the 3 groups received usual care by their GP according to national guidelines [5]. This included at least 1 thorough annual visit to their GP for measurement of HbA_{1c} level, blood pressure, blood lipid concentrations, waist circumference, body weight to calculate a body mass index (BMI), screening for late complications, lifestyle advice, and treatment adjustments. Additional visits were recommended to monitor HbA_{1c}, fasting glucose, weight, and blood pressure every 2-6 months according to the needs of the patient and to support self-management medical treatment.

Control Group

The participants randomized to the control group received usual care [5].

Few Touch Application Intervention

In addition to usual care, these participants received a mobile phone with the FTA self-management system. The FTA system provided the user with a diabetes diary app designed to increase self-management through awareness, overview of relevant factors, and motivational feedback through symbols such as smiling faces and color codes in the app [31]. The participants measured blood glucose level with a glucometer (LifeScan OneTouch Ultra Easy), which enabled automatic transfer of the measurement to the diary mobile app through a wireless Bluetooth connection and provided visual graphs, trend reports, and feedback through color coding (below normal, normal, and above normal). The app also consisted of a food habit registration system, a physical activity registration system, a personal goal-setting system, and a general information system. The user entered information about food intake, physical activity, and personal goals manually. Training was in person; a paper manual and a universal serial bus (USB) memory stick with further information were provided to participants. Technical support was available all weekdays between 9 am and 3 pm and was provided by technical staff of the project.

Few Touch Application With Health Counseling Intervention

In addition to the mobile phone, FTA system, and usual care, the participants in the FTA-HC group received health counseling for the first 4 months of the project period. The health counseling was based on the transtheoretical model of stages of change [25] and a problem-solving model [32], and used motivational interviewing as a counseling technique [21]. The health counseling in the present study was part of the mHealth intervention. The counseling was delivered as a booster at the start of the intervention. This may have enhanced participants' identification with the intervention and may have resulted in more autonomous participation and better compliance [22].

A diabetes specialist nurse delivered the health counseling. She had special training and additional education in diabetes, was supervised by a clinical psychologist, and received support from a dietician when needed. Diet is an important element in the app. The nurse used a client-centered style for enhancing behavior change by helping the patients to explore and resolve ambivalence related to aspects of self-management. We provided a low-intensity intervention with a short counseling duration with few contacts between the patient and health counselor [32]. The counseling was delivered through phone-based conversations each month for 4 months, 5 in total after randomization (with the start-up call), and with no refresher contact thereafter. The calls lasted for 20 minutes (mean) and contained 5 structured modules developed to support self-management and the use of the FTA. The health counseling is described in more detail elsewhere [29,30]. A few days before

the call, the diabetes specialist nurse sent a standardized text message through a secure system that allowed the participants to respond or send questions. The plan in the future is that the health personnel get access through their patients' registrations through a care portal for discussions and increased user participation in treatment (Figure 1).

The participants were recruited to the project because of an HbA_{1c} above the national recommendations (HbA_{1c}>7.0%, 53 mmol/mol) [5] and, therefore, they were recommended to measure their blood glucose as a part of their self-management irrespective of insulin use. Most participants not using insulin had been recommended by their GP or diabetes nurse to measure a monthly 24-hour profile of their blood glucose and as such to be aware of their normal blood glucose levels.

Use of the FTA system in GP consultations was an option for the intervention groups; however, the participants had to take the initiative.

Measures

Demographics

Demographic information were self-reported and included age, gender, education, employment status, and cohabitation (including those married and those living with a partner), and are described in detail elsewhere [29,30].

Clinical Measures

Clinical characteristics included HbA_{1c}, weight, BMI, blood pressure, diabetes duration, comorbidities, complications, medication treatment, hypoglycemia, self-monitoring, and lifestyle variables (smoking, diet, and physical activity). Data were obtained from the GPs or self-reported (diabetes duration, comorbidity, hypoglycemia, self-monitoring, and lifestyle). Of these, only HbA_{1c} and weight were collected at the 1-year follow-up.

Primary Outcome

Change in HbA_{1c} level after 1 year was chosen as the primary outcome because it is the main target measure when treating diabetes and is frequently used when evaluating interventions [15]. HbA_{1c} data were collected through the GPs and were assessed primarily with the Siemens DCA Vantage Analyzer a maximum of 2 weeks before or after the follow-up to reduce measurement bias [30,33].

Secondary Outcomes

The Health Education Impact Questionnaire (heiQ) [34] was used to assess self-management. This measure contains 40 questions on a 4-level Likert scale, grouped into 8 domains: positive and active engagement in life, health-directed activity, skill and technique acquisition, constructive attitude and approaches, self-monitoring and insight, health service navigation, social integration and support, and emotional well-being. This measure evaluates patient education and self-management interventions for people with chronic conditions. Higher scores reflect greater self-management, except for emotional well-being in which the scale is reversed. The heiQ is a validated measure for evaluating the effectiveness of health education and coping skills, and has been translated into Norwegian and several other languages [34,35].

To evaluate lifestyle and lifestyle changes, we investigated the participants' dietary habits including recommended food items and traditional Norwegian dietary habits [36], and engagement in physical activity based on intensity, frequency, and duration [37]. The Short-Form 36v2 Health Survey (SF-36) was used to measure overall health-related quality of life [38]. This survey has been translated into Norwegian and validated and tested in a Norwegian setting [39]. Depressive symptoms were measured by the Center for Epidemiologic Studies Depression Scale (CES-D) [40] using a cutoff of ≥16, which indicated that those below the threshold reported no depressive symptoms. For the demographic and clinical measures, a common dataset was provided from the RENEWING HEALTH project administration and data were gathered according to a protocol provided from the project administration [41]. In the analysis, age was dichotomized with a cutoff at ≥63 years, the age of early retirement in Norway. Further details about measures have been published in the study protocol [30].

Use of the Few Touch Application

Registrations of the use of the FTA system were collected continuously through automatic data transfer to a secure server and into a usage log. For the FTA-HTC group, further education on usage of the app was supported by the diabetes specialist nurse. A dichotomous variable of substantial or not substantial use of the FTA was made retrospectively based on the usage log. To be categorized as a substantial user, the participant had to be an active user for at least 6 months. An active user was defined as one who had performed ≥5 blood glucose measurements during each of these 6 months and who had ≥50 interactions in the parts of the diary not including collection of data (eg, viewing data or accessing general information).

Sample Size

An a priori power calculation indicated that 34 participants in each of the 3 groups would be sufficient to detect significant changes in the primary outcome HbA_{1c} level with an effect size of .35, a significance level of 5%, a standard deviation (SD) of the outcome variable of 0.5, statistical power of 80%, and a 2-tailed significance test. The sample was set to 50 in each of the 3 groups to allow for dropouts and 151 participants were included in total.

Randomization

Block randomization was performed through the Center of Randomization at the Unit for Applied Clinical Research at the Norwegian University of Science and Technology in Trondheim using the Web Case Report Form.

Ethics

The Regional Ethics Committee South East approved the protocol and all participants provided written informed consent before randomization.

Blinding

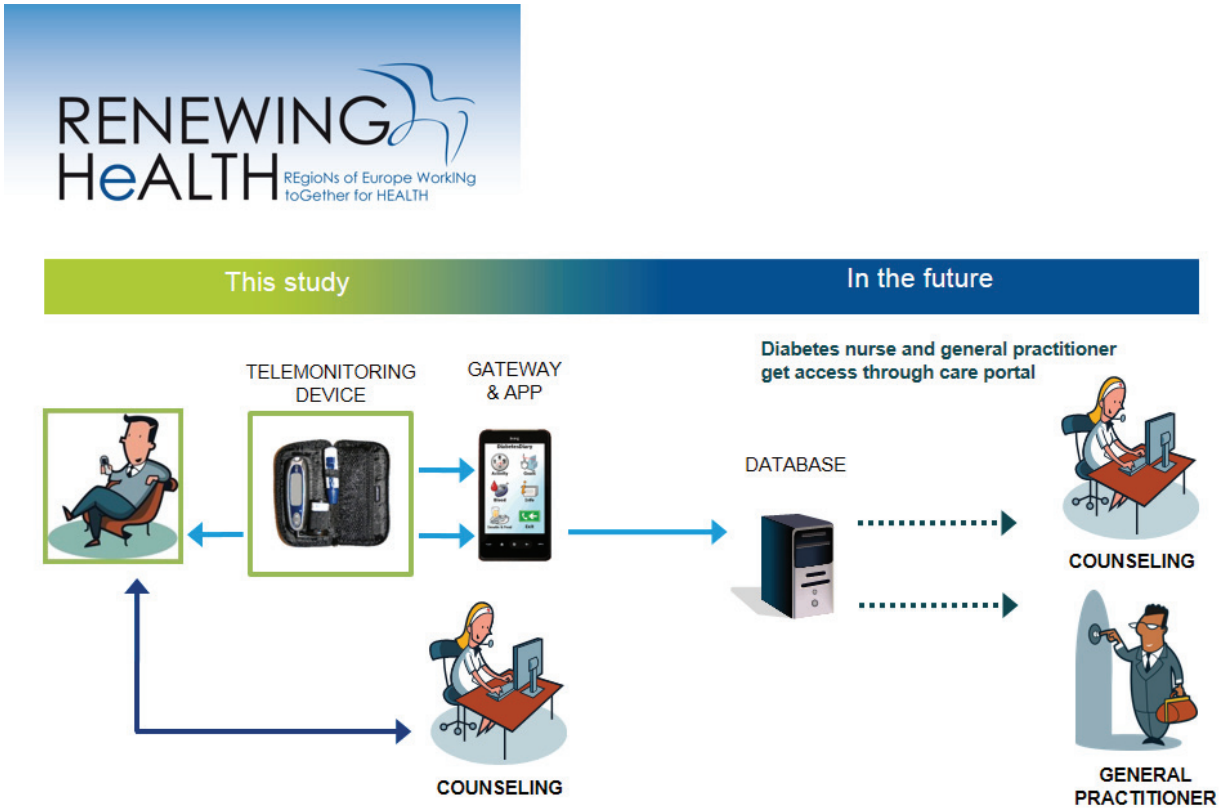
The study could not be blinded for the participants or GPs and health providers because of the nature of the intervention, which

required overt participation [42]. The participants could use the device at visits to their GP as part of usual care. The research team was involved in the assessment of eligibility, data collection, training of patients to use the devices, and follow-up. Thus, those who delivered technical support had to know which group the participants were allocated to.

Statistical Methods

The baseline characteristics are reported as mean and SD (continuous variables) and counts and percentages (categorical variables). Data not available were considered to be missing and the results were based on intention-to-treat. Baseline differences between groups were assessed with 1-way ANOVA (continuous measurements) and chi square tests (categorical data). Within-group changes were analyzed using Student *t* tests. Multiple linear regression and logistic regression analyses were used to control for possible confounding factors. The final models were adjusted for age, gender, and educational level. Changes in medication (glucose-lowering agents), BMI, depressive symptoms (CES-D), diabetes duration, and comorbidities were added one by one to the final models to investigate the possible confounding effects. When the preceding covariates were not statistically significant, they were not presented in the final model to increase statistical power and precision of our estimates. All tests were 2-sided. *P* values <.05 were considered significant. All analyses were performed using SPSS version 21 (IBM Corp, Armonk, NY, USA).

Figure 1. Self-management with the FTA supported by health counseling.



Results

Participant Flow

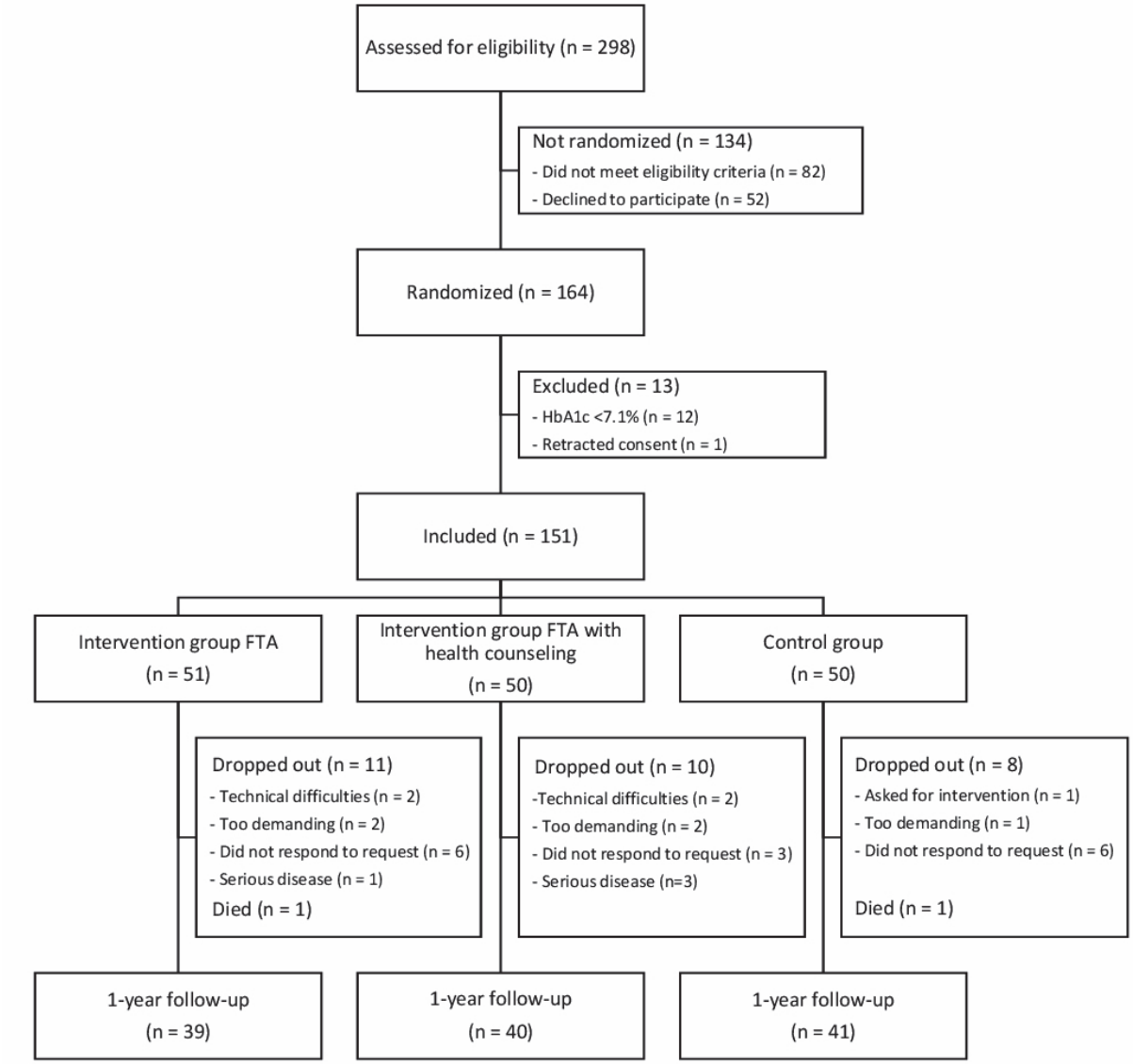
Through the recruitment period, 298 persons were assessed for eligibility; 134 persons were not included, 52 did not wish to participate, and 82 did not meet the eligibility criteria (Figure 2). Of these, 65 had an HbA_{1c} level below the threshold of 7.1% (54.1 mmol/mol), 6 had type 1 diabetes, 4 had interfering comorbidities, and 7 did not fulfill the eligibility criteria for other reasons. Randomization was performed for 164 persons (Figure 1), but 12 were excluded because of an HbA_{1c} level below the 7.1% (54.1 mmol/mol) threshold. One person withdrew consent, leaving a total of 151 participants to be included in the study; 51 were allocated to the FTA intervention, 50 to the FTA-HC intervention, and 50 to the control group.

