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mHealth: opportunities and challenges for diabetes intervention research

Mobile health (mHealth) calls for health intervention research approaches to adapt. This thesis uses the pragmatism paradigm to explore ways in which researchers can use mHealth resources as part of health interventions, data collection, and analysis to help ease the challenges of mHealth's speed of development, limited regulations and approaches to validation, unstructured data, and limited medical integration.

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Preface

A colleague once told me, “do you know what “Ph.D.” actually stands for? Personal holistic development”. I realized that this process did not just start when I received funding but has been developing for most of my life. While health and science research is praised for its objectivity – the reality is that both our personal and professional lives affect our purpose in and interpretation of research activities.

Family members on both sides live with Type 2 Diabetes and have struggled with making decisions and managing symptoms in addition to their everyday lives and responsibilities. Where they live – in the US – healthcare is not a given. It is expensive, time-consuming, and challenging to get answers to the questions that you need to take care of yourself successfully.

For nearly six years, I have been a researcher in the field of mobile health (mHealth). I have been part of the development and testing of an in-house developed diabetes self-management app. The focus of our team’s efforts has been on patient empowerment, patient-provider collaboration, and technology development that addresses end-users’ needs. Our publications – our voice in, and messages to, the academic community – have called for healthcare authorities and medical professionals to acknowledge and embrace mHealth as a means to engage patients in their chronic condition management. We have advocated for the potential of Do-It-Yourself, for peer support through social media, for treating individuals as partners in care, not objects of it, and we have called for the healthcare system to “keep up.” I have not only read about individuals’ accounts of diabetes self-management online but also heard first-hand how excited and optimistic individuals are to have a sense of control over their own health and well-being. From personal experience, this feels like power, like we are more than symptoms and that we can affect our health just like we learn any new skill. Having the power to track and change one’s health makes the chaos manageable, whether that be through learned skill, social support, or technology or all of the above. When that switch clicks and health information starts making sense, as it applies to ourselves, it can be a relief. It can lead us to feel hopeful and overwhelmed at the same time.

Given my personal and professional background, one would assume that I am pro-mHealth – all the way. I am not.

As a researcher, I am cautiously optimistic about technology in our lives. While technology has made several aspects of our lives easier – from the ability to heat leftovers for dinner to the machines that keep us breathing after a traumatic car crash - it has also made us vulnerable in different ways. The dangers of privacy violations, being hacked by those who would take advantage of my personal information, the potential to misuse or misunderstand how to use technology, and the spread of misinformation are a daily concern. Our level of risk only decreases with education, awareness, and scepticism for these dangers.

I believe in and have benefited from the compassion and training of care providers. I have been fortunate enough to work with care providers in several different fields who were willing to ask questions and listen to what I was experiencing to not only treat the symptoms but also understand the root problem and work through it with me. Since moving to Norway, I have experienced the benefits of being seen as not just a patient but a partner in my care – for anything from a cold to injuries. The

more I speak with healthcare professionals, through my work and personal life, the more I understand that these individuals want to help. They do not merely want to prescribe medication and schedule as many appointments in a day as possible – they want to provide their patients with guidance, support, and answers to the best of their ability. However, they also experience limitations and hurdles, just as all of us do when we aim to achieve something. Changes and limitations in funding, time, and specific fields of education, workforce, and other resources may hinder healthcare providers from helping an individual or a group.

No system is perfect, including the medical and health research systems. We are all doing the best that we can and, when we are presented with new tools, ideas, questions, or challenges, we have the opportunity to explore how these might benefit our efforts. The intention of my Ph.D. is to incorporate novel mHealth approaches and resources into research practice while respecting traditional knowledge.

Acknowledgements

While the PhD process is certainly an individual endeavour, no PhD candidate is an island. Without the support of my family in the US, friends and adoptive family here in Norway, and my cat Mulder I could not have achieved any of this – and certainly not with my sanity intact!

I never expected to leave the US. I had moved here in the Autumn of 2014, only expecting to stay for a 10 month Fulbright research grant. Very soon after I arrived and settled in, Tromsø felt like home. I was determined to stay so that I could continue to work with the creative, supportive and enthusiastic researchers at NSE (formerly NST). I often joke that applying for the PhD was my way of staying here with the reindeers, Northern Lights, snow and fresh air. Yet the idea of getting to work in such an engaging research environment – with a focus on collaboration instead of competition and mind-set of "well-being over blind productivity" - was a major draw for doing a PhD. To be fair, it was probably a 60/40 split.

So, for making me feel at home and a valued member of the diabetes/mHealth research team and NSE as a whole, I have to give the warmest of thanks and appreciation to Astrid Grøttland, Line Helen Linstad, Siri Bjørvig, Gunn-Hilde Rotvold, and Per Hasvold. I am grateful that you all had enough faith in me to let me try, to stumble and learn from so many different opportunities. Thank you also to Elia, Dillys and Pietro who have been wonderful co-workers and friends. Of course, the one, the only, Eirik Årsand deserves a special thanks as my main supervisor – for motivating discussions, for listening, for putting up with me, and of course for helping me grow as a researcher and person – despite some instances of stubbornness. To my other supervisors – all five of them – Monika Johansen, Ragnar Joakimsen, Paolo Zanaboni, Louise Pape-Haugaard and Anne Helen Hansen, I would like to thank you for your guidance, your constructive criticism and your patience during this process. You made the challenges of this process worth every step and I will be a better researcher for it. To Kari and Maryam for your much needed guidance and wisdom at a particularly difficult time at the end of the PhD process. To the partners and collaborators in the FullFlow Project, thank you for your contribution to these works. Also, to fellow researchers abroad, thank you for sharing your expertise and giving me the opportunities to learn, especially in fields outside of my own.

The past five years in Tromsø served as the setting of not only my professional development but personal as well. Toward the beginning, I received news that forced me to reassess much in my life. Over the following years, which coinciding with my PhD, I had to ask for help and receive support that I never expected I would need. While I struggled, my work gave me purpose and my friends and family gave me support and love. To Marit, Eirik, Siv and Gry - you were there to keep me going when I couldn't be with my own family. To my mom and dad – thank you for the funny and creative distractions, and cheering you-go-girl! when I needed encouragement to take a day off. To my close friends – Lauren, Anna, Jan, Denise, Milan, Kari, Hattie, Julia, Christiane, Gabrielle and Isabel - for knowing when I needed to be alone and when I shouldn't be alone. Whether here in Tromsø or abroad – cliché as it may be to say - you were truly always there when I needed to talk or receive a hug or funny picture. You set the bar for friendship and support.

If I did not mention you by name, please know that it is not because I do not appreciate your support, insights and friendship! If you are reading this, then you are someone who helped me – even if it was just to smile and say hello. The smallest forms of kindness have a greater impact than we realize.

Abstract

BACKGROUND: Traditionally, health intervention evaluations provide long-term evidence of efficacy and safety via validated protocols, following a positivist paradigm, or approach, to research. However, modern mobile health (mHealth) technologies develop too quickly and outside of medical regulation, making it challenging for health research to keep pace.

OBJECTIVE: This thesis explored and tested how research can incorporate mHealth approaches and resources to evaluate mHealth interventions comprehensively, which follows the pragmatism paradigm. The works described herein were part of a larger project that designed, developed, and tested a data-sharing system between patients and their healthcare providers (HCPs) during diabetes consultations.

METHODS: The pragmatism paradigm underpins the mixed-methods, multi-phase design approach to exploring this overall objective. The following methods were performed using a sequential exploratory strategy. First, co-design workshops invited individuals with diabetes and HCPs to design an mHealth data-sharing system. Next, a scoping literature review identified research practices for evaluating mHealth interventions to-date. Then, app usage-logs, collected from a previous longitudinal study, were analyzed to explore how much additional information they could provide about patients' self-management. Finally, a mixed-method study was designed to test the feasibility of combining both traditional and mHealth approaches and resources to evaluate an intervention.

RESULTS: Using the pragmatist paradigm as a scaffolding, these works provide evidence of how research can provide more comprehensive knowledge about mHealth interventions for diabetes care and self-management. Nine individuals with diabetes and six HCPs participated in the co-design workshops. Feedback included how a data-sharing system should work between patients and providers. The literature review identified how both traditional and mHealth-based approaches (n=15 methods, n=21 measures) were used together to evaluate mHealth interventions. Usage-log analysis revealed that changes in Glycosylated haemoglobin (HbA1c) differed between groups organized by usage patterns and duration of use of mHealth. The mixed-method study demonstrated how to collect comprehensive and complementary information when combining traditional and mHealth-centered approaches and resources.

CONCLUSION: Traditional positivist approaches and resources are not adequate, on their own, to comprehensively understand the impact of mHealth interventions. The presented studies demonstrate that it is both feasible and prudent to combine traditional research with mHealth approaches, such as analyzing usage-logs, arranging co-design workshops, and other patient-centered methods in a pragmatist approach to produce comprehensive evidence of mHealth's impacts on both patients and HCPs.

List of abbreviations

Apps	Applications ((software running on smartphones or wearables)
AQuAS	Agencia de Calidad y Evaluación Sanitarias de Cataluñ
BG	Blood glucose
BP	Blood pressure
CE-mark	Conformitè Europëenne mark
CGM	Continuous glucose monitor
COPD	Chronic obstructive pulmonary disease
DES-SF	Diabetes Empowerment Scale- Short Form
DIY	Do-it-yourself
DN	Diabetes Nurse
DSME	Diabetes self-management education
EBCD	Experience-based co-design
eHealth	Electronic health
EHR	Electronic Health Record
EU	European Union
FDA	Food and Drug Administration (USA)
GPs	General practitioners
HbA1c	Glycosylated hemoglobin
HCCQ	Healthcare Climate Questionnaire
HCPs	Healthcare providers
HTA	Health Technology Assessment
Hyper	Hyperglycaemia
Hypo	Hypoglycaemia
IoT	Internet of things

MARS	Mobile App Rating Scale
MDR	Medical Device Regulation
mERA	mHealth evidence reporting and assessment
mHealth	Mobile health
mTERG	mHealth Technical Evidence Review Group
NCDs	Non-communicable diseases
NHS	National Health Service
NIH	National Institute of Health
ORCHA	Organisation for the Review of Care and Health Applications
PDAs	Personal digital assistant
PGD	Patient-gathered data (via apps)
PHI	Personal Health Information
PROs	Patient-reported outcomes
RCT	Randomized control trial
SMART	Sequential Multiple Assignmnet Randomized Trials
SMBG	Self-management of blood glucose
SUS	System Usability Scale
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TIR	Time-in-Range
TOOR	Time-out-of-Range
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

1 Overview

The entrance of modern mobile health (mHealth) technologies in the commercial market, approximately 2008, affected all medical and health stakeholders – from patients and providers to researchers and health authorities [1]. Historically, for chronic illness care, e.g. diabetes, there was a stable flow of information and influence between patients, providers, health authorities/policymakers, and researchers (Figure 1). Healthcare authorities and providers relied on objective, quantitatively measured, reliable and generalizable evidence from research that suggested best-practice protocols for achieving the most benefit for the most people. In other words, numbers ruled. The introduction of mHealth technologies to aid in effective behaviour change in one's chronic illness self-management led to changes in the dynamics roles and needs of these stakeholders, especially the two end-user groups – patients and providers. Behaviour called to be understood, not measured.

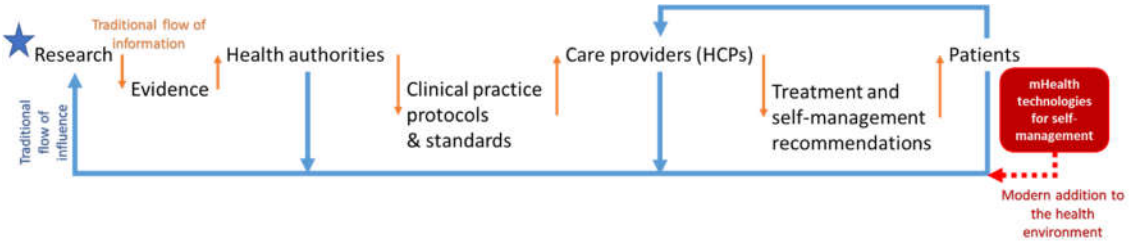
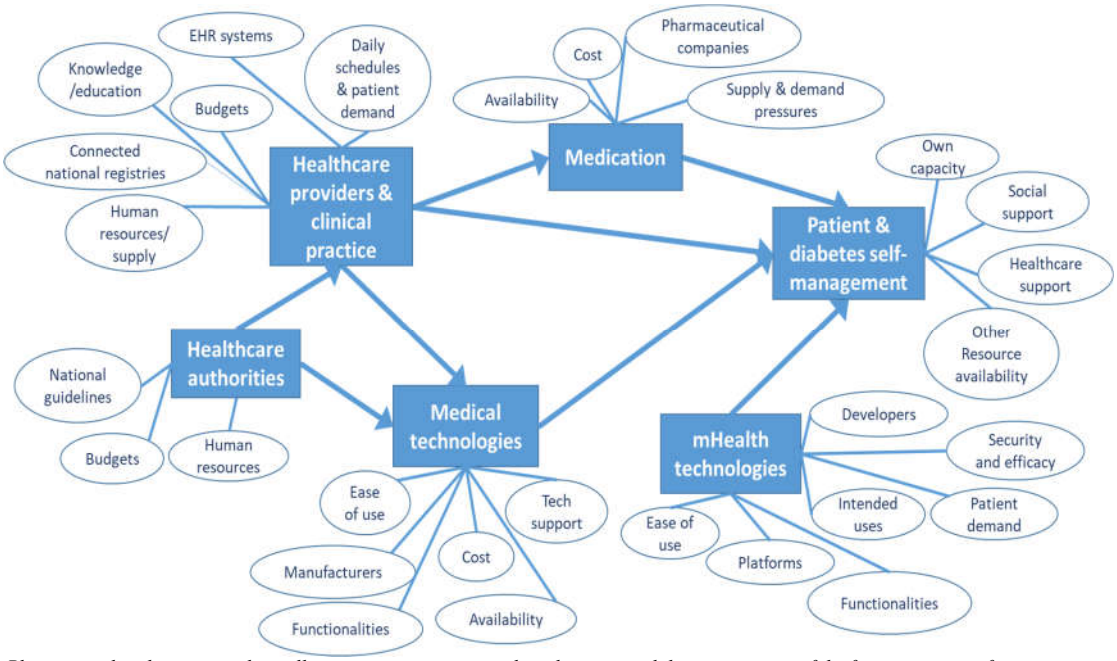


Figure 1 Traditional role of research in the production of information that is used by other stakeholders.

The orange arrows illustrate the traditional flow of information that each stakeholder produces and provides for the subsequent stakeholder; research presents evidence of safety and efficacy of a tested intervention for health authorities. Then, health authorities determine how to implement relevant evidence into guidelines for clinical practice protocols and standards for care providers to follow. Finally, care providers make treatment decisions and self-management recommendations for patients that follow these protocols and standards. The blue arrows illustrate feedback loops in which the traditional flow of influence is directed, i.e., stakeholders who receive information inform and influence the activities of stakeholders before them in the process.

The network in which diabetes care and self-management exist is complex. Main stakeholders to a patient's care include the patient and healthcare provider primarily, yet tangential and outside forces affect the independent choices of and interaction between these two actors. Figure 2 below exemplifies some of the actors and influences within this network.



** Please note that this is a simplistic illustration, is not meant to be exhaustive and the organization of the factors are open for interpretation and discussion.*

Figure 2 Illustration of some of the factors, actors and influences that contribute to the complexity of the diabetes care and self-management environment

As will be described in the background section of this thesis, all of these actors and factors have their own capacities, limitations and opportunities that affect their priorities, decisions and actions. Such a network is considered a "complex adaptive system", which is described by Plsek and Greenhalgh as "a collection of individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected such that one agent's actions change the context for other agents" [2]. For research, this means knowing how, or at least being aware that, these factors are constantly shifting and affect what questions are relevant to ask and how, as well as who determines what is relevant, in order to produce necessary information and knowledge. Therefore, any intervention that affects the organization or delivery of healthcare services for diabetes care should seek to incorporate such complexity into research practices. Research of such complex systems is consistent with the Pragmatist Paradigm, which is an evolution that takes the best from both the traditional Positivist and Constructivist paradigms.