Inclusion and randomization started in March 2011 and ended in September 2012. The first complete participant dataset was finalized in April 2012 and the follow-up data was finalized in October 2013.

After the 1-year follow-up, there was a total dropout attrition rate of 21% (31/151), with an equal distribution in the groups. Baseline analysis revealed no difference between those lost to follow-up and those who completed the study for all variables. For the primary outcome (HbA_{1c} level), data were obtained for

a total of 120 participants after the 1-year follow-up: 39 in the FTA group (dropout attrition 24%, 12/51), 40 in the FTA-HC group (dropout attrition 20%, 10/50), and 41 in the control group (dropout attrition 18%, 9/50). For the secondary self-reported outcomes, data were included from 119 participants, 38 in the FTA group, 40 in the FTA-HC group, and 41 in the control group.

Figure 2. Flowchart of enrollment.



Demographic and Clinical Characteristics

The demographic and clinical baseline characteristics of the participants have been described in detail elsewhere [29]. Overall, the mean age was 57 years (SD 12), 62 of 151 (41%) were female, and 51 of 151 (34%) had >12 years of education (Table 1). The mean HbA_{1c} level was 8.2% (SD 1.1), 66 mmol/mol (SD 12.3), and the mean BMI was 31.7 kg/m^2 (SD 6.03). None of the variables listed in the tables differed significantly between groups at baseline. However, a higher proportion of persons in the control group reported depressive symptoms compared with the other 2 groups. The numbers (percentages) of participants whose score exceeded the cutoff value of ≥16 in the CES-D were 17 of 50 (35%) in the control group, 10 of 51 (20%) in the FTA group, and 7 of 50 (14%) in the FTA-HC group (P=.04).

Table 1. Demographic and clinical characteristics at the baseline (N=151).

Characteristics	N	FTA (n=51)	FTA-HC (n=50)	Control group (n=50)
Demographics				
Age (years), mean (SD)	151	58.6 (11.8)	57.4 (12.1)	55.9 (12.2)
Gender (female), n (%)	151	17 (33)	25 (50)	20 (40)
Education[a], 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)
Employment status[b], n (%)	148			
Employed		22 (44)	31 (63)	26 (53)
Unemployed		13 (26)	11 (22)	17 (35)
Retired		15 (30)	7 (14)	6 (12)
Cohabitation status (cohabiting),[c] n (%)	151	37 (73)	36 (72)	37 (74)
Clinical characteristics				
HbA_{1c}				
HbA_{1c} (%), mean (SD)	151	8.1 (1.1)	8.2 (1.1)	8.3 (1.2)
HbA_{1c} (mmol/mol), mean (SD))	151	65 (12.0)	66 (12.0)	67 (13.1)
HbA_{1c} (%), median (range)	151	7.8 (7.1-12.4)	7.9 (7.1-11.3)	7.9 (7.1-11.6)
HbA_{1c} (mmol/mol), median (range)	151	62 (54-112)	63 (54-100)	63 (54-103)
Weight (kg), mean (SD)	132	98 (23.1)	91 (20.3)	96 (25)
BMI kg/m^2, mean (SD)	129	32.4 (6.5)	30.7 (5.6)	32.0 (6.0)
Systolic blood pressure (mmHg), mean (SD)	121	136 (17.9)	132 (13.7)	134 (14.5)
Duration of diabetes (years), mean (SD)	138	11.2 (7.3)	9.6 (8.4)	9.4 (5.5)
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)
Late complication: foot ulcer, n (%)	151	11 (22)	8 (16)	4 (8)
Late complication: eye, n (%)	151	7 (14)	3 (6)	9 (18)
Treatment variables, n (%)				
Glucose-lowering agents, n (%)	131			
Diet only		3 (7)	2 (4)	4 (11)
Oral agents only		20 (44)	27 (57)	16 (42)
Injections only[d]		9 (20)	7 (15)	3 (8)
Combination of oral agents and injections		14 (30)	11 (23)	15 (40)
Hypoglycemia (self-reported), n (%)	148	23 (46)	19 (39)	27 (55)
Self-monitoring blood glucose, n (%)	151	48 (94)	45 (90)	49 (98)
Lifestyle variables, n (%)				
Smoking (yes)	151	5 (10)	12 (24)	7 (14)
Physical activity (physically active)[e]	149	18 (37)	16 (32)	17 (34)

Characteristics	N	FTA (n=51)	FTA-HC (n=50)	Control group (n=50)
Daily servings of fruit and vegetables	148	2.8 (1.6)	2.9 (1.7)	3.8 (2.7)
Poultry >3 servings per month	146	33 (67)	26 (52)	28 (60)
Meat >3 servings per month	143	44 (88)	44 (92)	41 (91)
Fish >3 servings per month	148	41 (82)	38 (78)	37 (76)

[a] Education: some high school or less (<12 years), high school graduate (12 years), or some college or more (>12 years).

[b] Employment status: employed (state employee, private employee, self-employed, or employed part-time); unemployed (student, military duty, homemaker, unemployed, or unable to work); and retired.

[c] Cohabitation status: living alone (not married, divorced, separated, or widowed); and cohabiting (married or living with someone).

[d] Injections were both insulin and other blood glucose–lowering injections.

[e] Physically active: those with >60 min per week at an intensity of "being short of breath" or higher intensity.

Primary Outcome Measure: HbA1c Level

The change in HbA_{1c} level did not differ significantly between the 3 groups after 1 year. However, HbA_{1c} level declined within all groups and none of the participants in any of the groups reached their pretest levels at the 1-year follow-up (Figure 3).

Adjusting for age, gender, and educational level did not affect the change in HbA_{1c} level nor did inclusion of possible confounders, such as changes in medication (glucose-lowering agents), BMI, depressive symptoms (CES-D), diabetes duration, and comorbidities (Table 2).

Figure 3. Mean HbA1c levels (95% CI) at baseline and 1-year follow-up (N=119).

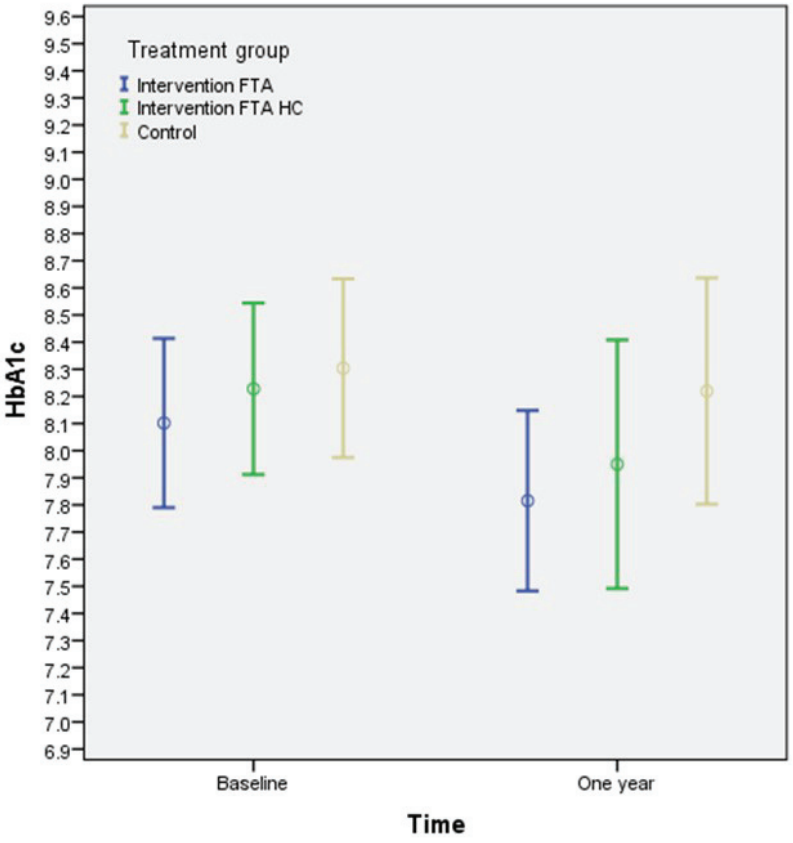


Table 2. Mean HbA_{1c} level, body weight, and heiQ domains at baseline and 1-year follow-up, and changes for those with 2 measurements.

Variables by group	n	Baseline, mean (95% CI)	1-year follow-up, mean (95% CI)	Change, mean (95% CI)
HbA_{1c} (%)				
FTA	39	8.1 (7.72, 8.53)	7.8 (7.48, 8.15)	–0.31 (–0.67, 0.05)
FTA-HC	40	8.1 (7.76, 8.43)	8.0 (7.49, 8.41)	–0.15 (–0.58, 0.29)
Control	41	8.4 (7.97, 8.76)	8.2 (7.77, 8.61)	–0.16 (–0.50, 0.18)
HbA_{1c} (mmol/mol)				
FTA	39	65 (61,70)	62 (58,66)	–3.4 (–7.4,0.6)
FTA-HC	40	65 (61,69)	63 (58,68)	–1.6 (–6.3,3.1)
Control	41	68 (64,72)	66 (62,71)	–1.7 (–5.4,2.0)
Weight (kg)				
FTA	33	96.3 (87.99, 104.64)	95.0 (87.54, 103.22)	–1.3 (–3.05, 0.43)
FTA-HC	34	89.7 (82.45, 96.90)	88.9 (82.28, 95.67)	–0.7 (–2.29, 0.84)
Control	36	94.3 (85.31, 103.22)	93.0 (84.44, 101.36)	–1.2 (–2.75, 0.54)
Positive and active engagement in life				
FTA	38	3.23 (3.08, 3.38)	3.19 (3.04, 3.34)	–0.04 (–0.18, 0.09)
FTA-HC	40	3.20 (3.08, 3.31)	3.22 (3.08, 3.36)	0.02 (–0.15, 0.19)
Control	41	3.12 (2.95, 3.29)	3.09 (2.94, 3.24)	–0.03 (–0.19, 0.13)
Health-directed activity				
FTA	38	2.78 (2.52, 3.04)	2.82 (2.60, 3.05)	0.04 (–0.16, 0.25)
FTA-HC	40	2.78 (2.57, 2.99)	2.81 (2.57, 3.04)	0.03 (–0.16, 0.21)
Control	41	2.71 (2.51, 2.92)	2.81 (2.58, 3.04)	0.10 (–0.08, 0.27)
Skill and technique acquisition				
FTA	38	2.92 (2.79, 3.04)	2.88 (2.69, 3.06)	–0.04 (–0.20, 0.12)
FTA-HC	40	2.89 (2.75, 3.02)	3.08 (2.96, 3.21)	0.19 (0.05, 0.33)[a]
Control	41	2.95 (2.83, 3.06)	2.94 (2.77, 3.12)	–0.01 (–0.14, 0.13)
Constructive attitudes and approaches				
FTA	38	3.17 (2.98, 3.36)	3.13 (3.00, 3.26)	–0.04 (–0.21, 0.13)
FTA-HC	40	3.23 (3.09, 3.38)	3.33 (3.19, 3.47)	0.10 (–0.02, 0.21)
Control	41	3.19 (3.02, 3.36)	3.19 (3.02, 3.36)	0.00 (–0.13, 0.13)
Self-monitoring and insight				
FTA	38	3.06 (2.95, 3.15)	3.09 (2.98, 3.19)	0.04 (–0.07, 0.15)
FTA-HC	40	3.09 (2.99, 3.18)	3.18 (3.06, 3.30)	0.09 (–0.01, 0.19)
Control	41	3.14 (3.03, 3.24)	3.15 (3.02, 3.28)	0.01 (–0.12, 0.13)
Health service navigation				
FTA	38	3.14 (2.97, 3.31)	3.03 (2.86, 3.20)	–0.11 (–0.25, 0.04)
FTA-HC	40	3.06 (2.91, 3.20)	3.14 (2.96, 3.31)	0.08 (–0.03, 0.20)
Control	41	3.16 (3.00, 3.33)	3.27 (3.09, 3.44)	0.11 (–0.05, 0.26)
Social integration and support				
FTA	38	3.04 (2.87, 3.21)	2.93 (2.77, 3.09)	–0.11 (–0.23, 0.02)
FTA-HC	40	3.02 (2.86, 3.17)	3.02 (2.86, 3.19)	0.01 (–0.09, 0.11)
Control	41	2.94 (2.74, 3.15)	2.95 (2.74, 3.16)	0.01 (–0.14, 0.16)
Emotional well-being				

Variables by group	n	Baseline, mean (95% CI)	1-year follow-up, mean (95% CI)	Change, mean (95% CI)
FTA	38	2.99 (2.77, 3.20)	2.98 (2.76, 3.20)	–0.01 (–0.16, 0.13)
FTA-HC	40	2.99 (2.81, 3.17)	3.04 (2.84, 3.25)	0.05 (–0.12, 0.22)
Control	41	2.81 (2.57, 3.05)	2.87 (2.64, 3.11)	0.07 (–0.11, 0.24)

[a] Change was statistically significant (P<.05).

Secondary Outcome Measures

Weight

Body weight was slightly reduced in all 3 groups at the 1-year follow-up, although not significant (Table 2). However, the change in weight did not differ between groups at the 1-year follow-up.

Health Education Impact Questionnaire

Table 2 presents the mean scores for the 8 heiQ domains and the mean changes at the 1-year follow-up. Except for skill and technique acquisition in the FTA-HC group, no statistically significant changes were found between groups. However, as shown in Table 3, there were significant differences in the changes in 1 of the 8 domains between the control group and 1 of the intervention groups.

Table 3. Changes in HbA_{1c} level, skill and technique acquisition, and health service navigation for the intervention groups versus the control group, unadjusted and adjusted for age, gender, and educational level in multiple linear regression analysis.[a]

Group	Unadjusted B	95% CI	*P*	Adjusted B[a]	95% CI	*P*
HbA_{1c} (%)						
FTA	–0.15	–0.68, 0.37	.57	–0.22	–0.75, 0.32	.42
FTA-HC	0.01	–0.51, 0.53	.97	0.01	–0.52, 0.54	.97
Control (ref)						
HbA_{1c} (mmol/mol)						
FTA	–1.7	–7.4, 4.1		–2.4	–8.2, 3.5	.42
FTA-HC	0.1	–5.6, 5.8		0.1	–5.6, 5.9	.97
Control (ref)						
Skill and technique acquisition						
FTA	–0.04	–0.24, 0.16	.71	–0.03	–0.22, 0.17	.79
FTA-HC	0.20	0.004, 0.40	.046	0.21	0.01, 0.40	.04
Control (ref)						
Health service navigation						
FTA	–0.21	–0.41,–0.02	.03	–0.19	–0.38, 0.01	.06
FTA-HC	–0.02	–0.21, 0.17	.82	–0.004	–0.19, 0.19	.97
Control (ref)						

[a] This table presents 3 final multiple linear regression models, all adjusted for age, gender, and education.