In the early years of modern mHealth development, many articles and reports, both scientific [3] and public [4, 5], propagated the belief that mHealth would reduce cost and lower demand on the healthcare system and individuals. The reality, however, was not as quickly achieved as many would have hoped. As of early 2020, the confusion, uncertainty, hope, and frustration with the impacts of mHealth on the healthcare sector remain. Stakeholders from within the medical field are affected – searching for the appropriate and safe uses of the technologies, questioning how to adapt healthcare practices and services to mHealth. Given the possibilities of mHealth technologies to allow individuals to much more easily track the effect of their self-management activities, to allow researchers the opportunity to collect more continuous data on such activities, and to affect the relationships and connections within the diabetes care network, the process of scientific inquiry requires us to take a step back and question how we as researchers could or should account for these factors in our research practices.

We as researchers are called to address and reflect changes in the real world in order to provide practical knowledge for healthcare. To understand how the new realm of mHealth interventions for diabetes self-management calls for changes in how scientific inquiry is approached and how research performed, I will provide the background of this complex adaptive system's network of stakeholders, influencing societal trends and technological developments that characterizes mHealth and that need to be considered when performing mHealth intervention research. In the Methods and Results sections, I will describe how we, as a research team, endeavoured to iteratively explore concepts of this complex network via related studies and gain knowledge and understanding about the potential impacts of mHealth intervention research. In doing so, I aimed to address the research questions of this thesis, which explore approaches in which mHealth research can be performed through the lens of the pragmatist paradigm. Finally, I will discuss the impacts and limitations of i) the outcomes of the studies themselves as well as ii) the research practices that were performed through the lens of the pragmatist paradigm.

2 Background

I will provide the background information for the thesis beginning with describing and understanding the needs and challenges of chronic illness care, as a whole, followed by a focus on diabetes as the chronic illness use-case. A particular challenge to be aware of is that, for complex adaptive systems, individual players are partly interdependent and independent of one another making it difficult to predict the activities within the network [6]. Therefore, understanding as many points as is reasonably possible will aid in the design, administration and interpretation of research inquiries. I will then introduce mHealth as a more novel trend in the field of health care and self-management and the specific sub-set of mHealth technologies that I will focus on for this thesis. Finally, I will describe how mHealth is changing the way we as researchers and health professionals need to address diabetes care, individual's self-management and intervention research through the foundational shift in research approaches, or paradigms.

2.1 Supply and demand for chronic illness care

In this section, I provide an overview of the growing imbalance between the supply of and demand for healthcare services and resources. The focus will be on the complex network of stakeholders related to chronic illness care. By understanding the relationship between these players (Figure 1), we can better understand how the introduction of mHealth technologies has affected these dynamics, and, in turn, the need for research evidence.

Today, type of demand is largely influenced by patients with chronic illnesses who have specific questions about their self-management habits, experienced symptoms or health status. Demand can include unpredictable and preventable uses of healthcare services and resources depending on the treatment and support requests of its beneficiaries, i.e. patients. The supply of these resources and answers, on the other hand, changes less quickly and can include hospital beds, on-hand medications, and available technologies within a care facility [7]. This type of care is influenced by some of the same factors that mHealth aims to address, e.g., patients seeking specific answers and continuous support for chronic illnesses, etc. For example, technologies can influence when patients ask questions about their health, which answers they seek and, alternatively, when patients need treatment for experienced symptoms as the result of poor decisions or understanding of their chronic condition. This is detailed further in the sections below.

2.1.1 An overview of supply and demand

The demand on health care and responsibilities assigned to providers has been on the rise for decades. A growing elderly population with complex medical needs, chronic illnesses, obesity, and other lifestyle conditions that require health intervention, in addition to the everyday scrapes, breaks, and colds – these are what awaits healthcare professionals when they enter clinical practice. The prevalence of those with chronic non-communicable diseases (NCDs) such as diabetes, chronic obstructive pulmonary disease (COPD), cancer, or cardiovascular diseases is growing. A 2016 report found that 14 million people in the United Kingdom (UK) lived with two or more chronic conditions [8]. In 2013, the World Health Organization (WHO) reported that the shortage of HCPs was 1.6 million, which was expected to rise to 4.1 million by 2030, with the largest shortage being that of 2.3 million nurses [9]. A Statista report comparing the demand for doctors in the European Union (EU) between 2012 and 2017, noticed an increase in the number of consultations sought per person in these years [10]. Unfortunately, the supply of those who can provide medical care has plateaued in comparison to these demands, with some fields decreasing overall [11].

It is hard to believe that in 2000, the US, for example, were considered to have more supply of, especially, primary healthcare providers than demand [12]. This trend has shifted drastically since then. A report published by the U.S. Department of Health and Human Services projected that by 2013, the demand for primary care providers would be far greater than the supply. By 2032, it is expected that demand for general practitioners (GPs) will exceed their supply by between 21 and 55,000 GPs [13]. Waitlists and rising costs in Europe follow this same trend, further constricting the ability of providers to deliver adequate information and necessary services [14].

Professions are designed to evolve over time. Many societies have undergone some form of healthcare reform in recent decades – whether it be initiated by healthcare findings and evidence of new treatment models or the reorganization of resources to promote more streamlined and cost-effective medical systems or more effective care coordination [15]. Throughout the European area, programs, initiatives, reports, and plans have been rolled out in overwhelming numbers [16]. This can mean reallocation or reduction of budgets resulting in more responsibilities for different provider specialties, fewer available hours and staff to see those in need of medical care in certain fields, focus on training for certain specialties and skills, such as newly available technology, and not others [11, 16, 17]. When these changes are initiated, providers must quickly learn and implement the new expectations of their practices. However, the resources in the medical system scheme needed to practically realize these expected benefits [18, 19], i.e., resources, specific practice guidelines from healthcare authorities, and funding lag behind, resulting in an extensive adjustment period and frustration for the healthcare community. For example, in Norway, the 2001 Regular GP Scheme was introduced to shift more responsibilities toward primary care [20]. It has been 18 years of adjustment, and while both patient and GP feedback has demonstrated high satisfaction, the added workload has some GPs concerned that at some point, they will soon have trouble providing the same frequency or continuity of care as before [21].

2.1.2 Self-management vs. treatment in chronic illness care

Individuals with chronic illnesses are especially susceptible to the ill effects of this limited supply of care services and resources. Chronic illness self-management is a time- and resource-consuming process that requires a patient's patience, willingness and understanding, and a healthcare provider's

knowledge. Such treatment calls for providers to guide their patients and often coordinate care amongst several other providers and practices.

Self-management is the responsibility of the patient. While there may be several different definitions for chronic illness self-management, the core principle is the same: patients have a responsibility to seek and apply an understanding of how their actions affect their health factors to improve or maintain their health [22]. Despite a certain level of dependence on care providers for formal guidance, clinical consultations for those with T1D typically only occur once or twice a year. And while those with T2D often seek more frequent contact and answers from their GPs, it is not always possible to gain all those answers in a brief consultation. Consequently, those with chronic health conditions spend more time on their own, reacting to changes in their environment or physical health by adjusting their habits or actions. Once diagnosed with diabetes, the roles and priorities of the individual should be to understand, track, and respond to changes in their lifestyle choices or the environment in order to self-manage their chronic conditions. Outside of the clinic, options such as formal educational courses, pamphlets, and general information are available for those who have recently been diagnosed within the medical network. As the condition continues, individuals need formal guidance and resources to help them decide how best to improve their own health and lifestyle situation.

GPs are also known as primary care providers. In many countries, you must first see a GP to assess your health concerns in order to be referred to a specialist, including those who care for diabetes, COPD, cancer, etc., when appropriate. However, those with T2D go primary to their GPs for treatment of their diabetes, as do the majority of the population. A survey of GPs in Norway in 2017 revealed an average workweek amounting to 55 hours - well over the typical Norwegian workweek of 37.5 hours - with a median patient list-length of 900-1200 and much variation between large and small municipalities [23]. As the gate-keepers to other medical services, it is important to acknowledge their capacity for care practice, i.e., their ability to identify patients' risk for disease and correctly direct them to the appropriate secondary care. However, in the same 2017 GP survey, it was noted that those with chronic illnesses account for nearly 15% of working hours devoted to those with complex care needs [23]. This is one of the main reasons that GPs are the most used and needed care resource [24].

Specialists, specifically internists, treat chronic illnesses related to organ structures. These providers are educated and trained to follow health policies and best-practice guidelines based on evidence produced by generations of medical testing and exploration. Specialists have historically acted as key resources of knowledge, guidance, and answers for specific chronic care needs. Individual patients can seek information about disease mechanisms, preventative measures, clinically approved treatment models, and general self-management recommendations. These general recommendations have been shown to work for the majority of the population. However, there needs to be an adequate supply of providers who can test, confirm, and recommend lifestyle changes to those diagnosed with a chronic condition.

Treatment has traditionally been the responsibility of healthcare providers. Upon diagnosis, providers establish a treatment plan for that patient. These plans are general approaches to medication, service, and self-care options to reduce the symptoms and progression and prevent the onset of complications. Especially for the care of chronic conditions, a provider's role is to continuously adapt their treatment plans and offer personalized recommendations based on the ever-changing needs of the patient and their health progress. When a patient schedules a consultation to seek answers about how to react to symptoms of, for example, frequent fatigue and lack of sleep, the provider looks at the evidence and

determines the best course of action for that patient. By reviewing lab results of blood chemistries combined with the patient's description of their symptoms, a provider can effectively come to the conclusion that the dosage of a new medication is too high for that individual, and it should be lowered.

For example, the diagnoses of diabetes or heart disease require individuals to change their lifestyles - whether that be diet, exercise, medication, or all of the above. As each individual is unique in their biological, psychological and socio-economic needs, patients and HCPs, together, must go through a series of trial and error to determine which medication, diet-exercise regimen or support services that individual may need to ensure that they are able to gain sustainable and effective self-management skills. This represents months or years of demand for healthcare services.

However, as providers struggle to help as many patients as possible in a day, there is less time to meet each patient. In the UK, those who have been diagnosed with a chronic condition, such as cancer, often must wait for more than two months to see a specialist upon referral [25]. Statista reported that throughout Europe, those seeking first medical examinations and treatment are not able to access a provider due to factors such as expense and wait times [26]. When patients are able to access providers, however, issues still arise. Health consultations today are generally limited to 20-minutes [27], during which only few questions can be answered, let alone discussed and explained at length. For those with chronic NCDs, 15-minutes once or twice per year, is hardly enough time to gain effective support in time [28].

2.1.3 Consequences of the supply-demand gap

Unfortunately, the numbers do not lie. One of the gaps that result from the supply-demand imbalance is unmet health expectations for those with chronic conditions. Not all who have been diagnosed with complex chronic illnesses have achieved evidence-based clinical targets, i.e., indications of their disease health. Several studies during the last decade have found that less than half of their participants with diabetes achieved recommended levels of blood glucose (BG), a key factor in diabetes health. Even less (approximately 10%) achieved all of the clinical goals related to adequate diabetes health [29, 30], e.g., lipid levels, blood pressure (BP), cholesterol, etc. Receiving the type and level of care and support that patients demand from providers is essential to achieving these goals. On top of the externally suggested health goals, patients themselves believe that more personalized recommendations from their providers about specific solutions, resources, or support would help them achieve better health [31].

Another gap is based on a mismatch between patient and providers' agendas and communication– a more self-management vs. treatment focus. Individuals need answers. A summary of a 2018 study reported that the common needs amongst 500,000 individuals with chronic conditions weighed more toward emotional support and specific answers about impacts of their illnesses on their daily lives, and less so on hard clinical outcomes [32]. Patients also have reported more and more desire to be part of the care process and contribute information upon which to base treatment and self-management decisions. A 2019 report by the Samueli Foundation found that while individuals with chronic conditions (72%) very much wished to discuss self-care strategies with their providers, approximately half of the providers who responded did not believe their patients would be interested in or able to hold such conversations [33]. The limited amount of time and tradition to rely upon consulting and

providing concrete, validated, and quantitative information about a patient's progress during consultations were also precipitating factors.

These gaps – in expectations, in agendas, in the understanding of one another, in approaches to care – leads to adverse consequences, both for patients and providers. Even when providers and patients may agree, for example, about the importance of educating patients and access to adequate health services, the financial, informational, and systemic limitations of medical systems pose a significant barrier [34].

When individuals do not receive the care they need and demand, mentally, there can be a disconnect and distrust of the medical system in its ability to help them [35], as well as confusion, frustration and lack of confidence in their ability to self-manage their own health.

Ideally, a more knowledgeable and capable patient would be able to answer and correct for health challenges that arise. As such, they would not require as much follow-up from their provider, would suffer fewer complications, and require fewer hospital admissions. However, if the services and resources are not available to a patient in order to gain sufficient self-efficacy in their chronic illness self-management, costly and resource-demanding consequences arise for both patients, providers, and the overall healthcare system.

The consequence of poor chronic illness self-management and treatment are health complications and their costs, decreased motivation and engagement in one's self-management, and lower levels of function in one's daily life or disability. Given the willingness and engagement of the patient, often, these consequences could have been avoided with more personalized attention and instruction for improved self-management.

2.2 Exploring the specific contexts of Type 1 and Type 2 Diabetes Mellitus

In this section, I describe diabetes as a use-case for this thesis. Diabetes requires a person to change their lifestyle, track their biological and habitual changes, participate in continuous coordination with HCPs, and cope mentally with the added pressure of learning and adjusting to their diagnosis. Research on mHealth interventions for diabetes self-management reflects the modern environment to which researchers, patients, and HCPs must adapt to produce effective knowledge and care for chronic illnesses in general.

2.2.1 Types and prevalence

There are three main types of diabetes mellitus: Type 2 Diabetes (T2D), Type 1 Diabetes (T1D), and gestational diabetes. The activities of this thesis focus on the two types of chronic diabetes, T1, and T2D. T1D is known as juvenile or insulin-dependent diabetes, as it is most commonly diagnosed in children, but can also be diagnosed in young adults, with cases rising >3% annually in Europe [36]. T2D generally develops over time and is, therefore, also called adult-onset diabetes. As the most common type of diabetes, T2D accounts for 90% of the population of those with diabetes (9.3% of the global adult population) [37]. However, in recent years, due to more sedentary lifestyles of children, youth (0-19 years old) are also at risk for and shown to be developing T2D (1.3% of those with diabetes in Europe) [37, 38].

In 2011, it was estimated that approximately 50% of those with diabetes globally remain undiagnosed [39], which rose to nearly 67% in 2019 [37]. Some of the significant contributions to being undiagnosed or unaware of one's diabetes are socioeconomic inequalities such as lack of access to health services and resources, lower education and health-literacy, lower-income, etc. [40].

2.2.2 Underlying causes

These diagnoses are based on imbalances in insulin and BG due to the ineffective functioning of the pancreas or the body's cells. In healthy individuals, when BG rises, for example, as the result of eating a cookie, insulin is released from the pancreas, which signals glucose to be taken from the blood and stored into our cells. If our BG is too low, we get hungry and eat, thereby raising the BG to healthy levels, making the glucose available as fuel for our daily activities.

Those with T2D have developed insulin resistance, largely due to sedentary habits, poor diets, and genetic susceptibility. The body is unable to effectively store glucose in the cells, leaving them to float around in the blood. While insulin is not typically needed for T2D, there are some cases, e.g., dangerously high prevailing BG levels, for which a HCP may prescribe a combination of insulin and oral medications. Those with T1D lack the ability to produce insulin and, therefore, must introduce insulin to maintain healthy levels of BG.