After adjusting for age, gender, and educational level, the mean change in skill and technique acquisition was still significantly higher in the FTA-HC group (B=0.21; 95% CI 0.01-0.40; P=.04). The mean change in health service navigation was significantly smaller in the FTA group before but not after adjusting for age, gender, and educational level (B=–0.19; CI –0.38 to 0.01; P=.06) compared with the control group.

When analyzing the effect of depressive symptoms independently of group allocation, we found that those who reported depressive symptoms (CES-D score ≥16 at baseline, indicating more depressive symptoms) reported a higher change in heiQ than those who did not report such symptoms. Both analyses of change in heiQ after 1 year were adjusted for age and gender. In the domains of positive and active engagement in life, the results were B=0.24, (95% CI 0.01-0.46; (P=.04) and for social integration and support were B=0.22 (95% CI 0.03-0.41; P=.02).

Health-Related Quality of Life and Depressive Symptoms

There were no significant differences in any of the 8 subscales or in the 2 summary component scores of the SF-36 between the 3 groups at the 1-year follow-up in both the unadjusted and adjusted analyses. The change in depressive symptoms measured with the CES-D did not differ significantly between groups for the total score (continuous variable) or for the number/percentage of participants with a score greater than the cutoff of ≥16 both before and after adjustments.

Changes in Reported Physical Activity and Nutritional Habits

There were no significant differences between the groups in self-reported levels of physical activity (inactive to active or opposite). The changes in the intake of fruits and vegetables, meat, chocolate, and fish after 1 year did not differ between the 3 groups (results not shown).

Use of the Few Touch Application and Health Counseling

Of those randomized to the FTA group, 20 of 51 (39%) were categorized as substantial users. In the FTA-HC group, 17 of 50 (34%) used the FTA part of the intervention substantially, and all these people attended ≥4 health counseling sessions; 42 of 50 (84%) attended ≥4 sessions of health counseling regardless of their FTA use.

Analyses of substantial versus nonsubstantial users of only the FTA, regardless of the intervention groups, did not reveal any statistically significant differences between groups regarding SF-36, heiQ, or depressive symptoms (CES-D). However, participants aged ≥63 years were more likely to be substantial users of the app (OR 2.7; 95% CI 1.02-7.12; *P*=.045) compared with younger participants.

Adverse Events

No serious adverse clinical events were reported from enrollment to the 1-year follow-up. However, a few undesired technical events were reported, such as trouble with the Bluetooth pairing required for automatic transmission of data from the glucometer to the app in the mobile phone. This may have been stressful for those affected and has been shown to lead to less satisfaction and decreased use of the technology in a previous study [13]. The project could not pay for mobile use if the participants were traveling abroad and some participants experienced high mobile costs for use of the mobile phone app in other countries (because of different rates for different network operators). However, we did inform all participants of this risk before they entered the trial.

Discussion

Although HbA_{1c} level declined in all groups, the change did not differ significantly between either of the intervention groups and the control group after 1 year. However, the mean HbA_{1c} level did not increase to the baseline level in any of the 3 groups. We found no effects on secondary outcomes other than a significant positive change in self-management reflected by the skill and technique acquisition scale in the FTA-HC group. Interestingly, participants aged ≥63 years were more likely to use the app.

In this study, we conducted a low-intensity mHealth intervention based on self-management with a mobile app and with a health-counseling booster for the first 4 months in one of the intervention groups. Previous reviews have investigated follow-up and intervention duration, and have found a trend of decreasing intervention effect over time [15,18]. Although interest in mHealth interventions may decrease over time [17,43], it has been shown previously that regular contact with clinical practice may improve glycemic control [15,16] and positive outcomes in general [17]. The participants in our study had only the health counseling intervention in one of the intervention groups at the beginning of the study and a more intense intervention during the 1-year follow-up or booster appointments could have strengthened their self-management and behavior change.

The finding that the FTA-HC intervention group tended to have a greater change in self-management, as shown by the increase in skill and technique acquisition, may mean that they had an increased ability to reduce their symptoms related to type 2 diabetes and to manage their health effectively, including greater skills for using technical aids. A lack of effect in the other domains of self-management could indicate that our intervention did not reach those at highest risk of a decline in health [44]. The degree of self-management may be less in people with type 2 diabetes compared with those with type 1 diabetes because of the intensity of treatment and need for self-measuring of blood glucose levels by those who are insulin dependent [15]. However, some type 2 diabetes insulin users are also in need of a similar self-management intensity. Reviews are inconsistent about whether mHealth is more effective in people with type 1 or type 2 diabetes [15,20]. Most of our participants reported that they were self-monitoring their blood glucose level at the start of the study, suggesting that they were already self-managing at some level irrespective of insulin use.

The HbA_{1c} level is widely used for evaluation of interventions, but its relevance to self-management has been questioned in the past few years [15,18] because the focus on glycemic control may not always reflect the degree of self-management. To date, few mHealth studies evaluating self-management have included a self-management outcome with appropriate measures [35,45]. The choice of outcome measures is critical. The emphasis in the present study is on self-management and the primary outcome, HbA_{1c}, may not reflect the relevant self-management outcomes for the participants. In this study, we found that many participants did not know their HbA_{1c} level at enrollment and many had a too low HbA_{1c} to be included.

Interventions are often designed without sufficient knowledge about the target group and without a theoretical framework [46]. Although this study used both theory and thorough analyses of the literature beforehand, more research about how to design and implement behavior change interventions is needed. An interesting framework has been developed with a behavior change model with essential conditions such as capability, opportunity, and motivation, including intervention strategies addressing these conditions specifically [46]. If a self-management intervention should improve HbA_{1c}, it must first effectively improve healthy eating, physical activity, and adherence to medication. Therefore, we need to know how we can support and effectively motivate a person's readiness for behavior change. Future research must include the users as part of the team when developing appropriate interventions tailored to their needs [11,46,47].

Lack of findings in many behavior change studies may also relate to a lack of key components in available apps for persons

with type 2 diabetes. Apps should be designed in the context of the current guidelines for treatment of type 2 diabetes to increase self-management [12,13]. It has been shown previously how integrated daily use is more likely if the self-management components are offered in a mobile phone app, and electronic diaries are thought to improve self-management [48], as in this study. Further, solutions are provided to reduce the potential for erroneous imputations for functions such as transfer of blood glucose data [12,13]. However, the perceived benefits must outweigh the effort of using the app, especially because self-management is an ongoing process that requires many iterations every day [2]. The most frequent component offered in mobile phone apps is blood glucose measurement, but education in self-monitoring of blood glucose [12] and in the use of the application [13,15] is often lacking.

There are also other possible explanations for the lack of difference in the change in HbA_{1c} levels between groups. A total 39% of participants were substantial users of the app during the 1-year follow-up. The lack of effects on predefined outcomes may also relate to low use of the FTA, partly caused by outdated technology at the end of the study. The actual use of a mHealth intervention may reflect the external validity better than does the rate of dropouts [43]. In this study, attrition occurred in participants who did not use the intervention or used it infrequently. The common limit for threatened external validity is a 20% dropout rate [49], but high dropout attrition is expected in trials investigating innovative technology because of technical difficulties and cumbersome user interfaces. Our attrition rates are relatively small in comparison with others [43].

Traditionally, the RCT is the gold standard for clinical trials. In this study, we achieved successful randomization with no statistically significant differences between the 3 groups at baseline. Moreover, all patients were recruited from the primary health care system, which may increase the generalizability of our results [18]. During this study, new and improved versions of mobile phones hit the market and participants reported this as the reason for some of the cases of low use of the mobile phones given to the participants. Outdated equipment may be a problem when using RCTs for testing mobile interventions because of the often-prolonged inclusion process. In future research within the digital area, we should consider other designs and evaluation methods that have a shorter turnover than RCTs.

Some of the results were unexpected, such as the increased use among the older participants (aged ≥63 years). In previous research, a lack of effect was attributed to a fear of technology with increasing age [14], although others have suggested that compliance may be higher in older people [20]. Our findings suggest that age may not be the barrier that many expect. Generalization of the results of this single trial must be made with caution because of the participants' motivation and preferences for entering the study. It is preferable that the characteristics of those interested in mHealth interventions in the target population should be investigated before the study starts [50].

In summary, we have successfully conducted a low-intensity RCT to test a mobile diabetes self-management system with and without health counseling. There were no significant differences in the change in HbA_{1c} between the intervention groups and the control group. Skill and technique acquisition increased in those who received health counseling in addition to the self-management app. This may be important to their daily self-management of diabetes. Our findings indicate that age may not hinder the use of technology, as suggested by earlier research, but further research is needed to confirm this finding.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
CES-D: Center for Epidemiologic Studies Depression Scale
FTA: Few Touch Application
FTA-HC: FTA with health counseling
GP: general practitioner
HbA1c: glycated hemoglobin A1c
heiQ: Health Education Impact Questionnaire
mHealth: mobile health
RENEWING HEALTH: REgioNs of Europe WorkING together for HEALTH
SF-36: Short-Form 36v2 Health Survey

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III

Original Paper

The Service User Technology Acceptability Questionnaire: Psychometric Evaluation of the Norwegian Version

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Abstract

Background: When developing a mobile health app, users' perception of the technology should preferably be evaluated. However, few standardized and validated questionnaires measuring acceptability are available.

Objective: The aim of this study was to assess the validity of the Norwegian version of the Service User Technology Acceptability Questionnaire (SUTAQ).

Methods: Persons with type 2 diabetes randomized to the intervention groups of the RENEWING HEALTH study used a diabetes diary app. At the one-year follow-up, participants in the intervention groups (n=75) completed the self-reported instrument SUTAQ to measure the acceptability of the equipment. We conducted confirmatory factor analysis for evaluating the fit of the original five-factor structure of the SUTAQ.

Results: We confirmed only 2 of the original 5 factors of the SUTAQ, *perceived benefit* and *care personnel concerns*.

Conclusions: The original five-factor structure of the SUTAQ was not confirmed in the Norwegian study, indicating that more research is needed to tailor the questionnaire to better reflect the Norwegian setting. However, a small sample size prevented us from drawing firm conclusions about the translated questionnaire.

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KEYWORDS

acceptability; factor analysis; health care; mHealth; telemedicine

Introduction

Patients' perceptions are important components of any health technology assessment when developing and introducing technological devices for self-management. Scientific and robust methods are necessary in the evaluation of the technology, including the use of a framework such as the Model of Assessment of Telemedicine [1,2].

In previous research, both qualitative and quantitative research methods and log data from self-monitoring have been used in the evaluation of acceptability. Many published studies use questionnaires [3,4], which are often self-constructed and not validated [4], making the comparison of results across studies difficult. Further, many of these studies are small, with few participants, and have methodological limitations [4]. In particular, limitations related to the development phase and psychometric evaluation of questionnaires measuring patient

satisfaction are present, with evaluations lacking data on factor structures, reliability, and validity [5].

There is no consensus related to the definition of the acceptability in mobile health (mHealth) research, although a long list of definitions exists, combining technology and health [6] with users' perspectives [7]. Previous research has defined users' perspectives within telemedicine as "issues related to the perception of the patient or the relatives of the telemedicine application including the patients' and relatives' acceptance of the technology" [1]. However, we have not been able to find the user perspective defined in terms of mHealth. The *acceptability* of digital solutions in health care is often used synonymously with the concept of satisfaction [7]. In the development of the acceptability questionnaire Service User Technology Acceptability Questionnaire (SUTAQ), Hirani et al aimed to investigate the concept of technology acceptance in more detail [8].

The aim of this study was to assess the validity of the translated Norwegian version of the SUTAQ acceptability questionnaire. This was tested on participants who used an mHealth tool, namely, a digital diabetes diary app running on a mobile phone and a blood glucose meter transferring blood glucose measurements to the app by Bluetooth in the intervention groups of a randomized controlled trial (RCT).

Methods

European Union Project

The European Union (EU) project, REgioNs of Europe WorkINg toGether for HEALTH (RENEWING HEALTH), was a research collaboration between 9 regions in Europe working with designing and implementing telemedicine services. The data used in this paper were drawn from the Norwegian study that was a part of this EU project. The acceptability of the equipment was measured at the one-year follow-up in an RCT (NCT01315756).

Participants and Setting

Persons with type 2 diabetes were randomized to 3 groups. The 2 intervention groups received a diabetes diary app that they had for 1 year, and one of the groups also received health counseling for the first 4 months. In addition, the study had a control group. The participants lived at home and were recruited from primary health care. Of the 101 participants who were randomized to the 2 intervention groups, 74.3% (75/101) completed the SUTAQ questionnaire. Other results from the RCT are reported in detail elsewhere [9-12].

Service User Technology Acceptability Questionnaire

The SUTAQ was developed for the Whole Systems Demonstrator (WSD) study in the United Kingdom, to measure acceptability and identify the characteristics of persons who were likely to reject technological health services (see Multimedia Appendix 1) [8]. The questionnaire has 22 items, measured on a Likert-scale from 1 to 6, reflecting more or less agreement with the item statements, respectively. The questionnaire has 5 subscales, where each contains between 3 and 9 items. The subscale containing 9 items was further divided into 2. The original items and the subscales are presented later in the paper. The original questionnaire was found to be reliable and valid [8].

As the partners in the RENEWING HEALTH study in 2011 had decided to include answers to SUTAQ in the minimum common dataset, the questionnaire was also used in the Norwegian trial, even though our data collection had already started. The questionnaire was not available in Norwegian when this study started. However, the translation process followed the procedure recommended by the European Organization for Research and Treatment of Cancer Quality of Life Group [13] and the published guidelines for cognitive interviews [14,15]. Two professional translators translated the SUTAQ questionnaire from English to Norwegian. The Norwegian research team considered the discrepancy between the 2 translated versions and the English version. We achieved equivalence with regard to aspects such as the meaning of words, expressions, concepts, and cultural context. A cultural adaptation of the questionnaire had to be done only for a few statements.

A native English speaker, a bilingual person, without any initial knowledge of the SUTAQ, backward translated the final Norwegian version. The research team, also with a good command of English, compared the backward translation with the original questionnaire, and no further changes were made.

Finally, we conducted cognitive interviews with 10 random participants who had answered the SUTAQ questionnaire. According to these interviews, the items were understandable to the participants, although some found the language somewhat cumbersome, leading us to make a few adjustments.

The report from the translation process can be obtained from the last author (LR).

Statistical Analysis

The sample was described using descriptive statistics. To assess the construct validity of the present domains in the SUTAQ questionnaire from the WSD study, we conducted a confirmatory principal component factor analysis on the 22 items, with Varimax rotation and with a fixed number of 5 factors in accordance with the WSD study [8]. To assess the internal consistency of each domain or extracted factor and for the entire questionnaire, we calculated Cronbach alphas. All analyses were performed using IBM SPSS Statistics v23 (IBM Corp, Armonk, NY, USA).

Results

Sample Characteristics

In total, we analyzed data from 75 participants, of whom 56% (42/75) were female. The age range was 35-80 years, with a median age of 59 years, and 49% (37/75) had ≥12 years of education. There were no differences between the 2 intervention groups for the SUTAQ findings. We found no differences in the baseline measures between the 75 participants included in the analyses and the 26 who dropped out during the study. More details concerning demographic and clinical results from the study sample are published elsewhere [16].