2.2.3 Self-management and support

Those with diabetes are often provided with general resources when they are diagnosed or have been found to have a specific issue with their self-management, e.g., carb-counting through Diabetes courses and diabetes self-management education (DSME) [41]. There are also official e-learning and online resources for information and guidance on how to perform effective self-management [42]. However, these do not cover many of the intricacies and situational changes that happen for individuals on a daily basis.

Health professions agree that there are four main determinants of diabetes health: diet, exercise, medication, and BG [43]. Upon diagnosis, individuals are instructed to track their self-management of blood glucose (SMBG), diet, and medication delivery, traditionally using a paper diary. While these individuals are given general recommendations, you have to figure out what works for you each day. Additional factors to these four cornerstones include, e.g., BP, sleep, depression, and social support, which significantly affect an individual's willingness and ability to maintain their health. In order to react appropriately with an effective self-management decision, you have to adjust the general recommendations to your lifestyle, changes in your body's needs as you grow older, or changes in your resources based on socioeconomic status [44]. Even your surroundings play a role. For example, taking a vacation in a hotter climate can affect the absorption and chemical stability of your insulin [45].

Those with T1D use different types of insulin, i.e., variations of short-acting and long-acting insulin, which have to be coordinated and administered throughout the day [46]. There are two medically available devices that aid a person in managing their insulin - insulin pumps and insulin pens [47]. Equipment used by the insulin pumps generally need to be changed, at the longest, every three days. Associated BG levels can be monitored by devices including CGMs, which track one's BG every 5-minutes, and flash glucose sensors, which require the users to hold a device up to the sensor in order to read the glucose level at that moment. These can be linked via Bluetooth and analyzed via algorithms

to coordinate the self-management of these two diabetes factors [48]. Except for the insulin pen, these devices are all connected to the body via a subcutaneous cannula or subcutaneous sensor. The use of the aforementioned medical devices for T2D is highly debated and is, therefore, not typically an option for these patients [49].

Glycosylated hemoglobin (HbA1c) is a cumulative measure of BG representing an average of the previous 3-4 months of BG levels [50]. HCPs use this measure as the gold standard to diagnose, as well as track an individual's overall diabetes health and risk of developing complications. HbA1c is typically taken together with other lab tests, e.g., lipid levels, at the clinic once or twice per year. Typically, the target HbA1c is <6.5-7% (53mmol/mol) [51]. While HbA1c is considered the gold standard for HCPs, it does not hold as much instructive or explanatory value for individuals living with diabetes. Luckily, advances in BG measurement technologies have allowed us to see more detailed accounts of individuals' BG levels for any given period of time, i.e., amount of time in and out of the goal range of BG levels.

Time-in-Range (TIR) and Time-Out-of-Range (TOOR or simply OOR) are measures of the percentage of time BG levels are in- or outside the target of 3.9-10 mmol/L (TIR). TIR and OOR more accurately demonstrate the variability of BG levels compared to HbA1c [52]. Whereas finger-prick tests, taken irregularly, give momentary measures of one's BG, CGMs provide the type of detailed information that allows for improved calculation of TIR and OOR [53]. Graphs displaying this information can tell individuals, for example, times of the day when their OOR levels typically occur, or, compared to diet and physical activity levels, can help that person determine why those OOR levels may be happening. These OOR measures are especially important for those with T1D or for insulin-treated T2D, whose BG levels the most throughout the day.

2.2.4 Consequences of poor diabetes self-management

The consequences of consistently addressing and acting upon the needs of diabetes, or any chronic illness, not only affect individuals and their relatives but also demands on the healthcare system. For both types of diabetes, damage to entire organ systems may occur. In order to avoid complications, those with diabetes are instructed to maintain a BG level between 70-180 mg/dL, or 3.9-10 mmol/L [54].

Short-term or rapid onset, consequences of poor diabetes self-management are usually seen in those with T1D. For this type of diabetes, BG changes can happen quickly due to nutritional intake, physical activity, and insulin – or lack thereof. Hypers, or hyperglycaemia, means that there is too much glucose in the blood, causing dehydration, severe fatigue, or blurry vision, to name a few [55]. A prolonged state of hyperglycaemia generally occurs in those with T2D, while those with T1D may experience several "hypers" and "hypos" throughout the day. Hypos, or hypoglycaemia, refer to lower BG levels, for example, due to excessive use of insulin or physical activity, or too little fuel (food). The symptoms of hypos include weakness and sweating or shaking, and, if left untreated, can lead to coma and death [55].

Long-term, or cumulative, complications of prolonged, poor diabetes self-management can include problems with circulation to kidneys and eyes as well as nerve damage, or neuropathy [56]. Amputation of, for example, feet or legs, may also be necessary as well as prolonged healing times for wounds [57]. Those with diabetes can often suffer from depression, anxiety, and stress as the result of

having to live with diabetes, leading to frustration, poor outlook on one's health and quality of life [58].

These consequences can then negatively impact how one functions socially, e.g., experienced stigma, and vocationally, not to mention financial stability due to the high cost of treatment and/or risk of job loss due to disability. Cognitive dysfunction, e.g., deficits in learning, concentration memory, has been recently acknowledged as a potential consequence of persistently high BG levels for both types of diabetes [59].

2.3 mHealth technologies and trends

In this section, I describe the origin and evolution of mHealth technologies for diabetes self-management, and what contributed to their growth in popularity and accessibility amongst individuals with diabetes, including societal, regulatory, and technological changes.

2.3.1 The evolving connotation of mHealth

Mobile and remote health technologies are not a new concept, evolving from electronic health (eHealth) and telemedicine to the modern-day mobile health (mHealth) devices. From desktop to hand-held systems, mobile technologies for both patients [60] and HCPs have been meant to ease the ever-evolving challenges of an overwhelmed medical system [61].

Various terms - eHealth, telehealth, and telemedicine – cropped up to describe mobile health technologies. While there are no explicit differences between these terms, a 2005 systematic review of publications describing eHealth innovations "suggests that eHealth may refer more to services and systems rather than to the health of people" [62], due to their focus on access and connectivity to formal care services and systems rather than the improvement of individuals' health measures or quality of life.

Remote health support also expanded its inclusion of decision-making power in 2012 with the WHO's statement that telemedicine and telehealth involved using information and communications technologies to enable greater access to healthcare services [63, 64]. Of note is the shift in language from the 2010 top-down description of "health information is provided to the right person" related to "diagnosis and clinical management" [65], to the 2012 version of "greater access to healthcare services." The 2012 version demonstrates a more bottom-up approach as patients were empowered to seek care instead of being instructed to. With a variety of intended uses, such devices allow for an individual to collect health-related measurements outside of the clinic as well as track and share this data with whomever they choose.

A major reason that contributed to the hierarchy, i.e., the disproportionate power in healthcare decision making, was access to information. HCPs were traditionally seen as the sources of information, health decision-making, and authority for chronic condition care. All information flowed toward and was filtered through them - from recent findings in research and condition-specific health goals developed by authorities, to patients (Figure 1). Technology was no different. The traditional role of health technologies was to supplement or extend healthcare services, enabling HCPs to track their patients' health progress and recommendation adherence between consultations. Their development also followed a traditional path. Before the interventions, end-users - typically patients and HCPs – were invited to participate, the technologies were iteratively developed, vetted, and made

available through a top-down approach [66]. Health authorities provided the direction via population-level or global health directives, e.g., Norway would provide goals for diabetes care for the country [67], and researchers would provide evidence for ways in which these goals could be achieved. It typically would take years to generate enough consistent evidence to ensure that the tested intervention was safe and effective enough to provide to the public. These new treatments or self-management care options would be made available to HCPs, e.g. as standards for healthcare practice, and the HCPs would then offer options to their patients based on what they believed would be for that patient.

Between approximately 2008 and today (2020), the power and authority to make healthcare decisions expanded to include not only HCPs and health authorities but also patients. mHealth supported this trend by empowering patients to use their own-gathered data to inform their self-management decisions outside of the clinic. mHealth has not only to acknowledge patients as the daily decision-makers and largest determinant of their health status but more or less authorized them to make health decisions without the involvement of formal medical services. With the option to track, educate one's self and respond to health needs as they arise through a device that is always available, in the palm of your hand, mHealth has contributed to the shift the power dynamic.

Today, patients are able to access not only general information about their chronic condition via the internet or their HCPs; they are able to generate their own information - their own power in decision making. By this, I mean that patients are able to take the general principals of their self-management and build upon that understanding by recording, tracking, and reviewing the outcomes of their own health actions. By using mHealth applications (apps), wearables, and medical sensors, individuals are able to build a library of evidence of which lifestyle choices, actions, and situations lead to positive or negative changes in their health. In other words, mHealth could potentially facilitate more informed and sustainable behavior change decisions. As a result, those with diabetes experience a greater sense of ownership, responsibility, and confidence in their ability to self-manage [68].

However, this freedom from clinical support presents risks – especially in the early years of modern mHealth. There are reasons why HCPs rely upon blood tests and standardized health measurements to support their clinical decision-making; a person's health, wellbeing, and ultimately their life, are in the HCPs' hands. To be so excited to try a new technology that promises ease-or-use, support, and answers that one trusts it without question is dangerous. HCPs' most prevalent concerns began with the potential for individuals to erroneously enter the wrong data and security and privacy of data stored in the app. While these are smartphone apps, they did and still do not have the ability to determine if you have entered the wrong measurements. Any suggestions about health, medication, or lifestyle changes that an app provides can be dangerous if those suggestions are based on faulty data. Also, when an individual pushed the "agree to terms" button, upon downloading the app, they often overlook or simply are unconcerned with the fact that these technologies are provided by commercial companies or individuals. A major difference between mHealth technologies and those developed as part of clinical intervention trials was that mHealth development did not follow the strict protocols and quality medical standards. These entities have the ability to develop mHealth apps and devices without a clinical background and with intentions of profit, not altruism. Following regulations, safety, and effectiveness standards are often secondary goals.

HCPs have been cautiously optimistic about the potential of these technologies to support patient self-management from the beginning. However, for these reasons, they are hesitant when reviewing

patient-gathered app data and urge individuals to take app-recommendations with a grain of salt. More recently, individuals have been encouraged to ask their HCPs about which app to choose, i.e., to take the act of choosing an app just as seriously as a change in medication by consulting a professional [69]. However, this presents yet another challenge and demand on HCPs that must be addressed. This trend brings another concern to the HCPs' table, i.e., not being able to relate to the patient-gathered data due to lack of clinical guidelines and protocols. Factors that have contributed to this network of concerns and possibilities are described below.

2.3.2 Factors affecting mHealth use

Several societal, economic, and technological changes contributed to the rapid growth of modern mHealth technologies. Figure 3 provides examples, between 2007 and 2019, of some of the major changes that occurred in parallel that contributed to the entrance and fast-paced growth and adoption of modern mHealth technologies. I focus on four major categories to illustrate the rapid development and capabilities of technology that coincided with an emphasis on patient empowerment - both of which outpaced the regulations regarding these largely commercial products.

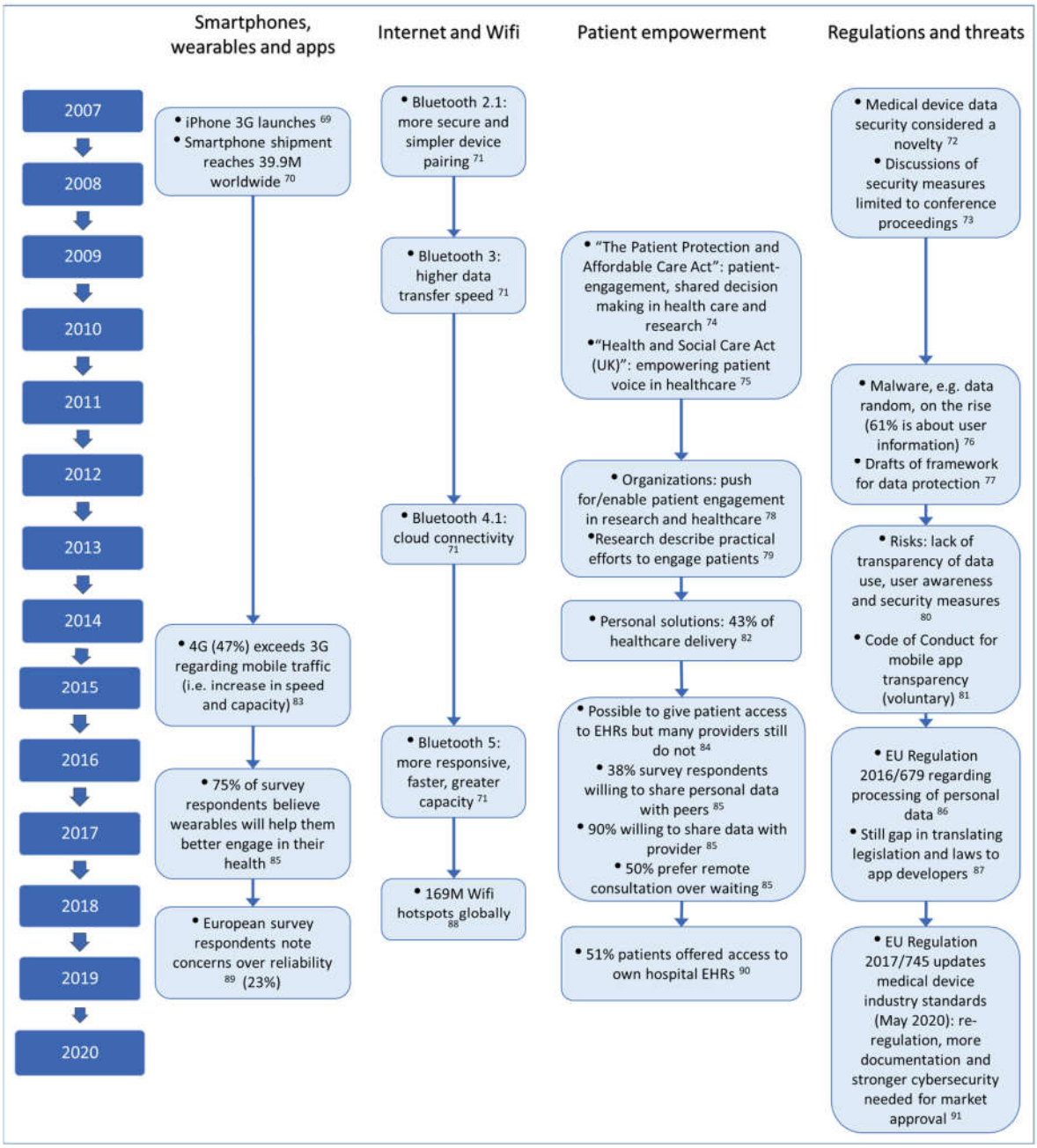


Figure 3 Timeline illustrating societal, regulatory and technological changes that occurred in parallel that allowed for mHealth spread [70-92]

The availability of smartphones, wearables and apps was made possible with the release of the modern smartphone – the iPhone – in 2007 and the boom of the App Store in 2008 [1, 93]. The use of smartphones began to outpace the use of regular cellular phone use in 2012, as consumers wished for more advanced functionalities as apps [94]. What made a smartphone smart, was its ability to access the internet.

Many of us can remember the sluggishness of a dial-up internet connection. The usability, popularity, and feasibility of smart technologies simply would not be possible without the "Internet-of-Things" (IoT), i.e., the ease of internet access [95]. With the ability to access the internet easily from the palm

of your hand, individuals could find health content via scientific literature or websites such as those hosted by fellow patients. Smartphones, wearables, and sensors grew ever more capable of collecting and storing detailed data sets thanks to their ability to connect to one another and access the internet via Bluetooth and WiFi.

Available platforms grew to include other smart-devices as smartwatches and other wearables [96]. These devices take advantage of the IoT to collect and store data from smartwatches, sensors, bio-patches, plug-in smartphone sensors, or even pair via Bluetooth with medical devices [97]. A key feature of these technologies was their ability to automatically capture data regarding an individual's physical activity, e.g., heart rate coupled with the selected type of exercise, sleep patterns, ambient temperature, or sun exposure, to name a few [98].