The median values for the original SUTAQ domains are presented in Figure 1, indicating that the participants accepted the equipment to a high degree within the 3 areas of *privacy and discomfort*, *care personnel concerns*, and *satisfaction*. This implies a high degree of acceptability regarding beliefs about the security of the monitored data, the impact of the equipment on the user, beliefs of the continuity and skills of the health care personnel facilitating the equipment, and acceptance and satisfaction with the equipment and the given service. The median value between 1 and 6 constitutes the middle value in the figure. The two categories, *privacy and discomfort* and *care personnel concerns* are based on items with negative statements, where high values reflect a high degree of agreement with the negative statements in these two categories, which means that low values represent a positive score. The remaining factors consist of positive statements. High values reflect a high degree of agreement. The participants reported being slightly more than medium positive concerning whether the equipment could improve their care or increase their access to health care within the domain *perceived benefit*. Results from the domain *kit as substitution* indicated that the participants were most critical about the statements concerning this digital solution replacing usual care.

Factorial Reliability and Validity

The measurement properties of the SUTAQ are presented in Table 1. Overall, the amount of missing data was minimal, no more than 8% for all items. The floor effect was small; only 4 items were far above 15%, considered to be problematic [17]. However, the number of items with ceiling effects was higher, with only about half of the items below the limit of 15%, and for 5 of the items, around 50% (34-40/75) of the participants reached the highest possible score.

The confirmatory factor analysis revealed that only factor 1 and factor 3 were consistent in the original study and this study (Table 2). The first factor, *Perceived benefit*, had 9 items in the original factor structure. Of the items in the Norwegian dataset, 7 loaded >0.400, which was the limit within the factors in the WSD study [8]. In the third domain, *Care personnel concerns*, all 3 items loaded >0.400. The Cronbach alpha coefficient for all 22 items was .851, which demonstrates good internal consistency [18]. Cronbach alpha values for each factor are listed in Table 2.

Figure 1. Median reported scores of the Service User Technology Acceptability Questionnaire domains.

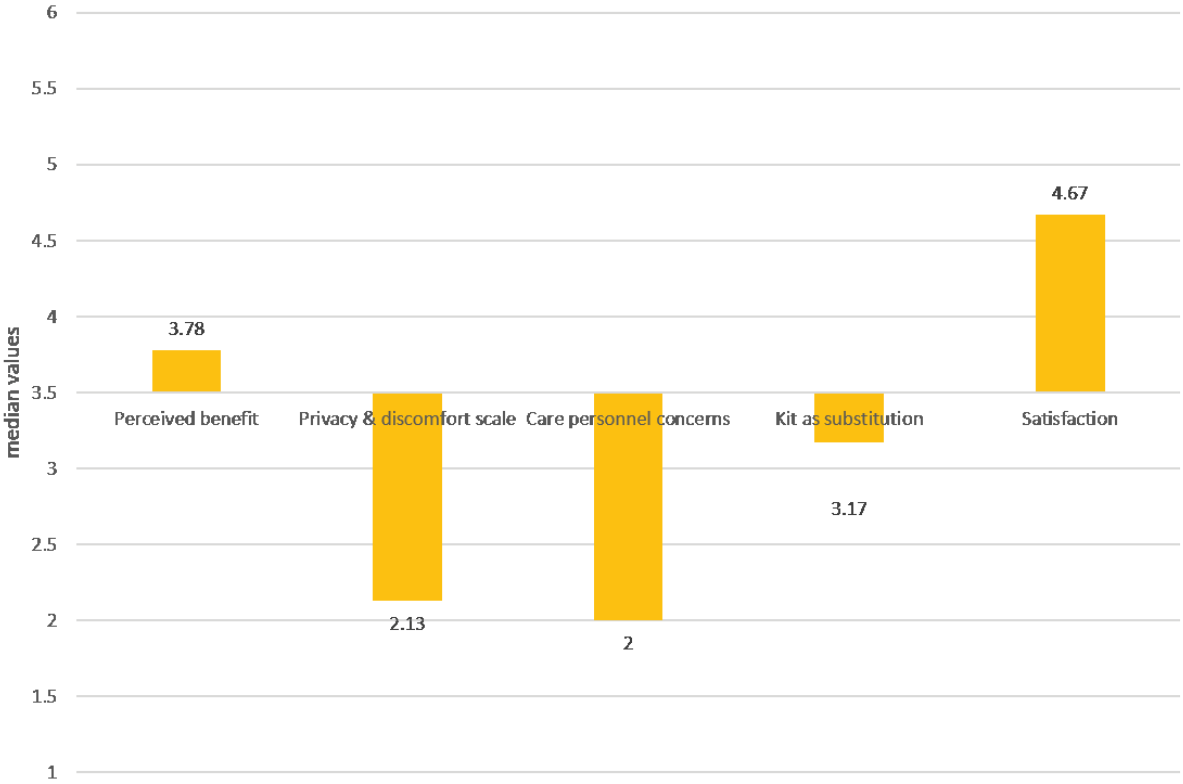

Table 1. Service User Technology Acceptability Questionnaire item descriptors.

Items (range 1-6)	Median	Missing, n (%)	Floor, n (%)	Ceiling, n (%)
The kit I received has saved me time in that I did not have to visit my GP clinic or other health/social care professional as often	4	4 (5)	1 (1)	17 (23)
The kit I received has interfered with my everyday routine	5	3 (4)	2 (3)	35 (47)
The kit I received has increased my access to care (health and/or social care professionals)	5	4 (5)	4 (6)	24 (33)
The kit I received has helped me to improve my health	3	3 (4)	7 (10)	8 (11)
The kit I received has invaded my privacy	5	4 (5)	2 (3)	23 (32)
The kit has been explained to me sufficiently	2	3 (4)	26 (35)	2 (3)
The kit can be trusted to work appropriately	2	3 (4)	17 (23)	10 (14)
The kit has made me feel uncomfortable, eg, physically or emotionally	6	3 (4)	2 (3)	40 (54)
I am concerned about the level of expertise of the individuals who monitor my status via the kit	6	5 (7)	0 (0)	40 (56)
The kit has allowed me to be less concerned about my health and/or social care	3.5	5 (7)	4 (6)	9 (13)
The kit has made me more actively involved in my health	3	5 (7)	7 (10)	8 (11)
The kit makes me worried about the confidentiality of the private information being exchanged through it	5	5 (7)	5 (7)	34 (47)
The kit allows the people looking after me, to better monitor me and my condition	3	5 (7)	11 (15)	8 (11)
I am satisfied with the kit I received	2	4 (5)	11 (15)	10 (14)
The kit can be/should be recommended to people in a similar condition to mine	2	5 (7)	18 (25)	7 (10)
The kit can be a replacement for my regular health or social care	4	5 (7)	5 (7)	17 (24)
The kit can certainly be a good addition to my regular health or social care	2	5 (7)	20 (28)	6 (8)
The kit is not as suitable as regular face to face consultations with the people looking after me	3	4 (5)	13 (18)	4 (6)
The kit has made it easier to get in touch with health and social care professionals	4	5 (7)	4 (6)	19 (26)
The kit interferes with the continuity of the care I receive (ie, I do not see the same care professional each time)	5	6 (8)	1 (1)	34 (48)
I am concerned that the person who monitors my status, through the kit, does not know my personal health/social care history	5	6 (8)	3 (4)	22 (31)
The kit has allowed me to be less concerned about my health status	3	5 (7)	6 (8)	11 (15)

Table 2. Confirmatory factor analysis showing Cronbach alpha values.

Item	Factor 1: perceived benefit	Factor 2: privacy and discomfort	Factor 3: care personnel concerns	Factor 4: satisfaction	Factor 5: kit as substitution
The kit can be/should be recommended to people in a similar condition to mine	*.880* [a,b]	.146	.060	−.077	.079
The kit can certainly be a good addition to my regular health or social care	*.821* [a,b]	.065	−.022	−.101	.220
I am satisfied with the kit I received	*.815* [a]	.257	.028	−.121[b]	.093
The kit has made me more actively involved in my health	*.779* [a,b]	.202	−.026	.253	−.098
The kit I received has helped me to improve my health	*.709* [a,b]	.276	−.132	.181	−.098
The kit has allowed me to be less concerned about my health status	*.693* [a]	.125	.050	−.168	−.005[b]
The kit has allowed me to be less concerned about my health and/or social care	*.676* [a,b]	.201	.057	.028	−.194
The kit can be trusted to work appropriately	*.682* [a]	.103	−.165	.066[b]	−.263
The kit allows the people looking after me to better monitor me and my condition	*.650* [a,b]	.292	.043	−.395	.072
The kit has been explained to me sufficiently	*.505* [a]	−.022	−.084	−.394[b]	.443
The kit I received has saved me time in that I did not have to visit my GP clinic or other health/social care professional as often	.291[b]	*.751* [a]	−.057	.006	.100
The kit has made it easier to get in touch with health and social care professionals	.402[b]	*.721* [a]	−.004	.134	−.067
The kit I received has increased my access to care (health and/or social care professionals)	.246[b]	*.668* [a]	.205	.042	−.131
The kit can be a replacement for my regular health or social care	.411	*.612* [a]	.169	−.243	−.117[b]
I am concerned that the person who monitors my status, through the kit, does not know my personal health/social care history	.119	−.048	*.824* [a,b]	.204	.234
The kit makes me worried about the confidentiality of the private information being exchanged through it	−.070	.130[b]	*.791* [a]	.095	.116
I am concerned about the level of expertise of the individuals who monitor my status via the kit	.038	−.040	*.738* [a,b]	.210	−.341
The kit interferes with the continuity of the care I receive (ie, I do not see the same care professional each time)	−.199	.383	*.656* [a,b]	.122	.318
The kit I received has invaded my privacy	.051	−.069[b]	.281	*.774* [a]	.065
The kit I received has interfered with my everyday routine	−.118	.187[b]	.336	*.606* [a]	.159
The kit is not as suitable as regular face to face consultations with the people looking after me	−.154	.287	−.223	−.138	*−.722* [a,b]

Item	Factor 1: perceived benefit	Factor 2: privacy and discomfort	Factor 3: care personnel concerns	Factor 4: satisfaction	Factor 5: kit as substitution
The kit has made me feel uncomfortable, eg, physically or emotionally	−.031	.420[b]	.243	.359	*.536* [a]
Cronbach alpha	.892	.721	.701	.766	.295
Explained variance, %	31.3	16.4	8.2	5.5	5.1

[a]Italicized values indicate loading in the present Norwegian data.

[b]Original loading in the Whole Systems Demonstrator study.

Discussion

Principal Findings

The Norwegian version of SUTAQ revealed good internal consistency, with a Cronbach alpha of .851. However, the original five-factor solution was not confirmed. On the contrary, our results indicated that a one-factor solution, or at most a three-factor solution, was sufficient, as the explained variance increased by <6% when adding more factors (Table 2). Moreover, only 2 items were loaded on each of the last factors (factors 4 and 5), indicating that they were superfluous. In addition, we found that the SUTAQ questionnaire had some items with a floor effect and even more items with ceiling effects.

Limitations

One limitation of this study was the low number of participants, as over 250 or at least 10 participants per item is recommended to enable precise conclusions from factor analysis [19]. Further, a factor loading above 0.7 per item is preferred according to Kaiser's criteria [20]. Thus, the small sample size might be one of the possible explanations for the lack of confirmation of all factors. Exploratory factor analysis would have been a suitable statistical method to explore the potential of the questionnaire in our Norwegian setting, although demanding a larger number of participants.

Differences in study contexts, health issues, and equipment could also contribute to the lack of common factors in the original study and this study. In the WSD study, interventions were given to patients with long-term conditions, not only diabetes but also chronic obstructive pulmonary disease, heart failure, and social needs [21]. Further, a far broader range of equipment was used in the WSD study: both telehealth and telecare. In this study, only persons with type 2 diabetes used the self-management app, and no telemonitoring was involved. Outdated equipment was also a problem in the Norwegian study because of a long inclusion process [10].

Our data were slightly skewed (Table 1), and to our knowledge, there are no references to an acceptable level of floor and ceiling effects in similar technological studies. Quality criteria available in the literature suggest that floor or ceiling effects over 15% will reduce the reliability of the item in health status questionnaires. In addition, such an item cannot distinguish between the groups of responders scoring at either end of the scale [17]. Only 6 of the 22 items had an acceptable level (≤15%) of both floor and ceiling effects. Other SUTAQ studies [8,22] did not report on the floor and ceiling effects of each item but did present histograms and means for the domains. It seems that the data on the domains *Satisfaction* and *Privacy and discomfort* were skewed in those studies [8,22]. Hirani et al [8] explained the skewedness of items as being linked to the dropout rate from their study, as persons dropping out could have scored somewhat different from the remaining participants, possibly leading to bias and reduced generalizability. The responders were expected to be more satisfied than nonresponders; this explanation could also be relevant for our Norwegian study. However, even if the remaining participants were more satisfied, the questionnaire did not capture details of their satisfaction.

Using an unvalidated questionnaire is a limitation as described by Streiner [18]. This refers both to the development of the questionnaire and to the generalizability of the translated version, which may lack equivalence with the original questionnaire. Being part of a large EU study, we agreed upon the selection of common questionnaires. Before our one-year follow-up, the partners decided to introduce the SUTAQ. At that time, we translated the instrument according to standardized procedures for translation [13]. This gave us knowledge about the participants' conceptual and semantic understanding of the items. If we had the opportunity to perform a questionnaire validation of the SUTAQ ahead of the study, this would have improved reflections about its validity. Another aspect is that SUTAQ was developed for the WSD study evaluating different technologies and measuring the acceptability of telehealth and telecare interventions, with a closer follow-up from health care personnel than that in the Norwegian self-management study. The differences in the content of the interventions between the original [8] and this mHealth study could have affected the validation analysis, as the SUTAQ might be more suitable for a different type of intervention than the one implemented in this study. Finally, even though we carefully followed the translation procedures, we cannot rule out the risk that the translation from English to Norwegian could have changed the understanding of the initial meaning of the statements in SUTAQ.

Originally, we aimed to perform a test-retest analysis to measure reliability, which would require data on 40-50 participants. Unfortunately, we did not reach the sufficient number of participants because of financial and logistical difficulties. We measured acceptability at the last point of follow-up in the study, making it difficult to collect additional retest questionnaires. Given that we had only 12 retest responders, we realized that we did not have enough statistical power to perform a meaningful test-retest analysis.

Implications for Future Research and Clinical Practice

In the diverse reality of technology and health, it is challenging to measure patient perception. Nevertheless, we are still in need of a questionnaire that measures the acceptability of digital interventions, given the current development and implementation of many new apps and Web solutions in health care. Health technology assessment as a systematic evaluation contributes to the evaluation of various impacts of health technology [23], so there is a need for validated measurements of the acceptability of the technology among users. The SUTAQ measures several such relevant aspects, such as the impact on relations to health care personnel, privacy, etc. A relatively small sample size has restrained us from drawing any firm conclusions. SUTAQ should be validated using a larger sample and possibly a modified version developed for use in the Norwegian setting.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The Service User Technology Acceptability Questionnaire (original version; published with permission from Shashi Hirani).

[PDF File (Adobe PDF File), 402KB - humanfactors_v5i4e10255_app1.pdf]

Multimedia Appendix 2

Permission to publish the SUTAQ.