Apps spread like wildfire thanks to the speed of regulatory change and emphasis on the individual. As the gap between healthcare supply and patient demand grew [10], HCPs and authorities pushed for patient-empowerment. In theory, the more resources and information that individuals could access on their own, the less time they would take from formal healthcare services.

The number of available apps reported by different companies and surveys varied widely over the years. As of July 2008, over 15,000 apps were available on the Apple App store, rising to 586,000 by 2012 [99]. However, the increase in popularity of certain categories of apps, ever-specialized functionalities, and rates of growth illustrate consistent characteristics of the app market, e.g., rapid development, personalization, and accessibility. By 2014, not only were there over 100,000 health apps available, most of these targeted those with chronic conditions [96]. A report by the same company, Research2Guidance, just three years later, confirmed the sustainability of this trend with more than 325,000 health apps published and a third of the market focusing on providing functionalities related to self-management and patient-provider connection [1]. For individuals aiming to self-manage their health using apps, the near-constant development of these personal and commercially available technologies, to collect and collate more and more data, became a necessity. By 2016, it was estimated that Android app downloads outnumbered iOS (Apple) app downloads 3-to-1 [100]. While overviews of the mHealth app market often note market growth in terms of revenue, many health apps could and can still be downloaded for free, with some offering in-app purchases depending on which level and functionalities the user chooses to use.

However, not everything progressed at such a rapid pace. Considering the methodical, systematic and cautious nature of the medical system, it is understandable that regulatory and legislative changes in the healthcare system were – and are- implemented more slowly than the face-paced world of the commercial market. The delays in these regulations, including how to test and validate these technologies, allowed for nearly a rule-free environment in which technology developers could produce health apps. App developers acknowledged a need for accessible and easy-to-use health aids for individuals and found that these solutions were relatively easy and quick to make. A quote from the movie *Pirates of the Caribbean* comes to mind when considering the beginning of health app development; "the code is more what you'd call "guidelines" than actual rules" – Captain Barbossa [101]. Even some years into the mHealth boom, apps were being produced in public and commercial markets without strict requirements, standards, or limitations for health app developments [102].

2.3.3 Modern mHealth: a buffet of app options and information for individuals

As a mainly commercial product, these technologies were constantly being covered in the news. many articles and reports, both scientific [3] and public [4, 5], propagated the belief that mHealth would reduce cost and lower demand on the healthcare system and individuals. The reality, however, was not as quickly achieved as many would have hoped. As of early 2020, the confusion, uncertainty, hope, and frustration with the impacts of mHealth on the healthcare sector remain. Stakeholders from within the medical field are affected – searching for the appropriate and safe uses of the technologies, questioning how to adapt healthcare practices and services. As someone researching and observing these changes as they happened, it was difficult to keep track of what was available and what was obsolete or no longer available [103]. The consequence of this was an overwhelming number of choices of health apps and information for everything from general health and wellness information to diagnosed chronic conditions.

When any new item hits the market, one of the first things we do, if we are interested in purchasing it, is to look at the reviews. We try to sort through the useful information vs. the noise to find what is relevant to our unique needs. While the Android and Apple App stores provided information for each app, several organizations provided "app directories," which included reviews and insights about specific apps by consumers and peers [104]. In doing so, they aimed to ease the daunting and overwhelming decision-making process for potential users, i.e., providing the individually relevant information that the healthcare system was not.

The organization PatientView was the first to produce a completed "European Directory of Health Apps" in 2013 [104], updated in 2016 [105]. These reports categorized apps based on specialization, e.g., cancer, children's health, or rare diseases, with information about app names, available platforms, languages, and countries, as well as descriptions, reviews from other patients, cost, and full descriptions of the developers. All of this was provided on one page per app. This meant an easy, searchable, comprehensive, and transparent overview of the intention of health apps with information that matters to end-users. The report published in 2016 included updated and relevant information for the time, including "Approved by," e.g., Conformitè Europëenne (CE) mark or the US Food and Drug Administration (FDA).

The UK's National Health Service (NHS) took a more formal approach in 2015 with the "Health Apps Library." These reviews were based on input from HCPs, which attempted to add a level of clinical relevance and approval. However, this process of vetting the apps was unfeasible, with questions of quality of the reviews and reliability of the apps' security [106], and the library was closed down for a time and relaunched more recently as the "NHS Apps Library" [107]. In this version, app developers review apps by including information provided by developers and input from HCPs. They were transparent in their app review process, describing that the developers were the ones who had to meet and submit reports of their compliance with standards of security, clinical relevance, etc. [108]. This "self-assessment" was positive in that it no longer required health professionals to take time from their schedules to evaluate apps, but also a challenge because it relied on developers to perform the work, i.e., the reviews and approval, which were not necessary for them to promote their apps.

These popular and public reviews demonstrate the difficulty of bridging the gap between the consumer and healthcare domains, specifically with providing quick, quality, secure, and relevant information to

end-users. Health researchers also attempted to provide medically and user-relevant reviews of both commercial and developing apps. However, their intention was more related to identifying clinical evidence, than information to individual users [109-111].

2.3.4 Thesis focus: patient-operated mHealth for self-management of diabetes

In this section, I will begin by explaining the appeal of mHealth technologies and the specific sub-group of these upon which I will focus the remainder of this thesis. I will highlight the aspects of the modern mHealth environment that are specifically relevant for patient self-management of chronic conditions, with a focus on diabetes. I will also explain how the lack of specific regulatory guidelines for research evaluation and clinical practice presents an opportunity for researchers to explore alternative approaches and resources needed to appropriately adapt research to mHealth interventions for diabetes.

Traditional medical device manufacturers target HCPs and healthcare organizations [112] to distribute their proprietary devices to the patients who demonstrated a need and ability to use them appropriately, as well as the ability to pay for them [113]. Although these devices were meant to aid in patient self-management, the collected and structured data were [114] and still are [115] meant to be analysed by the HCP, who would then explain to the patient which health habits should be changed. As such, most medical device companies did not provide all the support that patients needed outside of the clinic.

These prescribed technologies, such as continuous glucose monitors (CGMs), insulin pumps, and insulin pens are expensive. In terms of time, energy, and out-of-pocket financial burden of self-monitoring using such medical devices, the price for individuals is high [113, 116]. Imagine having to analyse each action you make or change in the environment to determine its effect on your health. It is a mentally exhausting endeavour. Technology took some of that burden away by acting almost as a personal self-managed secretary. However, not all individuals met the requirements that qualify to receive equipment to ease the everyday self-management burdens. For these individuals, few options existed to understand and aid patients in their attempts to follow self-management recommendations from their HCPs.

The availability and accessibility of these technologies presented a three-fold benefit. The first benefit is time; the ability of many mHealth technologies to collect and collate the data in an understandable way freed individuals to spend less time processing each self-management decision they made. The second benefit was the always-present nature of smartphones and wearables. Patients need to self-manage every day, not just during the consultations. They need specific answers when questions, symptoms, or other challenges to self-management arise. The third benefit coincides with control. Individual users are a primary target audience, initiators, and decision-makers. While HCPs can be secondary users of the data, i.e., taking on more of a supportive role rather than authoritative, the patient is in charge of their health, priorities, and decisions.

2.3.5 mHealth: empowering patients with choices

In this section, I highlight two key concepts that will be presented throughout this thesis – choice, and empowerment. Whereas health and research have historically focused on top-down suggestions, instructions, and recommendations from authorities and HCPs, mHealth has given patients options to

seek out on their own. These choices are important – the type of platform, functionalities, and data collected reflect how individuals use the technology to best suit them, not how HCPs and researchers assume the technology should be used.

> *"Others may think that an individual with a particular disease, say diabetes, needs treatment, but it is the individual that determines their own demand and whether they seek treatment." – SH Zuvekas [117]*

With knowledge comes power. By power, I refer to the core of "empowerment" or "the process of gaining freedom and power to do what you want or to control what happens to you" [118]. As individuals with chronic illnesses choose what is important to them, they invest themselves in self-education about their health. This leads to the power of one to take control and make health decisions, for themselves, in the moment. They have a greater ability to take information, including HCPs' recommendations, and turn them into actions. The beauty that mHealth apps promise is the ability to combine data from different sources patients themselves have control of in order to get a comprehensive understanding of how their lifestyle choices and environment affect the status of their chronic condition.

In 2010 Apple Inc. coined the phrase "There's an app for that" [119]. Not only did this make them an even stronger household name, but it also illustrated the seemingly endless number of options for app development as well as the functionalities that already exist. For some of those with chronic conditions, this may have sounded like a dream come true. Those with chronic conditions have to keep track of a myriad of factors, from the amount of medication to sleep to BG values or other biological measures.

Individuals have begun to gather an enormous amount of health data via always-available smartphones from not just one but possibly several devices and apps that track sleep, diet, exercise, BP, weight, BG, and even body temperature. Connectivity is a key functionality that has allowed for this mass-data collection, as well as the growing potential to extract information by linking data via Bluetooth, to multiple devices, and sharing data with peers, HCPs and informal carers [120].

Big data, algorithms, etc. are buzz words associated with one thing that all stakeholders need – information. Information about patterns of self-management, indications of harmful health choices, and opportunities for improvement lie in health measures that individuals deem relevant enough to be recorded.

However, at a certain point, individuals can only squeeze so much information and knowledge out of app-collected data on their own and are driven to seek outside help. The first and logical options are HCPs. While potentially informative, without clinical knowledge and medical training, an individual with newly diagnosed Type 1 Diabetes (T1D) may not be able to notice that their dangerously low BG levels at night are due to too much insulin or too few carbohydrates before bed. HCPs are trained to connect the dots and have the possibility to educate individuals beyond what they can learn on their own via the internet or their health apps. However, some problems cannot wait to see an HCP; those with chronic illnesses often need answers when symptoms arise, not at the next consultation.

With any new technology, there are both expectations of its potential as well as challenges to achieve these promises. Figure 4 below summarizes this double-edged sword of modern mHealth

technologies, for both main end-users, i.e., patients and HCPs; individuals with diabetes and HCPs expect a great deal from mHealth (up arrows) which are met with potential benefits and challenges (down arrows).

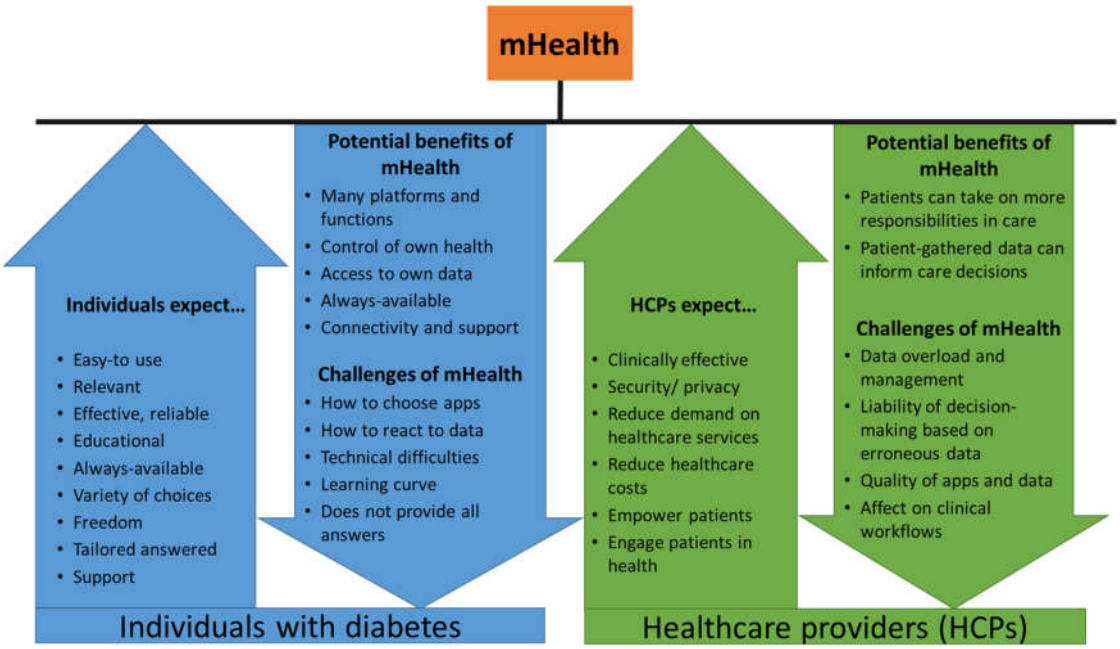


Figure 4 Summary of the potential benefits, challenges, and expectations of patients and HCPs related to mHealth technologies.

The modern mHealth technologies encourage and facilitate the patients' choice in self-management, with or without associated clinical support. This was the foundation for the expected benefits of mHealth amongst patients, HCPs, and healthcare authorities alike. The main benefits were interconnected and included i) reduction in cost and healthcare service demand, ii) increased patient-engagement in their health and improved self-efficacy as well as physical and mental health, and iii) personalized and detailed feedback from HCPs to patients based on their collected app data for individuals paying for medical care [60, 120].

HCPs had hoped that these tools could be educational and provide the immediate and daily answers that patients demanded. They also expected that, when they would meet patients, the collected data would help focus the consultation discussion so that they could give more tailored advice and guidance to their patients. By enabling self-education and facilitating motivation, patients could more efficiently use existing care services and participate in more collaborative care with their HCPs [121]. mHealth has the ability to strengthen the relationship between patients and their HCP in a way that will produce better clinical outcomes. Outside of the clinic, mHealth could theoretically enable them to be more adept at taking information and acting appropriately to avoid health complications, and subsequently, the need for more financially and resource-expensive healthcare services. In doing so, mHealth would give individuals the confidence and sense of control of their health that would ultimately ease their anxiety and improve their overall perception of their health [122]. However, the reality more closely resembles driving a highway of potholes to be aware of and avoid.

2.4 Caveats of mHealth: concerns that we must address

In this section, I discuss that, while mHealth offers many options and benefits, there are certain realities – both as a part of and surrounding the technology – that should be acknowledged before continuing the discussion of the impacts of mHealth on patients, HCPs, researchers and health authorities. I introduce the main concerns, limitations, and barriers of mHealth apps for patients with chronic conditions, with a focus on diabetes. I also post arguments against some of the assumptions of mHealth's ability to aid health stakeholders. These will be important to keep in mind when I present the impacts of mHealth on those with diabetes and HCPs and the role of research in the coming sections.

Apps can be used to facilitate patient empowerment in the patient-provider relationship and to aid HCPs' understanding of patient behavior and decision making. mHealth has affected the demand for the type, frequency, and accessibility of healthcare services and resources. Apps on their own cannot solve the problems of high demand for healthcare support; supportive services, information, familiarity, and training are needed. Technology requires a different type of support than health self-management. It is understandable that HCPs are challenged by the recent expectation to provide both forms of support, i.e., clinical and technical [123, 124]. Some patients may need more consultations with, e.g., nurses about the technology, i.e., health support with a different focus.

2.4.1 Are apps for everyone?

Largely due to the hype of "There's an app for that" and rapid development of technology in the last decade, it seems as though anything is possible - any request for functionality can quickly and easily become available. But technology has limitations too.

Just as there are certain recommendations or requirements that HCPs address when they decide which medical device to suggest for a patient, the same can be said about apps. While these technologies pride themselves on being easy-to-use, not all are as intuitive and often require a certain level of health- and technology literacy [125, 126]. The effectiveness of an app largely has to do with the capabilities of the wearable or measurement device, as well as the user's ability to accurately take the measurement. The concept of "the digital divide" is an important concept when considering who the intended end-users are. Motivation and willingness are also essential. Some individuals who are in poor health, disengaged with their self-management, and/or suffer many expensive health complications may not willing to use this information or technology. So, while the resources may be available, an mHealth app is essentially useless to this group unless they receive a different, more tailored form of support [127, 128].

For HCPs, the familiarity with apps, online platforms, and other publicly available is also limited. This might, in some cases, be due to a lack of interest or possibly a lack of time [129]. The breadth and depth of HCPs' formal health education and guidelines for how to approach mHealth and patient-gathered data in clinical practice have not caught up with the mHealth literacy of patients and informal carers.

Imagine depending on an app to warn you when your BG is too low or when to take the necessary medications. Then imagine that the app fails to perform as expected, leaving you, the user, to deal with the consequences [130]. Similarly, if a patient presents an incomplete or inaccurate data set to their HCP during a consultation, there is only so much interpretation and guidance that can be given

without all of the necessary, reliable information. This remains one of the major concerns of HCPs today.

2.4.2 Quantity or quality of use: apps don't need to be used forever to be beneficial

While there has been no conclusion as to how long you have to use an mHealth technology to reap the promised health benefits, how and why one uses an app determines its impact. It is reported that a significant portion of those who download mHealth apps do not use them often or for a long period of time [131]. While this is often due to frustration or dissatisfaction with the app itself, people do not necessarily need to use an app for the remainder of their lives in order to experience benefits. Health intervention studies, in which the effect of using new technology is measured, may only last a few weeks or months and still result in mental or physical health benefits [131]. Due to the diversity of available apps and wearables, one could simply use an app as an informational resource or trial self-management aid for a short period of time in order to gain the benefit of improved knowledge and perceived self-efficacy. One study found that participant knowledge of their health condition improved after only one week of using an educational app [132]. Similarly, an individual with COPD or diabetes could learn what factors affect them and go through trial-and-error using the app to track their progress for a short period of time and then implement that experience over the long-term. One study found sustained health benefits several weeks [133] and, for some participants, nearly a year after an intervention had concluded [134].

Despite some benefits seen from guided and controlled use of mHealth in studies, the mHealth environment is also an area in which much false information, misinformation, and misunderstanding are disseminated to, and amongst, individual users. In some cases, platforms such as YouTube and Facebook have been used by non-health professionals to propagate anecdotal and misleading information regarding the efficacy of some apps [135]. Apps themselves also do not necessarily follow the standards or guidelines about transparency or data use, set by health authorities [136]. Reliable groups, such as patient organizations, urge those who seek information about apps online to be cautious and judicious about which sources they choose to trust with their protected or personal health information (PHI) [137]. This is especially true when reviewing data protection and security content, as it was found that many developers and their apps do not follow standards to protect users' privacy, and can even share their personal data with third parties [138, 139]. Data security is one of the main concerns, if not arguably the biggest concern, with mHealth today due to the amount of identifiable and personal information stored via health apps.

2.4.3 Big data or data overload: human computational capacity and interoperability limitations

The type and density of data that you can store in a health app determines the level and quality of impact you can receive from that app. Theoretically, "Big Data" can provide the previously inaccessible answers to questions about individuals' health, challenges, and motivations. However, limitations exist when interpreting data [140]. For patients, even if an app summarizes and presents their meta-data, determining its meaning and deciding how to respond are dependent on their relationship with their HCPs and their guidance, the user's health-literacy, self-efficacy and capacity to sift through these different types of information. For HCPs, these limitations are mainly due to a lack of interoperability between information systems. For example, whether printed-out from the app or electronically transferred, if a patient brings sleep data and BG data that is not in the format that is

used by the medical electronic health record (EHR) system or familiar to the HCP, then the HCP cannot easily work with, let alone integrate, that data into their practice [141].

2.4.4 Reliability or liability: life-threatening technical errors and dangers of misuse

The limitations and effectiveness of apps and self-collected data do not stop at syntax and information overload. The impact of mHealth is also dependent upon the reliability and accuracy of the data that is entered into the app [142]. Several apps offer recommendations or advice to the users about how to respond to their, e.g., physical activity levels, weight, or BP. As with informed decision making in any context, information accuracy dictates how effective health-related decisions will be, whether they are made by an individual, their HCP, or based upon suggestions from their apps. Connectivity also presents several front-end challenges for the users, such as their own technology literacy, technical errors when transferring data, or app updates that happen at different times, causing interoperability issues [143].

Reliability and liability are also significant concerns for HCPs when it comes to app-gathered data. As more patients bring their apps and own-gathered data to the consultations, HCPs have to keep in mind that they are not only ethically responsible but also legally liable for any recommendations they give to their patients [144].

2.5 Regulatory oversight of mHealth

In this section, I describe the regulatory landscape that we, as mHealth researchers, must take into consideration when designing intervention studies. Between 2008 and 2020, there have been both legislative and commercial efforts to respond to the questions and expectations related to patient-operated mHealth for chronic illness self-management. Compliance with these standards and guidelines is one of the pillars that research stands on, to which we must adhere in order to render our outcomes useful and usable in real-world situations.

2.5.1 Main authoritative bodies

From the evaluation and regulation of single devices to scaling up, formal regulations seemed to change with each season, yet still not as quickly as mHealth development. The FDA approval [145], CE-mark [146], and other country-specific certification processed selected apps to review or called for app developers to submit their apps for approval. A product is granted a CE-mark and approved to be sold in the European Union (EU) after the owners or developers have submitted evidence of its safety and efficacy and have been found to meet “all relevant EU-side requirements.” These requirements include such standards as the “General Product Safety Directive,” ensuring that all available products are transparent with consumers about product risks and safety [147], and more specifically, the EU Medical Device Regulation (MDR) for CE-marked Digital Health Apps, defining apps based on their level of risk to the user [146]. The FDA has taken a similar approach by classifying apps based on their level of risk to the user, with apps that, e.g., provide static health information, being classified as low risk vs. those that offer medical advice based on patient-registered data as being high risk.

As illustrated in Figure 2 above, the lack of targeted regulatory oversight of mobile and digital health between 2008 and approximately 2016 allowed for the unrestricted development of personal health aids. Discussions erupted over concerns for patient and data safety. Iterative attempts have been made by healthcare authorities worldwide to determine what research needs to test, how they should test it,

and what evidence is necessary to ensure the safety and efficacy of the different types of mHealth technologies.

Three main issues persist. First, these activities occurred in silos, further delaying consensus, and realization of evaluation activities. Several organizations tried to adapt historical health device regulations to both the needs of mHealth and their specific agendas, e.g., region or country. For example, Catalonia's Agency for Health care Quality and Assessment of Catalonia (AQuAS) developed evaluation suggestions based on a hierarchy or taxonomy of health apps based on a combination of "person-specific risk" and "intervention-specific risk" [148]. Similarly, the Organization for the Review of Care and Health Applications (ORCHA) both provides an own review process based on selected standards and published results of health and care apps [149]. The UK also attempted a general recommendation directed at their developers, with identified requirements that applied to those in the UK [150].

To address the issue of ineffective silos, the EU and the US sought to find common ground between their respective regulatory policies for mHealth based on mutual challenges and goals. Both based their mHealth evaluations on a risk-based metric, with different levels of classification representing their risk to patients. While both relied upon developers to seek classification, the FDA focused on a sub-set of devices, and the EU's CE-mark cast a wider net on all mHealth to receive the correct risk classification [151]. Established in 2010, the Memorandum of Understanding for transatlantic Cooperation on eHealth/Health IT has been updated as mHealth has developed, with the last identified update being March 2016 [152]. However, it was noted that the FDA is developing its regulations more quickly [151]. To the best of my knowledge, while more costly and time-consuming, the FDA represents the state-of-the-art in specific mHealth evaluation policies due to their ability to address developments in the mHealth field in their regulatory policies more quickly than other countries. By understanding the differences and common challenges, e.g., evolving connectivity of devices, security and privacy concerns, etc., between mainly the EU and the US helps us as researchers to determine the gaps and unmet needs of evaluation attempts.

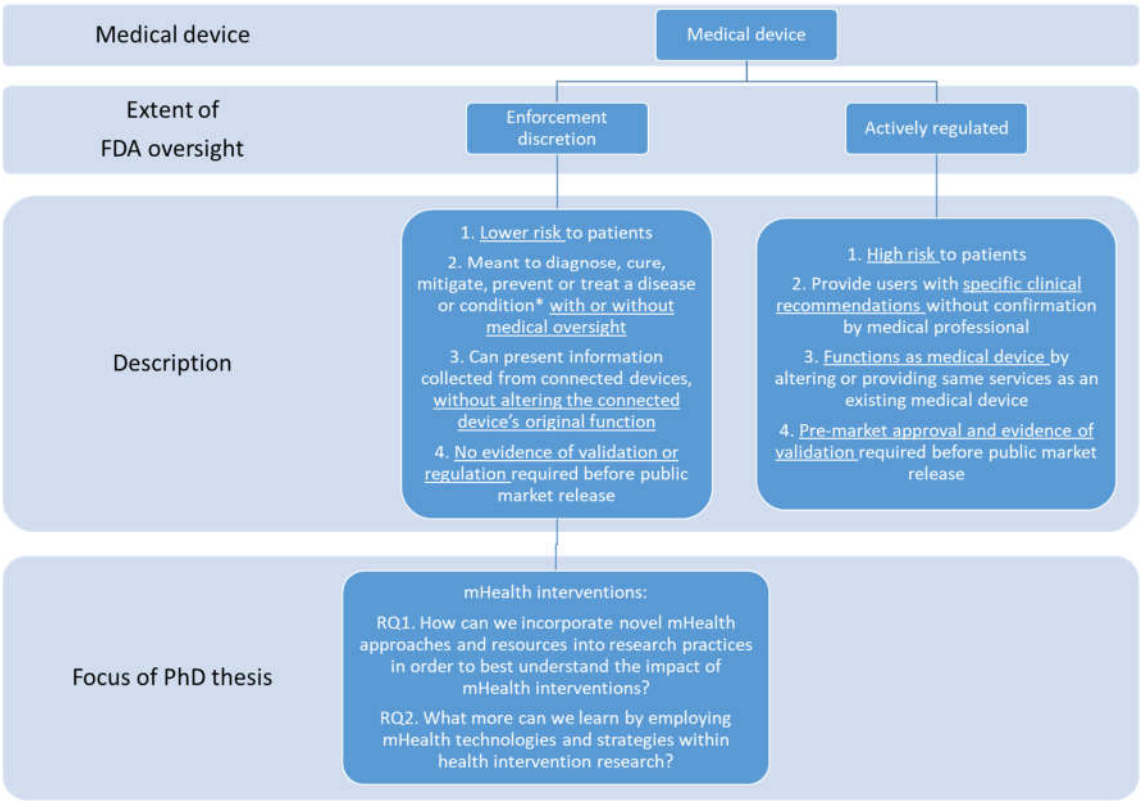
Second, guidelines were constantly changing in attempts to evolve in parallel with app development, making it difficult for stakeholders to keep up. Toward the beginning of the mHealth boom, the FDA took what some considered a "hands-off" approach to app regulation. In their draft guidance in 2011 and final guidance on mobile medical apps release in 2013, the FDA states only apps that were comparable and could be defined as mobile medical devices, presenting a high risk to the user, would be regulated, and not those that presented low risk [153]. Amendments were added in 2015 and 2019 to reflect changes in the mHealth environment and definitions related to mHealth [145]. Even organizations that attempted to address the issue of silos, such as the European Commission, who called on all member states to contribute to mHealth and telemedicine quality guidelines, still fell victim to the need to constantly change their discussions and recommendations [154-156].

Finally, enforcement of guidelines was limited. One problem is that many guidelines are "not legally binding," while others require developers to identify what is relevant for them through an overwhelming number of regulatory documents [157]. The intention with these guidelines was that with quality assurance, consumers would be more likely to use the validated apps – if patients demanded validated and tested apps, then developers would have to comply in order to stay relevant and maintain their market share. Larger developers who look toward the future interoperability and growth of their app do attempt to follow regulatory standards and achieve certification, e.g. through

self-certification models [158]. However, assurance of quality did not always outweigh or outpace the convenience of the online-available apps for consumers, and the struggle continued to provide regulatory influence on the mHealth app environment [159].

2.5.2 Governance of patient-operated mHealth

The patient-operated mHealth technologies exist under the FDA's purview, i.e., "premarket review and post-market regulatory requirements, including but not limited to registration and listing and premarket notification requirements" [160]. The FDA has released an updated guidance document that outlined how mHealth apps would be regulated in 2015 and again in 2019 [145]. In this document, they announced their oversight of mobile medical devices. Those that are considered "devices," intend to 1) "cause smartphones, computers, or other mobile platforms to impact the functionality or performance of traditional medical devices" and 2) "diagnose, cure, mitigate, prevent, or treat a disease or condition" [paraphrased] [161]. Figure 5 illustrates the main differences between those devices that will be actively regulated and those that will not be, i.e., those that research has the most difficulty evaluating due to the lack of specific requirements and guidance.



*Paraphrased from the FDA guidance document *[160]*

Figure 5 Hierarchy of mobile medical devices identifying the focus and scope of this thesis – patient-operated mHealth technologies for chronic illness self-management (copied and edited from Paper 2)

The guidance emphasizes that the level of evaluation and independent review should be commensurate with the risk posed. It encourages manufacturers to use continuous monitoring to understand and modify software based on real-world performance [162].

However, there are no specific instructions for which methods and measures should be used for their evaluation. Several attempts were made by health researchers to evaluate this sub-group of mHealth technologies.

2.6 mHealth intervention research

In this section, I describe more aspects of mHealth to which research could respond. The focus is on the research practices that have the potential to evaluate the technologies that have the least specific guidelines to follow and, therefore, the most potential and need for research innovation, i.e., those considered under the FDA's enforcement discretion. The overall aim of mHealth research can be to bridge the gap between the commercial and medical systems and between HCP and patients. This can be achieved if we appropriately and equally address the unique aspects of mHealth and the needs of stakeholders related to chronic condition care. I aim to describe how methods and approaches of mHealth evaluation are building upon – not replacing - the traditional health research toolbox (**Appendix A**).

2.6.1 The existing "Black Box" of intervention research

There are limitations to the depth and breadth of evidence that mHealth research can provide and, subsequently, what changes could be enacted in real-world settings. **Appendix A** provides an overview of the traditional methods, data, and data analysis approaches available for researchers to choose from when designing an mHealth study. Here I describe the limitations of the traditional pre-post measure study design, which introduces the challenge of the "Black Box" of unknown actions and experiences during an mHealth research intervention (Figure 6).

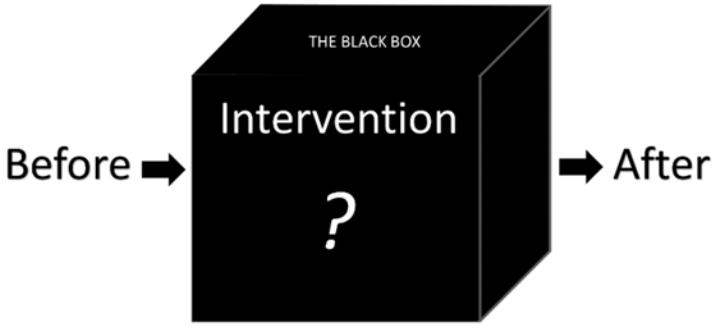


Figure 6 Illustration of the "Black Box" concept of pre-post research study designs

The concept of the "Black Box" is most familiar in the research fields of sociology, technology, and engineering, referring to a process in which you can only control the input and observe the outcome, but not what occurs between the two [163]. In the tradition of pre-post health studies, and randomized control trials (RCTs), research has largely been confined to the "Black Box" approach in its focus on merely finding an input that, ideally, improves the output of an intervention. In 1996, Vickers noted that "a useful analogy for the RCT might be the black box: all sorts of completed things might go on inside the black box…the RCT does not answer all questions of interest in healthcare" [164]. For example, researchers could introduce an intervention whereby the input is the addition of a treadmill and a 6-month exercise regimen to the self-management routines of those with COPD. The observed outcome would, hopefully, be a decrease in symptoms and hospitalizations of the participants. However, the researchers would not necessarily know what happened during that 6-months because

they only took measurements before and after. They could only answer what and how much a measurement changed after the intervention study concluded.