[PDF File (Adobe PDF File), 296KB - humanfactors_v5i4e10255_fig.pdf]

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Abbreviations

EU: European Union
mHealth: mobile health
RCT: randomized controlled trial
RENEWING HEALTH: REgioNs of Europe WorkINg toGether for HEALTH
SUTAQ: Service User Technology Acceptability Questionnaire
WSD: Whole Systems Demonstrator

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IV

Original Paper

Acceptability of an mHealth App Intervention for Persons With Type 2 Diabetes and its Associations With Initial Self-Management: Randomized Controlled Trial

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Abstract

Background: Mobile health interventions are increasingly used in health care. The level of acceptability may indicate whether and how such digital solutions will be used.

Objective: This study aimed to explore associations between the level of acceptability of a mobile diabetes app and initial ability of self-management for patients with type 2 diabetes.

Methods: Participants with type 2 diabetes were recruited from primary health care settings to a 3-armed randomized controlled trial in the Norwegian study in the RENEWING HEALTH project. At the 1-year follow-up, 75 out of 101 participants from the intervention groups completed an acceptability questionnaire (The Service User Technology Acceptability Questionnaire). In the randomized controlled trial, the 2 intervention groups (n=101 in total) received a mobile phone with a diabetes diary app, and one of the groups received additional health counseling given by telephone calls from a diabetes specialist nurse (n=50). At baseline, we collected clinical variables from medical records, whereas demographic data and self-management (The Health Education Impact Questionnaire) measures were self-reported. Log data from the use of the app by self-monitoring were registered continuously. Associations between initial ability to self-manage at baseline and acceptability of the diabetes diary app after 1 year were analyzed using linear regression.

Results: We found statistically significant associations between 5 of the 8 self-management domains and *perceived benefit*, one of the acceptability factors. However, when adjusting for age, gender, and frequency of use, only 1 domain, *skill and technique acquisition,* remained independently associated with *perceived benefit*. Frequency of use of the app was the factor that revealed the strongest association with the acceptability domain *perceived benefit*.

Conclusions: Our findings indicate that persons with diabetes may accept the app, despite its perceived benefit being associated with only one of the 8 domains of their initial level of self-management.

Trial Registration: ClinicalTrials.gov NCT01315756; https://clinicaltrials.gov/show/NCT01315756 (Archived by WebCite at http://www.webcitation.org/6z46qPhWl)

(JMIR Mhealth Uhealth 2018;6(5):e125) doi:10.2196/mhealth.8824

KEYWORDS

diabetes mellitus, type 2; patient acceptance of health care; acceptability of health care; self-care; mobile apps; smartphone; telemedicine; regression analysis; factor analysis; statistical

Introduction

Background

Self-management is important for persons with chronic illnesses to maintain their own health. Health care providers should engage in self-management support when there is a need for assistance to manage health challenges [1].Both self-management education and support are reported to improve metabolic control as measured by glycated hemoglobin (HbA_{1c}) levels for persons with type 2 diabetes [2]. Furthermore, mobile health (mHealth) interventions developed for diabetes self-management have shown some effects, although little is known about the full potential benefit of using mobile diabetes apps [3-7]. Successful use of mHealth tools and services requires an active user and cooperation with health professionals [4]. Use of mHealth often includes the possibility of sharing data between health professionals and their patients with diabetes, which could enhance the support to improve their self-management [6,7].

The acceptability of the provided mobile-based technology is important for their use and for its implementation into practice [8]. However, only sparse knowledge exists about factors that make mobile technology acceptable for persons with type 2 diabetes [9-11]. Findings from the Whole System Demonstrator (WSD) study indicate a positive association between self-management and higher levels of acceptability [12]. Other studies have found associations between satisfaction with the device and improved diabetes management [9], but to our knowledge, little is known about the associations between the acceptability of an app and the initial ability to self-manage one's own health, before introducing the app. We hypothesized that a person with a high degree of self-management at baseline would have the skills and confidence to accept and implement the use of available technical tools in self-care.

Objectives

The aim of this study was to explore associations between the initial ability of self-management and the level of acceptability of a mobile diabetes app.

Methods

Participants and Setting

The study sample in this study consisted of participants from the Norwegian randomized controlled trial (RCT) of the European Union project RENEWING HEALTH, which has been described in detail elsewhere [13-15]. Participants were persons with type 2 diabetes mainly recruited through general practitioners between March 2011 and September 2012. Eligibility criteria were (1) adults aged ≥18 years with type 2 diabetes, (2) HbA_{1c} levels ≥7.1%, and (3) capacity to use the equipment and to fill in questionnaires in Norwegian. The study was a 3-armed RCT with 2 intervention groups and 1 control group. Both intervention groups (n=50+51) received a mobile phone with a diabetes diary app developed at the Norwegian Centre for E-health Research [16] and a blood glucose meter (OneTouch Ultra Easy from LifeScan Inc. West Chester, PA, USA), equipped with an adapter for enabling Bluetooth communication (Polytel GMA from Polymap Wireless). One of the intervention groups received additional health counseling through telephone calls by a diabetes specialist nurse for the first 4 months of the study. At the 1-year follow-up, 75 out of 101 participants from the intervention groups completed an acceptability questionnaire (The Service User Technology Acceptability Questionnaire) after having finished the study.

Both intervention groups received the training needed to manage the mobile phone and the app provided by a team of researchers and assistants in meetings with the participants, in addition to a technical support telephone service available at daytime.

Despite the eligibility criteria "capacity to use the app, some participants expressed a lack of motivation or capacity to learn to use the app. Some therefore received additional training in face-to-face meetings with the technical supporters or others in the research team. In the health counseling intervention group, the diabetes specialist nurse focused on diabetes self-management and motivation, and at the same time, when needed, encouraged the participants to use the app [13,14]. Currently, we report findings from the 2 intervention groups that were assessed at the 1-year follow-up; in total, 75 of the originally enrolled 101 participants completed the self-report questionnaires (response rate; 74.3%).

Measures

The Service User Technology Acceptability Questionnaire

The Service User Technology Acceptability Questionnaire (SUTAQ) was developed, designed, and psychometrically evaluated for the WSD study, a large telehealth study performed in England. The 22 items aim to measure the users' beliefs and perceptions of the equipment. An expert panel of researchers and clinicians developed the questionnaire. Factor analysis from the original WSD study reported 5 domains: *perceived benefit, privacy and discomfort*, *care personnel concerns*, *kit as a substitution*, and *satisfaction* [12]. The answers to the statements for each item were rated on a Likert scale from 1 to 6, ranging from strongly agree to strongly disagree [12]. The psychometric evaluation of the Norwegian language version of SUTAQ is reported elsewhere, and the factor analyses only confirmed the domains *perceived benefit* and *care personnel concerns* [17].

Table 1. Sample characteristics at baseline for those who responded at 1-year follow-up (Service User Technology Acceptability Questionnaire, n=75).

Variables	Median	Range
Age (years)	59	35-80
Diabetes duration[a] (years)	9	1-36
HbA_{1c}[b], %		
Baseline	7.8	7.1-12.4
1-year follow-up[c]	7.6	5.6-13.0
Health Education Impact Questionnaire domains		
Health-directed activity	2.75	1.00-4.00
Positive and active engagement in life	3.20	1.60-4.00
Emotional distress	3.00	1.17-4.00
Self-monitoring and insight	3.00	2.33-3.83
Constructive attitudes and approaches	3.00	1.80-4.00
Skill and technique acquisition	3.00	2.00-4.00
Social integration and support	3.00	2.00-4.00
Health service navigation	3.00	2.00-4.00

[a]Missing from baseline: n=6.

[b]HbA_{1c}: glycated hemoglobin.

[c]Missing from baseline: n=2.

The Health Education Impact Questionnaire

The Health Education Impact Questionnaire (heiQ) was developed in Australia [18] to measure self-management after participation in education and or self-management support interventions for persons with chronic diseases. This questionnaire has later been adapted for multiple settings. In addition, Osborne has suggested new ways of use, such as incorporation of the instrument, or some of the scales, into standard assessment and as a care planning tool [1]. Each of the 40 items is rated on a Likert scale from 1 to 4, from "strongly disagree" to "strongly agree." They are organized into 8 domains as listed in Table 1, with 4 to 6 items in each domain. For all domains, high scores indicate a high level of self-management abilities, except for *emotional distress*, where high scores reflect high distress. The heiQ questionnaire has been validated in a Norwegian primary health care context in patients with different chronic conditions, including diabetes [19]. In this study, we used heiQ data from baseline measures before any intervention to investigate the users' initial ability to self-manage.

Log Data, High and Low Frequency of Use

The researchers in the team defined high frequency of use as ≥5 blood glucose measurements and ≥50 keystrokes in the app each month for at least 6 months of the 1-year intervention to differentiate between participants who used the app regularly, sporadically, or did not use the app. The app enabled registration of blood glucose level, diet and physical activity, setting of goals, and gave access to a diabetes-specific dictionary. The Bluetooth technology enabled automatic sending of blood glucose values from the blood glucose meter to the app. Diet and physical activity data were self-reported and entered manually into the app through graphical user interface. Keystrokes were registered for use of all the graphical user interface functionalities. Measurements of blood glucose, diet, and physical activity that were recorded with the app were sent to a secure server continuously during the study.

Demographic and Clinical Data

Demographic data such as age, gender, education, diabetes duration, and any comorbidities were self-reported through questionnaires at baseline. HbA_{1c} baseline values were obtained from the general practitioners' medical records.

Statistical Analysis

Sample characteristics are presented as counts and percentages for categorical variables and as median and range for continuous variables. Differences between the intervention groups and between the participants lost to follow-up and the responders were assessed using Pearson chi-square test for pairs of categorical data and the nonparametric Mann-Whitney Wilcoxon *U* test for continuous data. We modeled associations between initial ability to self-manage (heiQ) and equipment acceptability (SUTAQ) with univariate linear regression models, and thereafter adjusted for possible confounders such as age, gender, and frequency of use in multiple models. *P* values <.05 were considered statistically significant. All tests were two-sided. All analyses were performed using IBM SPSS Statistics (v 23; IBM Corp, Armonk, NY, USA).

Ethics

The Norwegian Regional Committees for Medical and Health Research Ethics approved the study, and the participants signed an informed consent when they entered. In addition, we performed risk analysis before start of the study.

Results

Sample Characteristics

Of the 75 participants analyzed, 42 (56%) were female, the median age was 59 years (age range 35-80 years), 37 (49%) had 12 years or more of education, only 10 (13%) had no comorbidities, and the median diabetes duration was 9 years (range 1-36 years). Almost half of the participants, that is, 48% (36/75), were high-frequency users of the diabetes diary app (Tables 1 and 2). No statistically significant differences in self-reported acceptability (SUTAQ) of the equipment or in baseline measures between the 2 intervention groups were revealed. Furthermore, between the participants lost to follow-up at 1 year (nonresponders) and the remaining responders in the interventions groups, there were no differences in baseline values regarding age, gender, education, diabetes duration, or HbA_{1c}; however, we did find a difference in the frequency of use of the app. According to the log data, only one of the participants lost to follow-up used the app frequently. Overall, heiQ baseline values were in the slightly higher ranges of possible values for all the measured items (Table 1).

Associations Between Self-Management Assessed With Health Education Impact Questionnaire and Acceptability Measured With Service User Technology Acceptability Questionnaire

We explored the 2 acceptability factors *perceived benefit* and *care personnel concerns*, which were the only domains of the original scale that were confirmed by the factor analysis [17]. The domain *perceived benefit* (SUTAQ) was significantly associated with 5 of the 8 heiQ (self-management) domains at baseline (Table 3).

In addition, our data revealed a significant crude association between gender and *perceived benefit*, where men experienced more benefit from the app than women (estimated beta=−.57, 95% CI −1.05 to −0.09, *P*=.02). Moreover, an association was revealed between gender and frequency of use, where 69% (25/36) of the high-frequency users were men (*P*=.02).

Furthermore, linear regression models confirmed that frequency of equipment use was the factor that was strongest associated with *perceived benefit* (SUTAQ), even when controlled for all of the heiQ domains separately, as well as for age and gender. Only the heiQ domain *skill and technique acquisition* remained associated with *perceived benefit* when adjusted for age, gender, and frequency of use (Table 3). No association was found between initial ability to self-manage (heiQ) and the SUTAQ domain *care personnel concerns* (results not shown).

Table 2. Sample characteristics at baseline, 1-year follow-up responders (Service User Technology Acceptability Questionnaire); n=75.

Variables	n (%)
Gender	
Female	42 (56)
Male	33 (44)
Education	
<12 years	38 (51)
12 years	7 (9)
>12 years	30 (40)
Comorbidities	
0	10 (13)
1-2	51 (68)
≥3	14 (19)
Use of app, log data[a]	
Low frequency of use	37 (49)
High frequency of use	36 (48)
Familiar with technology	
Familiar with use of computer	69 (92)
Familiar with use of mobile phone	75 (100)

[a]Missing from baseline: n=2 (3%).

Table 3. Linear regression and crude and adjusted values (adjusted for age, gender, and frequency of use), dependent variable *perceived benefit* (Service User Technology Acceptability Questionnaire).

heiQ[a] domains	Crude		Adjusted (age, gender, and frequency of use)	
	Estimated beta (95% CI)	*P* value	Estimated beta (95% CI)	*P* value
Health-directed activity	.44 (0.11 to 0.78)	.01	.31 (−0.03 to 0.64)	.07
Positive and active engagement in life	.40 (−0.19 to 0.98)	.18	.17 (−0.40 to 0.73)	.56
Emotional distress	.37 (−0.03 to 0.78)	.07	.20 (−0.20 to 0.59)	.32
Self-monitoring and insight	.89 (0.05 to 1.74)	.04	.53 (−0.30 to 1.36)	.21
Constructive attitudes and approaches	.45 (−0.01 to 0.91)	.06	.29 (−0.16 to 0.74)	.21
Skill and technique acquisition	.74 (0.17 to 1.32)	.01	.60 (0.03 to 1.17)	.04
Social integration and support	.69 (0.21 to 1.18)	.005	.37 (−0.15 to 0.90)	.16
Health service navigation	.64 (0.14 to 1.14)	.01	.40 (−0.11 to 0.92)	.12

[a]heiQ: Health Education Impact Questionnaire.

Discussion

Principal Findings

We explored associations between initial ability to self-manage and equipment acceptability using the 2 acceptability factors *perceived benefit* and *care personnel concerns*, which were the only 2 domains confirmed in the factor analysis. As hypothesized, we found a linear relationship between higher self-management and a positive experience of the mobile diabetes app as being beneficial for health care. However, after adjusting for age, gender, and frequency of use, this association was no longer statistically significant, except for the domain *skill and technique acquisition*. Furthermore, according to our findings, the use of the app turned out to have the strongest association with app acceptability.