While this is an adequate level of knowledge for the efficacy of new medications or, more recently, medical device functionalities, the impact of which are supported by established biological truths, mHealth for patients self-management brings to light more human-driven factors that determine the efficacy and success of these new health interventions.

> *"To see the world as a self-contained mechanical realm compounded of sets of point-to-point linear cause-effect sequences is out of date in theoretical physics (Capra, 1982), and it is odd that it should still have any claim in the scientific basis of therapeutics… What we need is a research method which devises models of and looks at patterns of interaction among variables, and thinks in terms of the interactive effects of mental expectation and physical treatment" – John Heron [165]*

However, mHealth not only relies upon more factors than standard prescription or adherence but also produces more unpredictable and diverse outcomes, for which there are few and unspecific standard methods of measurement and interpretation. A criticism by Heron succinctly described why we need to adapt and to look at more factors than a pre-post design in intervention research: that the controlled and stringent structures of medical trials tend to produce "limited and misleading view of the multidimensional reality within which practitioners and their patients live, work, and participate in therapy" [165].

Pre-post, longitudinal and randomized control trials are gold standards for producing reliable evidence thanks to their strict and unbiased designs. But – Is "what" has changed the only important factor for patients, clinicians, and researchers? Because mHealth technologies require evidence to be produced quickly and processes to be flexible enough to adapt to the ever-changing nature of these devices, and the different uses by patients, RCTs may no longer be the feasible or most appropriate option [166]. Some of the RCT characteristics that do not always fit with the needs of mHealth are i) control groups, as patients who enter into an mHealth trial can be disappointed if they do not receive the intervention, and make both healthy and unhealthy choices as a result of this, ii) because the same mHealth app, for example, may be used in so many different ways, those assigned to the intervention group may be too heterogeneous in their use for accurate analysis, and iii) the study design, exclusive recruitment criteria, and intervention designs are often so specific and controlled that they do not mirror real-world situations for end-users [167]. We might need to combine qualitative and quantitative methods of evaluation, without abandoning traditional standards or "reinventing the wheel", and identify more continuous, iterative, and patient-involved measures to truly understand not only <u>what</u> mHealth technologies impact but "<u>how</u>" and "<u>why</u>".

"How" and "why" changes occur are more relevant for the HCPs, patients, and the researchers who are designing interventions. These two questions refer to a patients' motivations, capacity, internal and external facilitators of their health self-management. While these factors do affect patients' use of any health technology, there are no prescribed standards or ideal ways for how to use them [168]. The patient's choice is the determining factor when it comes to how the mHealth technology will be used for health self-management and how effective it will be for that individual patient. These "how" and "why" factors have always been present, and we have simply lacked the ability to access them in interventions – in the "Black Box" of pre-post study designs.

2.6.2 Growing pains: adjusting research practice to mHealth

While public organizations and entities attempted to direct answers to consumers [105, 164], health researchers have and continue to work in the background. These consumer-directed solutions are in effect an initial defence or Band-Aid to evaluation challenges. Researchers, on the other hand, are taking the longer approach of developing evidence-based evaluation methods, working to bridge the gap between the consumer facing world and the medical. In 2011, the American National Institute of Health (NIH) organized the mHealth Evidence Workshop, calling for ways in which research can adapt and develop new approaches to evaluate mHealth [169].

mHealth evaluation in health research is a tall order. Challenges in research now include questions about i) how can we, as researchers produce a broader set of information for a more diverse set of stakeholders, and ii) how can we produce this evidence efficiently enough to rival the rapid development of mHealth technologies in the market. Many initial attempts chose to focus on one health area or one aspect of evaluation to avoid drowning in the diversity of uses and designs of mHealth technologies. Literature reviews published within the previous 10 years have focused on the following: barriers and limitations of two-way mHealth communication for those with diabetes, calling for more patient-driven research [170], functionalities and features, calling for more guidance and structure for evaluating reliability [171], and evidence of mHealth interventions' impacts on diabetes health, with a call for a greater quality in the production of evidence [172]. Those preceding these approaches focused on balancing the generalizability of mHealth evaluation with the specific nature of mHealth technologies.

The Mobile App Rating Scale (MARS), published in 2015, had the aim of providing evidence of an app's functionality, visual appeal, information quality, user engagement, and subjective quality [173]. Use of this measure has shown promise because of its quick and easy procedure [174]. A strength was that it could be used during app development to ensure its quality before the app was released to the public. There was also a user-version for individuals (uMARS) [175]. However, there was some question regarding the diversity of apps it could be applied to as it has only been used to evaluate specific types of apps [176, 177]. Some studies had to supplement the scale with additional measures of mHealth impacts, including behavior change. While thorough and comprehensive in their approach, this initiative still lacked two key needs of mHealth evaluation. The first is speed - by the time these evaluations are completed, the technology is often outdated or has been changed significantly based on consumer demands. The second is patient-involvement and measures of their use, perspectives, and needs. As described above, the questions of "how" and "why" patients use these technologies, in particular, are just as important as, and even determine, clinical health change, yet is often not addressed.

With the aim of providing even more accurately tailored evaluation approaches, alternative study designs have been proposed to meet the flexibility needs of mHealth evaluation. As opposed to providing one single, static intervention and study model, Micro-randomized trials (micro-RCTs) using mHealth technologies provide users immediately, or "just-in-time," support for their given health condition based on the users' demonstrated behavior [178]. The Continuous Evaluation of Evolving Behavioural Intervention Technologies (CEEBIT) approach addresses the need of a study intervention, i.e., the tested technology, to be changed at any time during the study. This allows the study to adapt to mHealth technology development as well as what is working and what is not during the intervention [179]. Sequential Multiple Assignment Randomized Trials (SMART) organizes a

study into a series of stages in which one major impact of the intervention is addressed. The outcomes of each stage provide information about mHealth impacts that aid future developments of the mHealth intervention [180].

These adaptive study and intervention designs provide an environment that more accurately reflects real-world situations– with constant changes in patient needs and technology developments. However, these efforts resulted in partial answers regarding effectiveness and relevant information. Given the traditional measures, e.g., static, objective measures of physical and mental health, researchers struggle to measure continuous behavior change and understand how an app is used and why.

We need to take a step back and, given what we know about how most mHealth is developed, consumed, governed and evaluated, ask, "Why are we not getting the answers that we aim for?" Perhaps what we aim for does not fit the mHealth dynamic. Therefore, if what we have been looking at are the effects, perhaps we should look more toward the root of our understanding. Perhaps we should be asking, "What should we aim to understand? How should we go about it? What resources should be used to gain knowledge about this field?" These questions point to the purpose of scientific inquiry, so that is where this discussion will lead – given the overview of mHealth as described above, what approach to inquiry fits the needs of mHealth intervention research?

2.7 The purpose of science: a paradigmatic approach to inquiry

The purpose of a scientific inquiry changes what and how questions are asked and which approaches, methodologies and specific methods and measures are used. After all, if there was only one purpose to research, e.g. only qualitative or only quantitative, we would be left without understanding of the probability and representability of our qualitative outcomes, or without real-world context and explanation for the quantitative outcomes of intervention groups. However, simply acknowledging the methods and measures used and arguing that one or the other will give us the best understanding, does not adequately describe the aim or purpose of research. To explain how and why we as researchers choose certain methods, measures and study designs, I will introduce research's philosophical roots, i.e. the different logical, ontological, epistemological perspectives and specific paradigms used to approach knowledge generation and understanding.

A paradigm is a "set of beliefs that guide action" [181]. It encompasses a set of values, beliefs, attitudes and methodologies that reflect assumptions about i) what the researcher believes is valuable and ethical (axiology) [182], ii) what is the nature of reality, or what is real or true (ontology), iii) the nature of how one knows what they know (epistemology), and iv) how one can and should go about discovering that knowledge (methodology an associated methods).

Here I will focus on three relevant paradigms and discuss how these shape the assumptions about the purpose, nature and approaches to diabetes mHealth intervention research. The three paradigms of positivism, pragmatism and constructivism can be described as existing on a spectrum – with positivism at one end, constructivism at the opposite end and pragmatism lying somewhere in the middle (Table 1) [183]. Although the most widely accepted view of these paradigms is that they are mutually exclusive, I acknowledge that it is possible to complete qualitative research using a positivist paradigm. For example, from an epistemological point, it is possible to describe regularly occurring relationships between distinct factors in a non-statistical way [184]. However, such practice is not

common. Acknowledging the traditional and distinctive paradigms that have been accepted for quantitative (positivism), qualitative (constructivism) and mixed-methods (pragmatism) research [185] can help us to distinguish between the main characteristics of these different approaches to demonstrate the scope, limits, values and future needs of these approaches when it comes to mHealth interventions research. While several other paradigms exist, I will focus on the comparison of these three paradigms in parallel to the characteristics of the mHealth self-management realm for diabetes, as described above, in order to illustrate why the paradigm of pragmatism is best suited to this thesis. Note that while this table is a simplification and stereotype, it allows us to compare the ways in which most research is performed and from which dominant perspective so that we can more clearly identify the best combination of approaches for this pragmatic thesis. Again, these paradigms are, in fact, not mutually exclusive but exist on a spectrum from radical positivism to radical constructivism.

Table 1 Illustration of the continuum of research approaches by explaining three established research paradigms

	Positivism	Pragmatism *(multiple paradigm/ dialectical pluralism approach)*	Constructivism
Purpose	Identify verifiable, generalizable patterns	Provide comprehensive understanding of phenomenon	Explore, understand a phenomenon
Logic	Deductive	Abductive	Inductive
Axiology	Facts are valid. Values are not (too subjective)	Objective & subjective points valued at different stages of exploration of a phenomenon	Values of researchers and participants shape/influence the outcomes
Ontology	Single objective reality	One reality that can be interpreted differently, e.g. changes with time, geography, personal perspective	Multiple realities influenced by one's environment
Epistemology	Knowledge is measureable	Use the most appropriate resource for the question at hand. Knowledge based on experience	Knowledge is individual
Methods	Quantitative	Mixed-methods	Qualitative
Strengths	Distinct and precise results, (assumed) generalizable	Flexibility, incorporate strengths of both extremes, qualitative can explain quantitative	Detailed, explanatory
Limitations	Does not reflect differing social realities	Not generalizable to different contexts, reality changes with time, potentially conflicting interdisciplinary perspectives	Not generalizable to other contexts

2.7.1 Positivism: the objective, quantitative approach to measuring a single reality

Each approach to research has its place, especially in the field of mHealth for diabetes and other chronic illnesses. As described in the previous sections, traditional research within medicine is largely quantitative and based on established, repeatable and largely generalizable patterns of biological occurrences, i.e. the natural sciences. In medical research, positivist approaches aim to provide evidence that has minimal bias and risk of misinterpretation. The outcome is largely traceable and relationships between intervention and outcome can largely be predicted and applied to general healthcare practices. The role of the positivist inquiry is to identify reliable patterns that we can, in the case of healthcare, base our decisions and actions upon in order to provide the most benefit to the most people. Its value is reflected in the progress and understanding of biological sciences and the successful improvement of patient care.

For diabetes, objectively measured relationships between, e.g. insulin, carbohydrates and blood glucose has provided significant benefit to individuals in their self-management practices. Understanding of insulin sensitivity factor and e.g. the rules of 500 and 300 have allowed for evidence-based yet person-specific and practical ways in which individuals can understand their own needs for insulin in response to carbohydrates, in order to achieve healthy blood glucose levels. A literature review of current knowledge of insulin sensitivity and dosing calculations demonstrates that the more data gathered about a phenomenon can lead to a more accurate understanding of that phenomenon [186].

Deductive reasoning or logic was and still is appropriate for drug trials and other interventions whereby the "behavioural" portion of the intervention is limited to the individual performing or not performing a prescribed task such as following a medication regimen. Common positivist practices within research within medicine include RCTs, standardized questionnaires and surveys [185]. These types of studies reflect the positivist paradigm whereby objective measurements, deductive reasoning and the acknowledgement of one, knowable and universal reality exists [185]. It is relatively straight forward and expected to objectively measure "what" has changed. Physical changes can be measured using specially developed technologies such as BP-cuffs, professionally calibrated weight scales, or blood tests. While it may be easiest to associate these largely quantitative methods with such measurements of observable and objective results, the Positivist paradigm also acknowledges ways in which subjective measures, such as wellbeing and self-efficacy, can be objectively accounted for. Psychological changes can be measured using understanding of human behaviours, often measured via standardized questionnaires or surveys, which are based on established theories of societal dynamics and human instincts [187].

This mentality spread from research approaches to evidence to healthcare education and practice [188]. The positivist paradigm is a means to make objective and evidence-based decisions – based on research - in care practice that can do the most good for the greatest number of people. "What" has changed, as the result of a health intervention, is most relevant for HCPs' decision-making when treating or guiding a patient. These changes would trigger the HCP to consult their library of learned knowledge or established clinical protocols to determine if that course of treatment is working or not. It is a cycle of how healthcare practice and research continue to reflect and impact one another, which explains how the positivist approach became the gold standard and foundation for today's approach to both chronic illness, including diabetes, care and self-management. In fact, Wilson provides a pointed summary of his opinion that health education and exploration traditionally has operated from a set of assumptions whereby health is independent of a person:

> *The definition contains several implicit assumptions. Firstly, the idea that disease can be considered as separate from the person with it, like other naturally occurring phenomena. This implies that apart from the doctor's biological interventions, a disease will continue to run a well-defined course, quite independent of the patient's context or beliefs. Secondly, the inherent logic is one of simplistic cause-and-effect: substance A will act on substrate B, causing effect C. Thirdly, the doctor is expected to remain 'distant' from the patient, rather like a natural scientist. This implies that the interaction between doctor and patient would have no influence on the outcome of the disease. The 'detached observer' is a well-known phrase that describes this 'correct' approach to the patient." [189]*

Wilson continues to explain how these assumptions are incorrect and inapplicable to the research of chronic illnesses today. While positivism's strengths were objective, and seemingly universal truths about disease function in response to traceable intervention components, positivist (quantitative) approaches to research on mHealth interventions do not give concise and actionable results. The understanding of more social sciences, in addition to natural sciences, is required for mHealth and diabetes care. The following aspects of diabetes and mHealth demonstrate this need: i) behaviour is a significant determinant in both type 1 and type 2 diabetes, ii) motivation, intention and ultimate action affects the benefit of mHealth, and iii) the diversity of mHealth technology uses clouds, to a certain extent, any cohort study (i.e. the basic assumptions of positivist approaches and objectivity, i.e. that reality is only that which can be observed by human senses, do not hold). In other words, positivism tries to focus on more objective factors than individuals' motivations, intentions and beliefs. Positivism can lead to the identification of patterns within observations but does not seek to understand why they are happening. For non-communicable chronic illnesses, including diabetes which is by definition is an illness dependent upon behaviour, this traditional doctrine, on its own, does not begin to scratch the surface of describing how diabetes care is or should be treated.

2.7.2 Constructivism: a subjective, qualitative approach to understanding different realities

While the positivist approach can provide a solid foundation of "what" can change, the interpretivist or constructivist paradigms, with their inductive reasoning, came about – yet only gaining popularity recently in the 1960's and 70's- as a response to the limited knowledge of "why" something has occurred [185]. Constructivism, characterized by qualitative approaches to inquiry, is more appropriate when the purpose of the research is to understand, for example, satisfaction with healthcare services and potential improvements to better engage individuals. It is the belief of constructivists that by understanding an individual's perception and experiences of, for example, their diabetes health, researchers can better explain and/or explore patterns in individual's behavior, e.g. motivations. In practice, constructivist researchers put this ontology and epistemology into practice using more interactive methods than positivism suggests, such as interviews, focus groups and/or observation of participants' every-day lives. This allows for previous assumptions and knowledge to be questioned, reassessed and updated given the more recent contextualized findings [185]. Within diabetes and intervention research, it is only through the qualitative approach that previously unaccounted for factors can be brought to light, and the impacts of which on the topic of inquiry explored.

Such qualitative inquiry and social science perspectives were considered a revolution to the health sciences when they were argued for in 1995, as an alternative to quantitative methods for understanding health [190]. While healthcare professionals considered RCTs as the gold standard - a valued positivist tool in medical research - many found it difficult to apply the RCT interventions and achieve the same outcomes as were demonstrated in published studies. In the case of diabetes, although a technology such as an insulin pump or continuous glucose monitor has been validated for its biological effectiveness, its ease of use and practicality affect an individual's willingness and ability to use it. So regardless of any beneficial impact it has shown from the positivist perspective, from the constructivist approach, a person's decision to use the tool and how they use it has the greatest impact on the technologies' effectiveness. Like the positivist paradigmatic approach to understanding health outcomes, constructivism applied to mHealth research does not give concise results. However, it can lead to new knowledge and actionable outcomes when, more or less,

generalized by identifying technical patterns from lay accounts of stakeholders' experiences, "constructing models of typical meaning" [191] or theories to explain a situation, i.e. the use of mHealth in diabetes consultations, which can then be further explored.

On the other hand, pragmatism as a "middle ground" focuses on how best to approach the field and formulate the research questions, without loyalty to one of the aforementioned paradigms. More importance is placed on exploring a situation or phenomenon instead of coming to a conclusion about that phenomenon. The pragmatist paradigm encourages researchers to approach a situation with the assumption that there is a single reality that periodically changes with time, which is possible to observe and interpret from different perspectives [192]. I continue this section by exploring the middle concept of the pragmatism paradigm and its appropriateness for diabetes and mHealth intervention research using mixed-methods.

2.7.3 Pragmatism: a mixed-methods approach to gaining knowledge about mHealth intervention research for diabetes

This thesis uses diabetes as a case, via the FullFlow Study, to explore how mHealth can help researchers adapt to the rapid change in technology used for individuals' own chronic illness self-management. mHealth technologies for self-management is a relatively new and unexplored field; systematic reviews have not led to a consensus about the medical impacts of, e.g. smartphone apps and wearables. Even while some systematic reviews suggest the potential medical benefits of using mHealth apps in conjunction with regular diabetes care coordinated via an HCP, they still do not answer how these can be accomplished in real-world practice [110]. Whereas positivist and constructivist paradigms have been most commonly seen as mutually exclusive- focusing on different phenomenon- I side with Johnson in his 2011 article describing Pragmatism as "dialectical pluralism" [193]. In this perspective, mixed-methods researchers can combine approaches to understand, not conclude on a single truth to explore multiple perspectives, accepting contradictions and basically living the phrase "it depends" through their practice and interpretation of research. Research fields or disciplines do not, and should not, "own" certain methods. If so, then researchers are deprived of resources when they are prevented from looking beyond the current trends in their own field of expertise. The benefit, Johnson argues, is that by approaching research in such a way, it is possible to bridge understanding between the varying values of different ontologies, epistemologies and methods. However, an important concept to keep in mind is that, due to the pragmatist assumption that reality changes with time, researches' ability to generalization outcomes is affected by time. In other words, generalizations may become less relevant or outdated given changes in the context and/or the progression of time.

In this section, I will explain how pragmatism reflects the needs of such research by separating out the three main concepts: i), mHealth interventions research, ii) mixed-method research, iii) diabetes self-management, care and research (Table 2). I will use the background of these three concepts, as described until now, to demonstrate how the pragmatist approach from the perspective of dialectical pluralism both addresses and parallels the characteristics of this multifaceted research field.

Table 2 Summary of how the characteristics of Pragmatism paradigm from the perspective of dialectical pluralism is an appropriate lens through which to understand the three main concepts of this thesis: mHealth, mixed-methods research in practice and diabetes.

	Pragmatist	mHealth	Mixed-method research practice	Diabetes
Purpose	Provide comprehensive understanding of phenomenon	• Aids patients in understanding their own health from perspectives of BG levels, impact of activities and decisions on health etc. • Aids healthcare providers in understanding their patients' self-management status more continuously	• Exploratory • Explanatory	Requires understanding of biological and emotional/psychological health, behaviours, available resources/ support etc.
Logic	Abductive		• Qualitative feedback can explain why, when and how quantitative measures of self-management were taken • Quantitative measures and their change can demonstrate the success of motivations, decisions and actions on health status	The success of treatment requires: • Deductive reasoning based on clinical measures • Inductive reasoning based on a person's experience of their health to determine the feasibility of the treatment
Axiology	Objective & subjective points valued at different stages of exploration of a phenomenon	• Recording BG, diet and other quantitative measures in a standard way is objective. • Reflecting on these measures allows for individuals subjectively judge the appropriateness and success of those self-management activities	Complementarity of qualitative and quantitative methods and measures explored via e.g. triangulation	• Disease is objective • Illness is subjective. • Understanding a situation/context requires both subjective and objective perspectives at different stages

Ontology	One reality that can be interpreted differently, e.g. changes with time, geography, personal perspective	• Patients, healthcare providers and authorities, informal carers and developers have different agendas and perceptions of what is needed to support diabetes care (including differences within groups). • The purpose and intention of app use changes with time and a person's increased knowledge/ self-efficacy and their provider's understanding of the patient's situation and the technology • While people may use the same app, they may use it in a different way. • Different geographical regions and other contexts either support or challenge individuals' use of mHealth, which affects their experience.	• Interdisciplinary research teams are often used • Participants can include end-user "experts" from different backgrounds • Triangulation of interpretation of data from related yet different studies	• Health influenced by behaviour • Illness is a personal experience affected by available resources, personal beliefs etc. • Reality changes with time, experience, shifts in society/resources etc. • Experiential learning • Generalization has been practiced in the clinic yet is being questioned as the appropriate approach to diabetes care today
Epistemology	Use the most appropriate resource for the question at hand. Knowledge based on experience	• The different functionalities allow for a variety of different uses. • Patients, and to some extent providers, can choose to use mHealth in the way that best fits their needs, i.e. heterogeneous intentions.	Different ways in which qualitative and quantitative measures can be used and interpreted depending on the study and research questions	• Self, health and technology efficacy based on experience. • Tailorable approaches to care being promoted in clinical treatment

Pragmatism for diabetes research

Annemarie Jutel describes it clearly and distinctly when she writes "disease is diagnosed, illness is not" [194]. Instead, "illness is the personal experience of sickness" in which a person experiences disruption to personal function as a part of society. As such, this concept of illness is affected by culture, external resources, self-efficacy etc., whereas, in the traditional biomedical model, disease and diagnosis are reflective of measurable biological dysfunction. This distinction between terms will help us to differentiate between what healthcare providers and individuals aim to achieve through self-management of an individual's illness, disease or both. This acknowledges that the distinct yet interconnected roles of patients and providers in the reality of diabetes care, which must act and exist separately and together. This complex adaptive system clearly calls for the ontology of Pragmatism, which can compensate for the diversity of moving parts and influencing factors in order to determine the needs of both parties separately, i.e. self-management and clinical care, and together, i.e. as a collaborative team in consultations (a goal of healthcare as described above). Both in clinical practice and self-management, the abductive logic of Pragmatism describes how patients and providers can use deductive reasoning to assess the individual's health status using, for example, blood glucose levels and HbA1c values, respectively, as well as inductive reasoning to understand if a suggested self-management recommendation or change is feasible given the individual's personal situation.

Understanding the concept that all input is considered differently yet equally is necessary when considering the various stakeholders, their priorities, needs and roles in diabetes care that are required

to work together to achieve interacting goals, the modalities to which evolve as technology and knowledge evolve. For example, while all may share the goal of improving an individuals' diabetes health, their motivations may vary from personal, e.g. the individual hopes to feel better and regain their loss of social function or wellbeing, to systemic, e.g. health authorities wish for those who can effectively self-manage on their own to do so in order to reduce the burden on health services.

Given the variety of medical, mHealth, social media and other channels of support, the Pragmatist epistemology of "use what works" is most appropriate when patients and providers make these recommendations. For example, the generalized treatment recommendations and "approved practices" historically have only been to prescribe insulin to those with T1D and not those with T2D. However, healthcare providers have found that more tailored approaches are called for to fit the needs of those, in this case, with insulin dependent T2D, which are reflected in *The Standards of Medical Care of Diabetes – 2020 [195]*.

As described by Maarouf [192], "The Reality Cycle" is a reflection of the ontology of pragmatism whereby knowledge is both built and evolves with time based upon new realizations and experiences. This cycle parallels the assumptions of diabetes self-management; the meaning and intention of an individual's diabetes self-management, use of health aids and healthcare services change with time. Examples of this change are a (hopefully) increased knowledge and self-efficacy as well as an improvement in their provider's understanding of their situation. Diabetes is their reality - which has measurable and theoretically predictable patterns of change, i.e. how diet or insulin affect blood glucose levels - but which is also experienced differently - it is shaped by a person's internal and external context.

Pragmatism for mixed-methods research

Mixed methods research values i) the complementarity and utility of multiple methods but also paradigms as well as iterative applications of inductive and deductive logics, ii) a range of research scopes from the empirical to conceptual, iii) acknowledging that the phenomenon in question are also living things – not static or universal [193]. Contexts that more commonly call for mixed-methodologies include health services research as a whole and more specifically . These represents "complex adaptive systems" of interconnected actors and influences, of which diabetes care is an example. Mixed-methods are becoming more common for diabetes self-management research as the qualitative understanding of an individual's behaviour, also through the aid of mHealth technologies, is seen as just as influential to understanding the impact of an intervention as quantitative clinical knowledge is about biological function.

A quick search through PubMed database using the search string [review AND diabetes AND mixed-method*] revealed few literature reviews for mixed-methods studies of adults with diabetes within the past 20 years found n=14 articles [196] and n=59 studies [197]. This demonstrates that while there is potential of understanding the addition of input and knowledge from "patient experts" to diabetes care research, it is not commonly practiced. Of the14 studies performed, it was found that the majority of mixed-method studies focused on the nursing profession, i.e. more patient experience related, rather than the medical profession, i.e. more clinically relevant information. This suggests that knowledge generated through mixed-method studies does not include nor is it transferred to clinicians. The lack of clinician participation and focus has a significant impact on how clinicians approach diabetes care; it perpetuates the lack of information and knowledge transfer about patients' experience and its impact

on diabetes care, to clinical practice and education. Instead, this suggests that the majority of the information that clinicians use for their evidence-based practice remains positivist, objective and quantitative.

Pragmatism for mHealth research

mHealth exists in a constantly changing world, and is affecting the world of health practice. The fact that these technologies were developed outside of the traditionally objective and positivist realm of medicine contributes to the need for research to develop "knowledge" instead of searching for "answers". Pragmatists believe that the ability of something to function in a way that helps the user to achieve their purpose or goal [198] parallels the diversity of potential uses of mHealth technologies which are based on the intention of the user. Dewey, a prominent philosopher of pragmatism, valued the understanding of the relationship between actions and consequences – another concept that is reflected in one of the primary purposes of mHealth, as a learning tool. The epistemology of pragmatism is that knowledge is based on experience [199] also parallels the idea that individual users of mHealth technology are "experts" in their own right, similarly to the expert knowledge of HCPs. Users can gather evidence of their self-management and reflect upon consequences of those actions. Individuals, as well as their care teams, can then learn from those decisions and outcomes in order to make better, more effective decisions in the future. As such, users of mHealth for diabetes can be described as pragmatists; they decide the best action to take to optimize beneficial consequences or outcomes based on their experience, i.e. gathered knowledge about their situation.

3 The Ph.D. setting, objective, research questions

The main objective of this thesis was to explore how we as researchers can adapt our inquiries about the use and impacts of mHealth, with the goal of providing more relevant and practical knowledge that is useful for mHealth stakeholders. Ultimately, I hope that this thesis will bring understanding to the conversation of mHealth in medical research and, subsequently, health care.

3.1 The thesis: part of a larger mHealth intervention project

In this thesis, I explored relevant approaches, methods, and measures that could be used during health intervention research to understand the impacts of modern mobile health (mHealth) technologies. These works were completed as part of a larger project, *Flow of health data between patients and the health care system* (FullFlow). The FullFlow Project was funded by the Norwegian Research Council's IKT Pluss program and coordinated through the Norwegian Center of E-health Research (NSE). The Full flow project acted as an environment in which I could test specific approaches methods and measures to determine what effects we could measure and information we could gather from introducing patient-gathered app data to diabetes consultations.

The FullFlow Project itself aimed to design, develop, and test a system for sharing patient-gathered diabetes data from patients' mHealth devices to their healthcare providers (HCPs during consultations. The intention was to design and test a system that would enhance collaboration between patients and their providers related to diabetes treatment and self-management decisions by identifying and presenting relevant data to act as the basis for discussion.

The approach of both my thesis and the activities of the FullFlow project (2016-2020) was to explore how mHealth could be used as part of the intervention as well as a means of data collection through a series of smaller research activities followed by tests of learned concepts as larger studies. Included were the challenges and opportunities that mHealth brings to medical research and services. In doing so, we aimed to systematically understand the complex, fast-paced and interdisciplinary nature of sharing patient-gathered data (PGD) from mHealth technologies. Concepts that were found to be feasible and sustainable in this environment were pursued in the central FullFlow Project activities.

My Ph.D. included four central studies, detailed through the four main, chosen papers: a literature review to gain a basic understanding of this area and use three cases. I tested theories for how researchers can utilize mHealth approaches and resources to address the opportunities and challenges of evaluating medical and health research interventions. These followed the sequential exploratory strategy.

The introduction of mHealth technologies, approaches, and resources has certainly affected expectations and opportunities of research for chronic illness health interventions. With diabetes as a use-case, I will exemplify how these technologies answered patients' demands for support and how this, in turn, presents opportunities for the medical system to adapt, which evidence research should and could produce.

3.2 The setting of Ph.D. activities

In this section, I describe the regional setting of the Ph.D. activities with a focus on the population, health status, and healthcare access. I aim for this information to provide context to the generalizability and limitations (described below) associated with living with T1D or T2D or similar chronic conditions.

Tromsø, Norway: a region of northern Norway, situated north of the Arctic Circle with a population of approximately 167,000 (2019). Approximately 65% of the population is between the ages of 15-64 years old [200].

Population: Residents of Norway enjoy a relatively high average income compared to other EU countries. Employment rates are steady, with only a -0.1% decrease from 2018-2019. In Norway, 80% of employees in the fields of "human health and social work activities" were female, with nearly 12,000 employees in Tromsø between the ages of 15-74 as of 2019, showing an 800 employee increase since 2016 [201].

Health overview: When compared to EU statistics, Norwegians fare significantly better with regards to mortality rate, unmet healthcare service and support needs, and health status. Norway also has the highest life expectancy of 82.7 years, compared to the EU average of 80.9 years (2019). A contributor to this is a decrease in risk factors, including alcohol consumption, smoking, and obesity in the past 20 years. While these are still less than the EU averages, poor diet and tobacco use are associated with 15% of deaths, each, in Norway. Leading causes of death in 2016 were noted as COPD and heart disease. Following the global trend, obesity is also a growing concern among children (16%), and adults (14%) [200].

General access to care: All residents have access to public healthcare services and resources with universal care in Norway. Healthcare is referral based, meaning individuals must go through their

assigned general practitioners (GPs) in order to seek specialist care. Within this sector of services, patients pay an annual maximum of just over 2,000 NOK before receiving care free-of-charge. Out-of-hours and emergency services are also available. Individuals may have access to private specialist care more quickly if they are willing to pay out-of-pocket [202]. Care for those with chronic conditions accounts for 28% of total care spending, which is significantly higher than that of other EU countries [200].

General healthcare providers: Each GP office has from 2-10 GPs practicing at any time, each operating as individual economic entities, with the addition of nurses in some surgeries [200]. While patients are assigned to a GP, they have the option to change GPs.

Specialist and hospital HCPs: Prevention rates for chronic illness complications in Norway is second only to Denmark, meaning less unnecessary hospital admissions [200]. Hospitals work as a network, with one central hospital in each region surrounded by hospitals with more capacity for acute care. Waiting times are still an issue for elective procedures [200].