The SUTAQ domain *perceived benefit* contains statements regarding improved health, increased involvement in health treatment, and the use of the app and the equipment as a supplement to usual care. In contrast to what we assumed, the initial ability to self-manage did not seem to be associated with acceptability; however, the participants who used the mobile phone app reported benefits of the app independent of the level of perceived self-management before its use. There are several barriers for persons with type 2 diabetes concerning the use of digital tools in their treatment. These barriers could be related to the potential user, to the technology, or to the health care offered [20-22]. Technical difficulties [9] and technological illiteracy [20,21], in addition to low health literacy [23,24], are associated with less engagement with technology for persons with type 2 diabetes. We did not find initial low self-management to be a barrier in our study, as our nonresponders had similar levels of all items of heiQ. However, it may not have been a coincidence that the domain that remained statistically significant in the analyses was skills to manage symptoms, which include skills to make use of equipment [1,18]. The participants were motivated to use the technology when they volunteered to enter the study, and inability to use the technology was an exclusion criterion. We can speculate that a lower self-management could have been a barrier at an earlier stage with regard to showing interest in the study. This is a limitation to the generalizability of our findings as all our participants scored relatively high on heiQ. In contrast to our findings, Hirani et al found an association between several of the heiQ domains and the SUTAQ domains, which indicates that those who accepted the intervention reported higher levels of self-management [12]. However, Hirani et al did not report the baseline values of heiQ. Therefore, it remains unclear whether their findings reflect a change in self-management during the use of the digital tools, where use of the tools enhances self-management skills and attitude, or whether the level of self-management was unchanged from baseline.

Strengths and Limitations of the Study

The participants' technical literacy, which was an inclusion criterion in our study, could bias our findings, as all participants were able to manage the equipment at some level, increasing the probability of acceptability. Nevertheless, we experienced a noticeable diversity in technical skills, and we gave technical support when needed through the study, implying that participants with different levels of technical experience and preferences were included, although persons with lack of technical skills were not eligible. It would have strengthened our study if we had measured the initial level of technological skills in more detail than only their experiences with mobile phones and personal computers. All the participants had previous experiences with use of mobile phone, yet not necessarily smartphones. Another possible limitation is the definition of frequency of use. It is difficult precisely to define an anticipated use because of between-persons differences in needs and stage of progression of their disease. Our definition of use aimed to differentiate between the participants' use of the app regularly and the ones who had sporadic or no use of the app.

In addition, it would have been interesting to know their level of motivation to enter the study, as we do not know much about who were initially eager to try new technology or whether they attended for other reasons. However, we have performed a qualitative study with interviews at the end of the RCT when the participants left the study and gained more in-depth knowledge about the participants' acceptability. These findings have recently been corroborated (A Torbjørnsen et al, unpublished data, May 2018).

In our analysis, we pooled together 2 heterogeneous groups of participants testing the app, with 1 group receiving initial health counseling. Potentially, the group receiving health counseling could have responded differently to the acceptability questionnaire than the intervention group that only had the equipment with the app. As an example, the health counseling group could have reported higher acceptability caused by enhanced access to health care and technical support; to the contrary, the health counseling could add a burden, and exhausted the participants, and thus, resulting in lower acceptability by some. As we did not find any differences between the groups, neither for acceptability nor for other measures, we pooled the 2 groups. We have previously discussed the effect and intensity of the health counseling [14,15].

Implications for Future Research and Clinical Practice

Our findings suggest that use of a diabetes diary app could be acceptable regardless of initial ability to self-manage, as the crude correlation between the 2 scales disappeared when adjusting for age, gender, and frequency of use, except for the domain *skill and technique acquisition*. Further research on which factors may influence the use and benefit of an mHealth solution would be of interest.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V.1.6.1).

[PDF File (Adobe PDF File), 1MB - mhealth_v6i5e125_app1.pdf]

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Abbreviations

HbA $_{1c}$: glycated hemoglobin
heiQ: Health Education Impact Questionnaire
mHealth: mobile health
RCT: randomized controlled trial
SUTAQ: Service User Technology Acceptability Questionnaire

WSD: Whole System Demonstrator

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Users' acceptability of a mobile application for persons with type 2 diabetes: a qualitative study

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Abstract

Background: The use of mobile health apps is now common in diabetes self-management and acceptability of such tools could help predict further use. There is limited research on the acceptability of such apps: use over time, the factors and features that influence self-management, how to overcome barriers, and how to use an app in relation to health-care personnel.

In this study, we aimed to obtain an in-depth understanding of users' acceptability of a mobile app for diabetes self-management, and to explore their communication with health-care personnel concerning the app.

Methods: The study had a qualitative descriptive design. Two researchers conducted 24 semi-structured in-depth interviews with adults with type 2 diabetes who had used a digital diabetes diary app for 1 year, during participation in the Norwegian Study in the EU project RENEWING HeALTH. We recruited the participants in a primary health-care setting. The transcripts of the interviews were analyzed using qualitative content analysis on developing themes, which we interpreted according to a theory of acceptability. We used NVivo 11 Pro during the process.

Results: The users' acceptability of the app diverged. Overall, the responses indicated that the use of a digital diabetes diary requires hard work, but could also ease the effort involved in following a healthy lifestyle and better-controlled levels of blood glucose. Crucial to the acceptability was that a routine use could give an overview of diabetes registration and give new insights into self-management. In addition, support from health-care personnel with diabetes knowledge was described as necessary, either to confirm the decisions made based on use of the app, or to get additional self-management support. There were gradual transitions between practical and social acceptability, where utility of the app seems to be necessary for both practical and social acceptability. Lack of acceptability could cause both digital and clinical distress.

Conclusions: Both practical and social acceptability were important at different levels. If the users found the utility of the app to be acceptable, they could tolerate some lack of usability. We need to be aware of both digital and clinical distress when diabetes apps form a part of relevant health-care.

Trial number: https://clinicaltrials.gov/show/NCT01315756 March 14, 2011

Keywords: Type 2 diabetes mellitus, Acceptability, Satisfaction, Patient perception, Self-management, Healthy Lifestyle, Mobile apps, Smartphone, mHealth, Qualitative research

Background

The foundation of successful diabetes management is education in the disease, promotion of healthy eating and physical activity, as well as the use of medication to regulate blood glucose and prevent complications [1]. Self-management support is necessary to strengthen a person's ability to live well with diabetes, whether the intervention is behavioral, educational, psychosocial, or clinical [2].

Digital solutions, such as applications ('apps') on smart phones, are increasingly in use in health-care in general, and for diabetes care in particular [3,4]. The number of apps is increasing rapidly and they are easily accessible [5]. Mobile apps are recommended in Norwegian diabetes guidelines to track physical activity in combination with blood glucose registration [6] and in US guidelines as a part of preventing the development of type 2 diabetes [7]. However, the European Society of Cardiology guidelines, in collaboration with the European Association for the Study of Diabetes, recommend multifaceted strategies acting through multidisciplinary teams without mentioning the use of technology [8].

The use of mobile apps can give persons with chronic diseases, such as type 2 diabetes, improved glycemic control, symptom control, and improve their health outcomes in general [9,10]. Previous research has found that such apps can improve patients' collaboration with health-care professionals and that good interactions when first diagnosed can increase the benefits of using an app for persons with type 2 diabetes [11-14]. In addition, it is beneficial if the features in the app are tailored to the users' needs. In this regard, McMillan *et al.* have suggested that if the glucose and physical activity feedback were visual, it could increase the participants' motivation for self-management. Use of behavioral change theories to develop the technology could make it more useful [15]. However, there are several barriers for use of the technology in terms of issues related to the app, to the user, and to environmental factors [12,14,16,17].

If an app is to be practical, it needs to be accepted, and the persons targeted must be satisfied. Acceptability depends on a certain level of usability, but it must also facilitate some improvements in self-management [18]. Satisfaction with a tool could lead to changes in behavior even when medical outcomes might be unchanged [19]. Although we know much about how to design apps that are useful, there is limited research on their acceptability [15]. We also know less about the factors that influence their use over time [11]. Further, there is little knowledge about the factors and features in apps that influence self-management for persons with chronic diseases in general, and for persons with type 2 diabetes in particular, and how to overcome barriers to the use of technology in health-care [4,9,16,19,21]. There is a need to find out more about the degree of intensity, and what approaches could enable the technology to be an effective support in health-care [22,23]. A recent review concluded that diabetes apps might have the potential to reduce glycated hemoglobin (HbA_{1c}) levels at a population level, and that these apps can contribute to lifestyle changes [24,25]. However, exactly how apps contribute to such changes is unclear [26]. Greater insight into how to integrate apps with diabetes self-management care is required [27], informed by the understanding that self-management incorporates cognitive, behavioral, and emotional approaches [28]. This qualitative study aims to contribute to investigations on how diabetes apps can be accepted and used to support daily self-management challenges, and how they could form a part of health-care consultations.

Aim

To obtain an in-depth understanding of the users' acceptability of a mobile app for diabetes self-management, and to explore their communication with health-care personnel concerning the app.

Framework, acceptability

Acceptability has earlier been described as "whether the system is good enough to satisfy the needs and requirements of the users" [29]. Within the field of technological solutions for health-care, acceptability and satisfaction have been used as synonymous for an explanation of the persons' perception of a technological device [30]. Patient satisfaction could be defined as "the fulfilment of the expectation or perceived needs of an individual in a particular situation" [31]. Others identify satisfaction as a concept subordinate to acceptability [32] or even as an aspect of usability, which in turn is subordinate to acceptability [29]. Acceptability of health-care devices is necessary for use and «depends on the interactions between a 'felt need' for assistance, the recognition of 'product quality' – the efficiency, reliability, simplicity and safety of the technology or device, and its availability and cost» [33]. Hirani *et al*. developed an acceptability questionnaire originally for use in the Whole System Demonstrator study in the United Kingdom and later in the RENEWING HeALTH (European study REgioNs of Europe WorkINg toGether for HEALTH), of which the present study was a part (see below). They took into consideration that the contact with health-care personnel was significant for the users' acceptability of digital medical devices. They divided the domains into perceived benefit, privacy and discomfort, care personnel concerns, satisfaction, and kits used as substitutions for health-care [32]. Some factors described as part of acceptability could be more important than others, depending on the particular technical solution and the person using the technology. A person's acceptability of a digital medical device can also be affected by demographic factors such as age, gender and education, expectations, and usability (ease of use). The factors play different roles within individual variations [34].

The concept of *acceptability* is complex, and researchers have described multiple factors. Nielsen distinguishes between social and practical acceptability in his acceptability model, where practical acceptability covers usefulness (utility and usability), cost, compatibility, and reliability. Usability refers to learnability, efficiency, memorability, and error reduction and what is considered

subjectively pleasing. Social acceptability is less elaborate as a concept, but reflects a person's attitudes toward technology. High practical acceptability scores do not necessarily reflect high social acceptability scores [29]. We have used elements from this model to interpret our findings. These are covered in the Discussion section, where the distinction between social and practical acceptability is emphasized.

Methods

In the presentation of the methods, we have followed recommendations of the Consolidated Criteria for Reporting Qualitative Research (COREQ) [35].

Design

This qualitative study was part of the Norwegian Study in RENEWING HeALTH: an intervention designed as a randomized controlled trial with this study performed at the end. An evaluation of the process was performed on completion of the trial [36]. We wanted to explore the RCT findings in depth, and to identify and explain variations in the experiences with use of a mobile phone-based diabetes diary app. We therefore applied a descriptive design with semi-structured interviews to acquire more knowledge about the participants' perceptions of the intervention. We conducted the interviews when the participants left the trial successively after the last assessment point in the evaluation of effects.

The randomized controlled trial in RENEWING HeALTH

The Norwegian study in the EU project RENEWING HeALTH was a 1-year, three-armed randomized controlled study (RCT). Inclusion criteria for participants in the RCT were age ≥18 years, having type 2 diabetes, an HbA_{1c} level ≥7.1%, the ability to use the equipment, and being capable of filling in questionnaires in Norwegian. Detailed descriptions of the RCT have been published elsewhere [37-39].

The participants included in the two intervention groups were given a smartphone, i.e., the HTC HD Mini® Windows® Mobile 6.5 containing a digital diabetes diary on an app (the Few Touch application [40]), along with a OneTouch® Ultra Easy® LifeScan Inc., Milpitas, CA, USA, which transferred the blood glucose measurements to the app via Bluetooth. The diary also contained functions with the possibility of setting personal goals, and manually registering daily activity and diet. In addition, an encyclopedia with diabetes-relevant information was included in the app. One of the intervention groups received health counseling from a specialist diabetes nurse for the first 4 months as a boost. The purpose of delivering the app and providing health counseling was to enhance the self-management of diabetes. The intervention was provided outside usual care, but the participants were encouraged to show the app to their health-care personnel. Specific instructions as to how often the participants should use the app were not provided since their needs varied. The mobile app had been developed earlier and tested in collaboration with 12 persons with diabetes [40].

The research group

The research group included four nurse researchers (SH, LR, MR, and AT) and one researcher with a background in technology (AG). More specifically, their competences were: Professor and experienced qualitative researcher (SH): Associated Professor with a PhD and a diabetes researcher (LR); Associated Professor with an MNSc (MR); Assistant Professor with an MSc and being a PhD candidate (AT); and an information and communication technology chief advisor with in-depth knowledge about the technology of the project (AG). Different reflexive accounts were obtained during the qualitative data analysis and interpretations due to the diverse professional backgrounds of the researchers.

Participants and setting

MR and LR interviewed 26 persons with type 2 diabetes living independently in the north and south of Norway. The study participants were recruited via general practitioners. In addition, some of the participants were followed-up by diabetes specialist nurses or health-care providers in the municipality or at hospital [39]. All participants had a 1-year experience with the use of a diabetes diary app throughout the study. The interviews were performed between May 2012 and March 2013.

Participant selection

The participants in the intervention groups were asked to participate in an interview after they had completed the self-reported questionnaires and delivered their personal journal data at the end of the study. They were asked to participate in the interviews either by telephone, or at the last meeting with the researchers. If they agreed to participate, the interviewers called them to make an appointment and sent them written information in addition to the information and informed consent they had given earlier at first inclusion in the study. Of the 89 participants receiving a smartphone during the study, we assessed the first 50 participants leaving the trial for eligibility. Of these, five refused to participate and 10 were not asked for participation for various reasons (we could not reach them, they spontaneously stated that they would not participate further, or they had bad health). The remaining 35 were willing to attend; however, we were not able to reach seven of them and two were ill. Adequate power to ensure sufficient richness and depth of analysis was reached after conducting 26 interviews [41]. The study had a broad study aim exploring how persons with type 2 diabetes accepted a digital diabetes diary app according to their acceptability with the device. Further, we recruited persons consecutively when they had finished the RCT, without any configuration of the sample, and continued the recruitment until we had a broad scope of participants. The quality of the interview dialogue was good, and the data collected were useful and of interest. Each of the interviews lasted between one, and one and a half hour. Because of technical

difficulties, only handwritten notes were available from two of the interviews. We excluded these notes from the analysis, and thus analyzed 24 audiotaped and transcribed interviews in this article.

Setting

Of the 24 interviews, MR performed 14 and LR 10. The participants chose where and how they were comfortable to meet. The interviews were performed at the researcher's office (n = 4), at the home of the participants (n = 7) or by telephone mainly because of geographic distance (n = 13). All the interviews were performed as soon as possible after the participants had completed questionnaires when leaving the RCT study. None of the interviewers had any contact with the participants during the RCT study.

Data collection

MR and LR developed a semi-structured interview guide (Table 1) in accordance with the MAST model [42] where patient perspectives constitute one of the assessment domains. The interview guide contained open-ended questions and was approved by the project team. This contained questions about living with diabetes and the use of a digital diabetes diary, and the interaction with the app and the others (e.g. general practitioners and family members) concerning their diabetes. In addition, the researchers asked questions about the health counseling offered to those participants in the intervention group who received this. The participants gave one interview each.

Table 1. The key themes from the interview guide

THEMES	DESCRIPTIONS
PRIMARY THEMES	Satisfaction with, or accept of the use of the mobile app for diabetes self-management Communication with health-care personnel about the app
SPECIFIC THEMES	User experience of the app and its different elements Value of the app to the user Influence of the app in effecting self-management Effectiveness of the app in improving knowledge of diabetes Efficacy of the app enhancing user independence Strength and weaknesses of the app Advantages and disadvantages of using the app The extent to which the app was to liaise with general practitioners and others, and the degree to which data were shared or discussed The effectiveness of the technology in general Use of the study mobile phone as their ordinary phone
ADDITIONAL THEMES	The extent to which the participants experienced that their health improved during the study The future of the app and its potential to manage diabetes The identification of participants to target who would most benefit from use of the app Whether or not the individual right to privacy was upheld during the study

Analysis

Data analysis

We used qualitative content analysis to systemize and analyze the data, inspired by the work of Schreier [43]. Qualitative content analysis was used to obtain an overview of the data collected from the interviews. Relevant text segments were selected and similar segments were sorted using coding. Thereafter, their hierarchical order was deliberated to inform the interpretation of themes. As researchers, we moved back and forth between text segments and the transcribed interviews in its origin in order to ensure that our interpretations of the data were in accordance with the context in which they arose during interviews (Table 2). In the analytical process, a combination of a data- and concept -driven strategy was applied [43]. Initially, a data-driven strategy was selected to support the inductive approach used to develop a coding frame and the themes (Results section). Later, a concept-driven strategy was applied to interpret the themes according to the acceptability framework (Discussion section). AT read and summarized the transcription of the interviews, selected relevant text segments concerning use of the app, and coded the themes related to the research question. The authors derived the codes from the data material, and identified units of codes within three different themes. The authors held regular meetings while working on the content analysis and discussed the progression and interpretations. We discussed the interviews, the text selection, the coding frame, and themes during these meetings. The data driven themes are presented in the Results section. As a next analytical step, the authors interpreted and discussed the themes within the frame of the Acceptability Model [29] to gain an understanding of the relation between the themes in our findings and the theoretical concept of acceptability. As a final result the authors suggest a broadening of the Acceptability Model. The software NVivo 11 Pro (QRS International) was used to explore relevant text, sort the themes and sub-themes to track some trends in text material arising from each participant's characteristics, such as age, gender, frequency of use, perceived usability, and duration since diagnosis.

Table 2. The stepwise approach used for the data analysis

STEPS	DESCRIPTIONS
STEP 1	The entire data were read through to obtain an overview
STEP 2	Text segments that were relevant to the research question were selected
STEP 3	The text segments were sorted and coded
STEP 4	The codes were categorized into themes and sub-themes
STEP 5	The interpretations were confirmed by moving back and forth between the data segments and the context in which they arose during the interviews
STEP 6	The themes were interpreted by applying a theoretic approach in accordance with the parameters of an acceptability model

Reporting

The findings are presented in a descriptive way under three main headings in the Results section, using selected quotations to depict the sub-themes. We removed any repeated and unnecessary words from the quotations to make the sentences complete and understandable, but still retained their meaning. Professional interpreters translated the quotes from Norwegian to English.

Research ethics

The Regional Committees for Medical and Health Research Ethics in Norway approved the study (REC no 2010/427). The participants had to give their written approval in an informed consent form related to their participation in the main RCT, and they gave their permission to be contacted for query of participation in qualitative interviews when they had finished the trial.

The interviewing researchers gave some additional written information to the participants about the implementation of the interviews, the interview themes, and the interviewers' contact information. Code numbers were used to replace names in the transcribed interviews and we have removed identifying information. The audiotapes were stored in a locked safe.

Results

The median age of the participants was 61 years (range 38 – 79). Eleven of the participants were men and thirteen women. The median HbA_{1c} level at baseline for the RCT was 7.6%; 1 year later at about the time of the interviews, it was 7.7%. Median diabetes duration was 12 years (a range of 1–22 years; mean of 11 years). Only nine of the persons used long-acting insulin and three of them used short-acting insulin additionally. Many of the participants reported using the app steadily through the year (*n* = 12), while others used it, but could at times put it away (*n* = 6). Some stopped using it rather quickly after it was obtained (*n* = 6).

In our analysis, we found that an overall theme was that the use of a digital diabetes diary app required hard work, but also that the app could ease the effort in aiming for a change in lifestyle and for better-controlled blood glucose levels. Three themes emerged from the data. Firstly, the app has the potential to contribute to the establishment of *meaningful routines*. Secondly, assuming that this can be achieved, it has the potential to give a *meaningful overview* over their progress and ensure a more balanced blood glucose levels. The third theme was *meaningful interactions* with health-care personnel with or without use of the app. We found that the three themes formed a circular process (Figure 1).

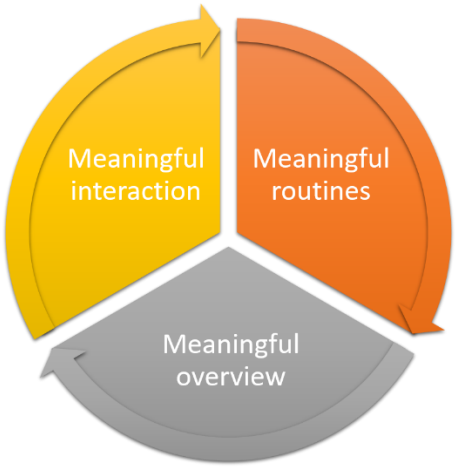

Figure 1. Aiming for a healthy lifestyle supported by the app

Meaningful routines

The participants who used the app had established routines for its use. The participants' needs and severity of diabetes were diverse; likewise, the routines they established were diverse, but they experienced them to be meaningful for their particular needs. The themes appeared with different sub-themes and with different experiences described by the participants (Table 3).

Table 3. Overall theme, themes, and sub-themes

THEMES	**DESCRIPTIONS**		
OVERALL THEME	**Aiming for a healthy lifestyle supported by the app**		
THEMES	**Meaningful routines**	**Meaningful overview**	**Meaningful interactions**
SUB-THEMES	Inspiration: To establish or keep up routines	Understanding the test results: The app identifies healthy lifestyle patterns	Decision support: Confirmation of the decision from health-care personnel
	Barriers: To use of the app	The need for interpretation: Difficulty to understand the relationship between lifestyle choices and glucose levels	Treatment-related support: Help to interpret the results
	Routine support: Suggestions on how to use the app	Interpretative support: Suggestions on how to understand the patterns	Alternative support to the app: Suggestions on other types of health-care support

Inspiration

Using the app could both inspire the participants to establish and give them an obligation to keep up routines in diabetes self-management. Several factors contributed to establishing meaningful routines. Easy accessibility to the app was one of them. The participants reported that it was easy to make notes in the app, the smartphone was always available, and they appreciated the automatic transmission of their blood glucose levels. Another advantage of the application was that

it provided a structure. It was easy to organize measures of blood glucose, diet and activity, and easy to read with graphs and charts associated with each part.

> *«I've never been the type to make notes in a journal and check measurements and diet and things like that. But it was easier to make notes using the phone.» Participant (P)19, female*

Barriers

Even though the app could make it easier to follow planned routines, the participants described some barriers. A major one for conducting a routine was the cost of time and effort. To manually enter measurements such as physical activity and diet in addition to blood glucose was time consuming in a busy everyday life. It could be forgotten easily, or on the other hand, the constant reminder to be vigilant and diligent could be stressful, and choosing not to use the app could represent a relief. For some, poor health may have limited the ability to perform physical activity, and the purpose of using the app routinely disappeared. Another major barrier was the lack of usability of the smartphone, and to some extent the app. The transfer of blood glucose levels did not always work, and the smartphone was small with small buttons and features that sometimes did not work for all as they should. Several of the participants had to use their own mobile phones in addition to the smartphone, which in turn made additional use of time and effort and could hinder their routines for using the app. Some mentioned traveling as a barrier for routines, with changing circumstances, extra costs with use of data traffic and several devices to manage outside their home.

> *«If you're almost never home, you don't really have much energy left when you do come home, and then you have to gather up the energy to start all over again.» P15, female*

Routine support

The participants had different suggestions about how to be supported in making routines. The app itself could be improved with a more usable technology, freedom of choice and flexibility between devices to make it easier to use, and more features such as reminders and automatic tracking to ease the entering of data. Sending the data to health-care personnel could even be a stronger incentive to establish meaningful routines. To know that the health-care personnel required the data was described as a motivation of importance.

> *«I wish there was something that could give me some advice about nutrition and things like that. It didn't do that at all. It was more of an overview, reminders, and everything related to measuring blood sugar.» P8, male*

> *«It shouldn't be a problem for the same information to pop up on the doctor's screen. I need a little push.» P1, male*

Meaningful overview

When the participants had found a meaningful routine in using the app, some of them were able to interpret the entered values of blood glucose, and sometimes diet and activity, to find the relationships among them and how they interact, and to understand what to do to balance their blood glucose at an acceptable level.

Understanding test results

The overview that was given in the app made it easier to understand the causality within the different test results in a shorter time, and they were able to find out what they did wrong sooner. Additionally, the overview made it easier for the persons to understand their condition when they had the measures gathered in one place, with easily readable curves, and with a feeling of control.

«I can see more quickly what I've done wrong and how I can do it correctly.» P14, male

The need for interpretation

Difficulties were encountered trying to identify meaningful data patterns. Not all the participants found the app helpful in interpreting the data and in stabilizing their blood glucose levels. For some of the participants it became too much of a barrier to use. Always needing to be aware of the blood glucose level, and always having to look for explanations in diet and activity were too demanding for some. Even a systematically gathered and meaningful amount of data could be challenging to interpret if the app did not reveal obvious patterns in blood glucose in comparison with other data. The interpretation could possibly be challenging because of different disease courses, with some more complicated than others. In such cases, the use of the app could turn out to be burdensome rather than helpful. Dietary registration was especially difficult to understand, with registration of high and low carbohydrate meals, which could make the data interpretation confusing. Others did not need the app to stabilize their blood glucose; they knew how to stabilize the levels or used other methods such as pen and paper, or possibly, only a blood glucose meter was sufficient.

«Yes, the [blood sugar] varied. Sometimes it was high and that might be caused by other things – I don't know. But I did become kind of stressed.» P27, female

Interpretative support

Interpretation support describes the participants' suggested added features to support their interpretation of the generated app data. Some of the participants reported additional needs for interpretation support and gave several suggestions for improvements in the app such as additional knowledge about how to control blood glucose levels and how to make healthy choices. Further, the participants requested educational content in the app, such as a manageable menu and more detailed feedback, including on physical activity.

Several of the participants said that the technology did not give sufficient support.

«You can put a lot more in your phone than if you, for instance, just measure yourself and write down the values. You can put a lot into your phone if you want to, and if you use it properly.» P23, male

In addition, the time for when the app was introduced, was a subject of comment among several of the participants. Many of them would have appreciated getting the app at an earlier stage of the disease to enable more benefits from interactions with the app. However, one stated that the app could benefit all persons with type 2 diabetes independent of blood glucose level. Further, it was expected that one should be ready to make changes if one wanted the use of the app to be beneficial. Others stated that the app gave an inspiration to change.

Meaningful interactions

The participants demonstrated different needs in their communication with health-care personnel thanks to the use of the app.

Decision support

Some of them were able to make decisions about self-management of their type 2 diabetes as a consequence of using the app. However, they wanted to discuss the findings with the health-care personnel, make future health-related plans, and obtain verifications of their interpretation. Some of the participants were in an ongoing interaction with health-care personnel, as in this example where they were trying out different solutions and discussing the results.

> *«I work hand in hand with my doctor, and we try to find out what's best. We look at the results together and then we see how things go.» P4, male*

Treatment-related support

Others were unable to interpret the data on the app and expressed a need for more support from health-care personnel, support on understanding how to stabilize blood glucose, and the ability to exchange data within the app with the health-care personnel between consultations, in order to increase the pressure on maintaining a healthy lifestyle. In this context, treatment-related support refers to assistance with the medication taken and the promotion of a healthy lifestyle. One participant suggested the need for more frequent contact by telephone between the consultations: a positive experience from a previous health intervention.

> *«Once or twice during the 'home period' she calls you and you can bring up whatever problems you have, what you're feeling, and you try to solve it together.» P14, male*

Another participant appreciated having the measures on the smartphone because it was not easy to remember them during the consultation, which was easier with the app.

> *«Even if you may know that above this much is too high, and below that is too low…what's good about this is that after a few weeks, you don't really remember. If you're wondering*

about something, you can just take it out and look. You usually have your phone with you.»

P24, male

Alternative support to the app

Some did not show the app to the health-care personnel. Either they did not want to show it or the health-care personnel did not ask for it. They considered that the HbA1c values taken in the consultations gave the necessary amount of knowledge to the health-care personnel. For others, self-managing of diabetes was a minor topic in the consultations. The participants had different opinions and different experiences. Some were pleased with the situation and some asked for health-care personnel with more diabetes-specific knowledge. One recognized that digital solutions could give better health-care in rural areas.

One of the participants attended the project with the aim of reducing his HbA_{1c} level. He used the app daily; it was no effort, and he noted the potential in the app for more functions. However, he expressed a need for a strategy that aroused, or challenged people more. He did not show the app to his general practitioner as he considered it was of no interest:

«Because it's the long-term blood sugar the (doctor) looks at» P23, male

Discussion

In this study, we explored users' acceptability with a diabetes diary app for persons with type 2 diabetes and their voluntary communication with health-care personnel concerning the app. However, the findings were divergent in both the use and the perception of the app. We found that the app in one respect, could lead to stable and meaningful routines and as such an aid for easier living. However, it was also ascertained that having to manually input diet- and activity-related data in the app was demanding, and could represent a barrier for use. Further, the app could also give an overview and be helpful in gaining control over their blood glucose levels in interactions with health-care personnel. Some, but not all participants, used the app in their communications with health-care personnel, but for different reasons. However, there were some barriers for use, such as technological problems, time used on the technology, and motivational and disease issues. Another concern was that some of the participants became stressed by the mobile phone and/or the app and searched for other solutions. Below, we discuss our findings and earlier research, conducted within the parameters of Nielsen's framework of practical and social acceptability [29], as described previously.

The app: practical acceptability

Our findings varied, but showed that for some participants the app could be useful for establishing or maintaining routines and in measuring or implementing a healthy lifestyle. Barriers affected the use of the app to a varying extent. The technology was not always to be trusted. Earlier research has identified multiple barriers for use of technology. Among others, technological challenges could be a major barrier to both the use and the satisfaction of the aids provided [14,18,44]. Our findings are consistent with how Nielsen [29] described practical acceptability, where usefulness is one of the components that affects the acceptability of a technology.

Usability

Many of the participants described usability as being a challenge: some did not find the app useful for managing routines, while others overcame the challenges, included the app in their routines, and found it useful. This aspect was defined by Nielsen as *utility.* The perspective of *usability* was somewhat complex. As an example from an early smartphone, we found that the Bluetooth system was one of the major usability issues when there was a need for support to reconnect the devices. However, the most valued feature of the app was its ability to transfer blood glucose data to it using Bluetooth. Our usability data were less reliable due to recall issues and outdated equipment. Accordingly, compatibility and reliability were considerably reduced after one year of app use.

Because of the usability of the app, another point raised was that the time spent using the app was challenging for some participants, while others emphasized that the app was easy to use and available when needed. One of the components of usability described by Nielsen [29] is *efficient to use* which is explained as the time used by an expert user to perform a task with the technology. In our findings, the burden of time using the app did not necessarily have to do with the app itself, but with the burden of the requirements of the app, and the routines of monitoring body and lived life. Other studies have described the burden of treatment where there are multiple demands to care for health. Thus, learning about the disease, continuous self-monitoring, and at the same time struggling with barriers to self-care and diverse health-care provider obstacles, can cause major challenges for individuals [45,46]. Studies focusing on the prevention of obesity, in which changing diet is a key issue, have highlighted how difficult it is for individuals to change their diet. This can be caused by both internal barriers such as food preferences develop from an early age, and external barriers aroused from how the food industry and associated politics are organized [47]. Our app did not address any of these issues, but could exacerbate the conflicts and difficulties participants meet when the app reminds them about a required change in their lifestyle.

It could be an ethical issue as to whether the app and the smartphone become additional burdens to self-management because of technical challenges. Previous research has pointed out the lack of research on ethical issues related to the use of technology within health-care. Ethical considerations have mostly been associated with the technology itself and its use. Studies have discussed to a lesser extent what the technology is supposed to replace, or what it should be for the users from an ethical perspective [48]. In addition, Korhonen *et al.* emphasized that from this perspective on digital caring we should know the users' expectations and experiences, both with the use of the technology and the care [49]. Nevertheless, we found that the use of the app could cause an experience of failure, both in terms of digital data entry and clinical. We could view such *digital distress*, albeit with some limitations, as part of an expected burden when participating in a study aiming to investigate the use of health technology. A certain amount of *clinical distress* is associated with type 2 diabetes [50], but there will be a limit when the clinical distress associated with an uncontrolled disease is caused by using the app, and becomes both unintended and undesirable from a health-care perspective. We should have addressed the crossing of this limit all the way through the year of the study. With newer technology, it will be possible to include awareness, of both digital and clinical distress, but it could require other kinds of self-monitored registrations. However, this would impose additional burden on the users and require a systematic digital follow-up by health-care personnel.

This emotional aspect of acceptability (Figure 2) has not been adequately described in Nielsen's model. Thus, we considered the matter to be one of usability. However, the assumption made was that social acceptability is threatened by emotional distress, both with respect to attitudes and psychological support.

Utility

Utility is a part of practical acceptability, as mentioned previously [29]. Based on our findings, we suggest two different aspects of use: *supportive use* and *educational use*. Supportive use is when the app contributes to establish and maintain diabetes self-management routines, and educational use is when routine use leads to new understandings of the relationships between diet, activity, and blood glucose levels. National standards for diabetes treatment in the US, lists both diabetes self-management education and support as obligations for health-care personnel in their care for persons with type 2 diabetes. Education is the process to facilitate the knowledge, skills, and ability for diabetes self-management while support involves a more informal ongoing assistance to implement and sustain the needed behavior. Such support could be both behavioral, educational, psychosocial, and clinical [2].

Supportive use of the app in our study did not necessarily lead to new knowledge, but was helpful in maintaining a desired lifestyle. The users valued different features to solve different tasks such as storing blood glucose measures or motivating physical activity. We found educational use of the app in our data to some extent by a systematic gathering of lifestyle measurements that the app presented in an interpretable way. Within the app, we had written material as practical examples of use (tutorials), short and longer texts of relevant facts, in addition to the bestowment of “smileys” as rewards. Based on the interviews, it was assumed that neither of these features assisted learning, as only a few participants mentioned that they valued any of them. What was experienced as useful was the linking of blood glucose measurements to other influential factors. Other studies have emphasized that there is a need for apps providing diabetes education, and not apps with only single features [4,51,52]. Earlier research on “e-learning” and pedagogy has suggested the effectivity of experimental learning coupled with competent tutoring. The learners are in control of the learning process with help from a tutor [53]. Sharples *et al.* demonstrated that this could involve parallel learning processes, both digital and interactional, such that the digital process can support interactive learning, and that they become woven together. Control, context and communication

could be necessary conditions for learning [54]. From this perspective, we could explain the educational use in our study as experimental. The written material and practical examples were of less use, but communication with the health-care personnel was a necessity for optimal learning, where the digital use of the app was a facilitator.

As a conclusion from our discussion of practical acceptability, we found challenges for all participants, but some found the app useful. Nielsen divided the term *usefulness* in terms of practical acceptability into two components: *usability* and *utility*. Usefulness is the app's capacity to make the users reach a goal; utility is how the features in the app give an opportunity to perform the desired tasks, and usability is how easy it is to use the features [29]. In our study, it seems that if the users experienced utility and the app could meet a need for supportive or educational use, it was accepted, even when usability came to be a challenge. As we found in our study that the app led to different uses and covered different needs and creativity in the use, and as the participants expressed a wish to use one, it seems that an app that considers the need for different kinds of use - both supportive and educational - could eventually stand with some lack of usability.

The app: social acceptability

All our participants volunteered for the study and knew about the diabetes diary app intervention. Therefore, we could assume that to some extent they might have intended to use the app from the start. They had a basic attitude that the app was going to be of benefit, and as Nielsen described *social acceptability* as an attitude toward technology [29], we anticipated that the app would be socially accepted initially. However, after a year of use, attitudes diverged among the participants. While practical acceptability failed for some of the users, others found that in various ways the app could enable them to establish routines and thereby improve management of their

diabetes. When the users reported the app to be inspiring, we interpreted this as an attitude toward the use of the app, and an expression of its social acceptability. We need to question whether the participants accepted the app as itself, with its technological possibilities, or with certain reservations, such as the importance of additional support.

Some users in our study suggested the app as a tool for communication with health-care personnel, either directly or implicit. Some users envisioned the app to cover a need for self-management support: either as an external motivation for establishing routines where the health-care personnel were actively involved in use of the app, or a more withdrawn role where experience from the app formed the basis for greater understanding through conversations during consultations. As such, the social acceptability of diabetes apps in health-care would depend on a shared understanding of the app between the persons using the app and the health-care personnel. Only a few of our participants used insulin, even though the median duration of their diabetes was long (a median and mean of 12 and 11 years, respectively). Measurements and recording of blood glucose levels was the highest valued feature in the app and a necessary part of its educational use, but in addition, we found that the participants suggested that the use of self-monitoring would be especially important when recently diagnosed with diabetes. However, with self-monitoring of blood glucose levels, earlier research on diabetes management showed lack of evidence on the benefit of self-monitoring glycemic control for persons with type 2 diabetes not using insulin after their first year with their disease [55]. In addition, there is a risk of treatment overuse by both general practitioners and their patients [56]. The guidelines recommend that self-monitoring should be considered in certain disease phases. Patients can benefit by determining how diet and activity affect blood glucose levels at diagnosis, when they are not achieving their treatment goals, and when medication changes or treatment with an intensive insulin regiment are needed. Health-care providers should make decisions about medication in collaboration with the patient, according to personal needs and self-management goals [6,57,58]. Health-care personnel might hesitate to recommend broad self-monitoring because there is a lack of evidence on effect. However, social

acceptability of the use of apps in self-monitoring could depend on shared understanding between the patient and their health-care personnel of the benefits of such monitoring.

Hirani *et al.* extended the concept of acceptability and asked for the users' attitudes toward the app to be a substitution to face-to-face consultations with health-care personnel [32]. Our findings suggest the opposite: that the use of the app in diabetes self-management could represent a valuable contribution, but not a substitution for consultation. When US standards for diabetes treatment initially described the strategy of giving diabetes self-management education, support was not a part of the claim for better treatment. The earlier focus on education lacked the psychosocial aspects of treatment, and diabetes self-management support was introduced as an addition to secure this perspective [2]. Other research has indicated that social interactions are essential to learning processes [59]. The lack of psychosocial support within the app in our study might explain why the users emphasized the need for support from health-care personnel with knowledge of diabetes care. This is in line with other findings suggesting that if such mobile health (mHealth) interventions are to be successful they will require active participation from patients and health-care personnel [24,25,60].

In conclusion, the app could have a positive influence on both practical and social acceptability, in terms of the ability to be time efficient, interpretable, adaptable/adjustable, inspiring, and communicative. However, the ability to understand the influence of multiple self-management efforts (which constitutes a type 2 diabetes lifestyle) could be an essential addition to the app. Collaboration between the person with diabetes and competent health-care personnel would also remain an anchor in the basis for treatment, where the app still could be acceptable as a valuable tool used for both supportive and educational purposes. Our adaption of Nielsen's acceptability is depicted in Figure 2.

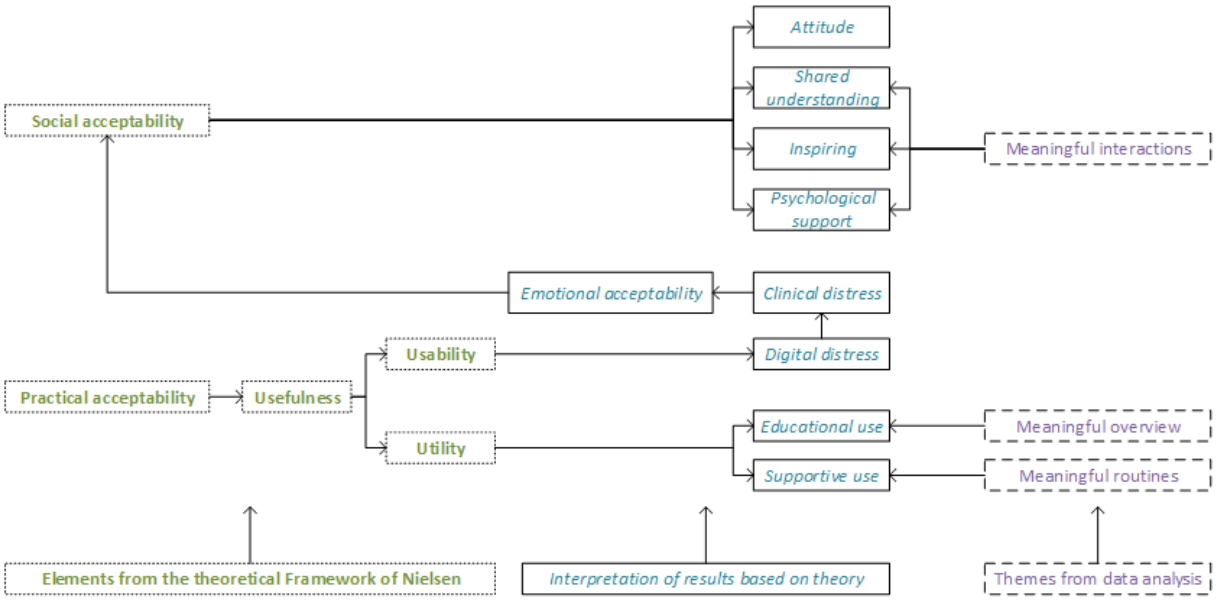

Figure 2. Model illustrating the interpretation of the results and their relationships to the theory (left) and the themes from the data analysis (right)

Future perspectives

In future mHealth research, with the current technology we are on our way to secure practical acceptability in self-management technology. The main issue will be the utility of the system and the social acceptability from the perspective of the users and the health-care personnel, and the personalization of the interventions to the user. Milani and Franklin emphasize that when using artificial intelligence, it is possible to design algorithms aimed at chronic disease management and expert systems. This can enable an overview over a large amount of information, including the user's own demographic and clinical data as well as personal preferences. Based on this, it is possible to receive even more tailored feedback than with previous interventions [61]. Our findings emphasize the importance of interpersonal and qualified support, and the risk that the technology might cause both digital and clinical distress. With complex systems, further research could develop feedback logarithms and possibly replace nuances in momentous face-to-face meetings with health-care personnel.

Strengths and limitations

We have based our findings on the use of a digital diabetes diary. Our findings might be of interest not only for persons with type 2 diabetes, but also for those with other chronic illnesses using other kinds of self-management apps. This is because acceptability of such technology depends on finding a way to utilizing such apps to meet present patient needs and incorporate their use in a self-management fellowship with qualified professionals. However, this study had some limitations. A study design weakness could be that our sample comprised participants provided with a diabetes diary app for self-management purposes who were taken from a larger RCT. Although they were a homogeneous group, they had differing sociodemographic and clinical characteristics. They represented an adult group of all ages and both genders, each with a different disease history and condition, and therefore with different app requirement.

The focus of the participants' experience was solely concerned with the use of a single app, and this might have provided less rich information in terms of answering of the research question. In addition, other sources of information such as login data and observational data could have given a richer contribution to our understanding of the app's acceptability. The participants were provided with an HTC Corporation Microsoft Windows mobile smartphone. This was one of the early models; the screen was small, the ease of use was not the best, and smartphones were not widespread at the start of the RCT study. However, a strength of the study was that all participants had the same starting point. Moreover, factors related to technology and usability were the same for all, with diminished reliability owing to recall issues. This afforded us the opportunity to emphasize other aspects of acceptability such as utility and social references. Even though the smartphone could be difficult to manage, the app was developed in collaboration with persons with diabetes [40]. The possibility of automatic integration of blood glucose levels was at an early stage, even though the participants were required to enter diet- and activity-based information manually; far better systems

are now available with wearables and sensors. Another strength in the study is that many of the participants had used the app for a year, which gave us data based on prolonged use.

Our data were not rich enough to be able to divide them between different health-care providers and to interpret different results for individualized treatment areas.

Conclusions

In our study, we found that users' acceptability of a mobile app for diabetes self-management differed, and we found both practical and social acceptability to be important at different levels. In the present study, we adapted Nielsen's acceptability model according to these assumptions. If the app is used regularly, it could be useful in different ways, both supportive and educational. In contrast, it could turn out to be a burden requiring too much time, and not contributing to the efforts needed in changing lifestyles. From the perspective of social acceptability, we found some support from health-care personnel with diabetes knowledge parallel to the use of the app. The utility of the app for educational and supportive use could overcome the eventual lack of usability and establish its practical acceptability. We emphasize the need for raised awareness of vulnerable groups who could experience both digital and/or clinical distress beyond the intentions of the initiators of a mHealth intervention.

List of abbreviations

App: Application **EU:** European Union **HbA1c:** Glycated hemoglobin **RENEWING HeALTH**: the European study REgioNs of Europe WorkINg toGether for HEALTH **COREQ:** The Consolidated Criteria for Reporting Qualitative Research **RCT:** Randomized controlled study **MAST:** The Model for Assessment of Telemedicine **REC:** The Regional Committees for Medical and Health Research Ethics in Norway ***P:*** Participant **mHealth:** Mobile health

Declarations

Ethics approval and consent to participate

This study received ethical approval from The Regional Committees for Medical and Health Research Ethics in Norway (REC no 2010/427). All the participants provided signed informed consent.

Consent for publication

Not applicable.

Availability of data and material

Data are available from the corresponding author on reasonable request.

Competing interests

The authors have no competing interests to declare.

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Authors' contributions

MR and LR designed the interview guide, conducted the interviews, had them transcribed and have written another article based on the complete interviews. AT made condensed versions of the transcriptions and selected the relevant text segments, which all the authors discussed. All authors (AT, LR, MR, AG, SH) worked initially with the analyses and interpretation of the data. AT has written the paper and continued in the intensive period of writing with further analyses and interpretation, with support from SH and LR. All the authors (AT, LR, MR, AG, SH) contributed to the final writing and have approved the latest version of the article.

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