3.3 Objective

In this thesis, the purpose of mixed-method research is to measure changes and reasonably explain the correlations between, as well as differences, deviations and variations of outcomes. The way in which the methods and results are presented should of course be detailed in such a way that others can replicate the activities and draw their own conclusions to contribute to the foundation of knowledge that research, or in some cases, draw conclusion about the positive and/or negative impacts of a health intervention. However, the aim of this thesis is not to conclude upon or disprove the effectiveness of other research methods or health interventions, based on the paradigm of pragmatism. The aim of this thesis is instead to contribute to the foundation of knowledge – of understanding – upon which we base our future research and questions and actions related to mHealth interventions for diabetes self-management.

3.4 Research questions

RQ1. What information, support, and functionalities do patients, general practitioners, and specialists who work with diabetes, need and expect from mHealth tools?

RQ2. What approaches, methods, and measures are being used to collect data for the evaluation of mHealth interventions for chronic illness self-management?

RQ3. Can mHealth usage-logs and patient-centred analysis be used to provide more evidence and information about what, how, and why changes occur during an mHealth intervention?

RQ4. How can mHealth approaches and resources supplement traditional methods and measures in a protocol describing how to measure impacts of an mHealth intervention on patients and HCPs?

The structure of this thesis is to first present the methods that were used to address the research questions. In the Methods and Materials, I will describe the main purpose of each method and how it was used in this thesis. In the Results, I present the outcomes of utilizing mHealth approaches and resources in these methods via four papers. These papers describe the major results of our use of trialled methods. The discussion and conclusion cover how these works contribute to our

understanding of how intervention research can incorporates mHealth approaches and resources to not only address the challenges and opportunities that mHealth technologies present to patients and HCPs, but also to researchers and health authorities.

The works described in this thesis (Table 3) illustrate a step-by-step process through which I i) explore what both patients and HCPs deem important and relevant, ii) identify the state-of-the-art for how researchers are evaluating modern mHealth interventions, and iii) trial two ways of incorporating mHealth approaches and resources into the evaluation of an mHealth intervention for sharing patient-gathered diabetes data, which aimed to meet the needs of patients and HCPs.

Table 3 Corresponding methods and results that address each Research question

	Research question	**Methods used**	**Results published in…**
RQ1	What information, support, and functionalities do patients, general practitioners, and specialists who work with diabetes, need and expect from mHealth tools?	- Patient survey and HCP workshop	Appendix C
		- Co-design workshops	Paper 1
RQ2	What approaches, methods, and measures are being used to collect data for the evaluation of mHealth interventions for chronic illness self-management?	- Grey literature review	Appendix D
		- Scoping literature review	Paper 2
RQ3	Can usage-logs and patient-centred analysis be used to provide more evidence and information about what, how, and why changes occur during an mHealth intervention?	- Usage-log analysis from the Tailoring project	Appendix E Appendix F
		- Usage-log analysis from RENEWING HEALTH project	Paper 3
RQ4	How can mHealth approaches and resources supplement traditional methods and measures in a protocol describing how to measure …	Development of a mixed-method feasibility study protocol	Paper 4 Appendix K Appendix P-Q
	…impacts of an mHealth intervention on patients and HCPs?	Feasibility study results	Appendix G-J Appendix L-O

3.4.1 Candidate's contributions to thesis studies and papers

Each of the smaller and more iterative studies described in this thesis culminated in larger studies to confirm and expand upon the results found during the smaller studies. These larger studies are described in the thesis Papers 1-4, while the smaller studies are detailed in the appendices. My contributions to each of the activities is detailed in the Table 4.

Table 4 Details of candidate's contributions to each study described in this thesis

Activity	Study design	Literature review (reviewing literature in the field)	Choice and refinement of study methods	Design of data collection tools	REK application and PVO	Recruitment	Data capture and cleaning	Data analysis and interpretation	Write-up
Appendix C	X	N/A	X	X	X	X	X	X	X
Paper 1	X	X	X	X	X	X	X	X	X
Appendix D	X	X	X	X	X	X	X	X	X
Paper 2	X	X	X	X	N/A	N/A	X	X	X
Appendix E		N/A					X	X	X
Appendix F		N/A					X	X	X
Paper 3	X	X	X				X*	X**	X
Paper 4	X	X	X	X		X	X	X***	X
Appendix G-J****	X	N/A	X	X	X	X	X	X	X
Appendix K	X	X	X	X	N/A				
Appendix L-M****	X	N/A	X	X	X	X	X	X	X
Appendix N	X	N/A	X		X				
Appendix O****	X	N/A	X	X	N/A	X	X	X	X
Appendix P	X	X	X	X	N/A	X	X	X	X
Appendix Q	X	X	X	X	N/A	X	X	X	X

*Cleaning only
**Guided by second author of the paper (I contributed approximately 40% of the analysis)
***Data analysis and interpretation of data as a result of the study protocol provided in Section 6.5
**** All of these activities were part of the mixed-method feasibility study (the protocol for which is described in Paper 4)

Journals allow us to designate (via symbol in the author list) who contributed to the study and manuscript. According to the Vancouver rules, those who contributed to the study and/or manuscript should be offered co-authorship. However, it is not always possible to differentiate which persons contributed to the study vs. the manuscript. In the manuscripts included herein, many of the co-authors contributed primarily to the study design and coordination and therefore are listed as contributing equally, and, yes, were involved in approving and editing the manuscript but were not equal contributors during that process compared to myself and co-authors listed in more senior positions of the author list. That being said, I am sole first author for all four manuscripts included in this PhD thesis and include details in Table 5.

Table 5 Points justifying candidate's sole first authorship in each paper included in this thesis

Paper	Generation of research question(s)	Contributed to analysis plan	Invited and coordinated communication between co-authors*	Generated all drafts of manuscript*	Creation of figures and tables	Identification of journal (role of corresponding author***)
1	X	X	X	X	X	X
2	X	X	X	X	X	X
3	X	X	X	X	X****	X
4	X	X	X	X	X	X

*Co-authors for each manuscript were invited based upon their expertise in that particular field to guide the appropriate and clear methodological approach
**Included: requesting and incorporating input from co-authors for each major draft of the manuscript as well as editing the manuscript in response to journal reviewers' and editors' comments.
*** Included: securing and coordinating publication funds and being solely responsible for all tasks of submission and publication once accepted
****Drafts and confirmation of figures used in Paper 3 were secured through second author of the paper

4 Materials and Methods

I present the type of information that can be obtained by using mHealth-enabled research approaches including a) involving end-users throughout a research project, b) utilizing data and associated information that end-users gather by using mHealth and c) using a mixed-method approach to more comprehensively understand how an mHealth intervention can affect patients and providers together.

Based on the description by Onwuegbuzie and Combs (2010), this project involved analytical techniques of mixed-methods research that are applied iteratively, largely following pragmatism as my research paradigm. I use the purpose/rationale of i) triangulation of the data (using multiple sources and analytical approaches, often involving an interdisciplinary team to increase credibility/applicability of research outcomes, i.e. understanding of a phenomenon from multiple view points by comparison and integration of quantitative and qualitative results gathered from different but related studies) [203], and ii) exploration (understand a phenomenon and test propositions resulting from earlier qualitative phase, in a "Sequential exploratory strategy" [204], which is often used when designing a new tool or intervention. We followed the design type, as described by Subedi as a multi-phase design [205], following the phases of i) deciding an overall project objective, ii) performing a qualitative study (or studies), which informed iii) another qualitative or quantitative study, which informed iv) a mixed-method study (Figure 7).

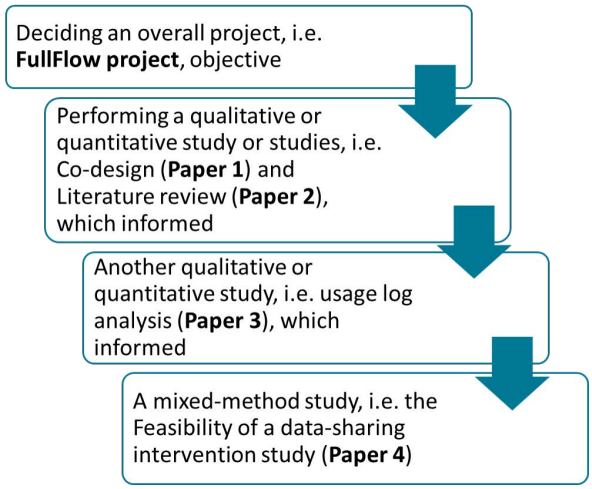


Figure 7 Details of the sequential exploratory strategy of inquiry for the presented thesis

The aspects of pragmatism that are reflected in this thesis include subjective researchers, involvement of end-users in the iterative design and testing of the intervention, basing the design and purpose of subsequent studies within the project on end-users' needs and priorities in diabetes care, flexible and exploratory study designs, the intention of applying gathered knowledge to an eventual possible solution to the initially identified problem.

4.1 Co-design workshops

A series of co-design workshops were arranged to understand the end-users', i.e., both patients and HCPs, needs for a system to share diabetes app data during consultations. These activities aimed to answer **RQ1** and were carried out as part of the FullFlow Project.

Co-design, or Experience-based co-design (EBCD), is a participatory research method whereby those who would be the end-users of a product or service are invited to help design and develop said product or service [206]. By addressing specific users' needs and understanding their expectations, co-design aims to produce something that will be used sustainable and perform the way in which the end-users need.

In the case of the FulFlow project, it was intended that the data-sharing system be operated by both patients and HCPs, together. The design and development of the system itself needed to be informed by i) both HCPs' and patients' reported needs related to diabetes care, and ii) which questions and activities could be used during the workshops to empower these two end-users to offer input and constructive ideas about how mHealth could meet those needs.

4.1.1 Patient survey and co-design workshops with HCPs

The series of co-design activities aimed to address these points began in 2016 with an anonymous survey, which was accessible via a link posted on various patient Facebook groups in Norway. Questions were multiple choice and addressed i) the patients' ideal consultation discussion, given the chance and time to share their own app-gathered data, and ii) their experienced diabetes self-management challenges. Patient responses were then presented to HCPs during a workshop. HCPs were called upon to i) comment on these responses in general and ii) imagine how a system for

sharing patient-gathered diabetes app data should function during a consultation to address the reported needs of the patients and clinical practice of GPs and specialists in diabetes care. The HCP workshop was audio-recorded, transcribed, and translated into English for analysis.

4.1.2 Co-design workshops with both patients and HCPs

The results from the separate patient and HCP co-design activities were used to inform the design of joint workshops. Building upon these results, we held two final workshops: one in 2017 for patients with T1D and diabetes specialists, and one in 2018 for patients with T2D and general practitioners. Each workshop consisted of three sessions: one for patients and one for HCPs in the mornings and a joint session, including both parties in the afternoons. By conducting joint sessions – an uncommon approach due to the typical hierarchy experienced during clinical consultations - we aimed to demonstrate the amount of information that could be gathered by encouraging both patients and HCPs to discuss opportunities, challenges, and solutions for an mHealth data-sharing system, together.

The discussion guide for the separate sessions included an introduction and ice-breaker, followed by a series of rapid-fire and discussion questions. Rapid-fire questions allowed participants to establish their own opinions, without interference from others, before group discussions. Discussion questions allowed participants to reflect upon their own and one another's responses. Included questions addressed a) participants' perceptions of their roles and responsibilities in diabetes care and mHealth and b) the potential of sharing patient-gathered data during consultations.

The discussion guide for the joint session allowed patients and HCPs to collaborate on the design of a system for sharing patient-gathered data during diabetes consultations. Participants were asked to summarize the main points from their separate sessions to one another and discuss their ideas and designs for the ideal mHealth data-sharing system. Activities were structured in the same way as the separate patient and HCP-sessions, rapid-fire, or "post-it note," questions followed by discussion questions. However, the topics of these questions now focused on ideas for what, how, and when the ideal system for sharing patient-gathered mHealth data with HCPs during diabetes consultations should be conducted. Finally, we invited participants to "Design-It-Yourself" and design a paper prototype. We provided paper representations of functionalities, information, and technologies that they could use to build their own paper prototype of such a system. Each session was audio-recorded, transcribed, and translated from Norwegian to English for analysis.

4.1.3 Analysis of workshop transcripts

An abductive approach [207] was taken to thematic qualitative analysis, which was performed on each of the seven transcripts (one for the HCP only workshop and six for each session of the separate and joint patient and HCP workshops). Narrative summaries were created for each transcript and shared amongst the participating researchers to ensure a common understanding of patients' and HCPs' perceptions and expectations of mHealth and data-sharing. The abductive approach allowed us to deductively answer the research questions posed prior to the workshops by identifying broad themes and then inductively build more specific and emergent topics [208]. While there is no standard for how to perform an abductive approach to thematic qualitative analysis, the inductive approach was applied as independently from the deductive approach as possible; several weeks were taken between the generation of seams and more detailed review of the transcripts to identify emergent topics. Codes were generated for each time someone spoke. Common initial codes were grouped into secondary codes, i.e. pertaining to more than one code, and then sub-themes. These sub-themes were then

assigned to the most appropriate theme that was generated from the deductive approach. Paper prototypes were paired with their associated quotations from patients and HCPs that described which and how data should be presented, discussed, and used by both patients and HCPs during diabetes consultations.

4.2 Literature reviews

Literature reviews aimed to answer **RQ2**. While the FDA provided requirements for how to assess those mHealth technologies that qualified as "actively regulated," they did not provide clear expectations for how to evaluate those under "enforcement discretion" (Figure 4) [160]. For mHealth, evaluations are not confined to medical or health research environments, and different, relevant information can be found in both scientific and grey literature. Both forms of the review were conducted with the intention of identifying all approaches, resources, methods, and measures being used by professionals in a variety of fields to understand the impacts of mHealth technologies on stakeholders, with a focus on patients and HCPs.

Scientific literature is produced by researchers, and published and controlled by commercial journals. Within the scope of mHealth for self-management, this literature describes how researchers choose to structure an evaluation and which questions to ask to answer a specific question about a health intervention. A scoping review of the literature specifically aims to provide a foundational understanding of a novel field of research, or one in which limited information has been published [209].

While scientific literature produces results of research activities, grey literature includes documents, websites, and other forms of information generated by government or business organizations, industry, or academia [210]. In attempts to comprehensively address the large-scale, i.e., regional or national impacts of mHealth technologies, independent organizations developed evaluation frameworks, guidelines, and services to meet the information and evidence needs of app consumers.

4.2.1 Grey literature review

Grey literature reviews are used to identify reports, research project outcomes or results that have not been published in scientific journals, government documents, website information, news or social media articles and other forms of information surrounding medical research and practice both including and not otherwise found in scientific databases. While there is no one standard protocol for performing grey literature reviews, "databases of media reporting" and "internet search engines" are likely places to find grey literature [210].

A 2017 grey literature search was conducted to identify reports, government websites, statutes, and policies, published and available online in English between 2013 and 2018 that address activities related to the evaluation of mHealth technologies within the EU and were ready and available for immediate use by stakeholders. GoogleScholar, Google and PubMed were searched using iterations of the following terms: [activity-performed] evaluation, evaluate, assessment, validat*; [type of technology assessed] "mobile health", mHealth, eHealth, app*, tablet, wearables, sensors; and [resulting recommendations] framework, checklist, service, report, strateg*, toolkit, model, guidance, process, recommendations. Focus was placed on working frameworks i.e. those that are already implemented, final and published evaluation plans, guidelines and statutes. Ongoing research and development studies aiming to design and evaluation framework were excluded, as these were not yet

ready for implementation or to be used by stakeholders. Two authors reviewed the identified documents independently. Only initiatives and frameworks describing nonmedical devices (see Figure 5) were considered. Press releases or initiatives that had been cancelled by the time the search was performed were excluded. Data were extracted on the following topics: framework type, name, country of origin, responsible organization, target audience, mHealth criteria assessed (e.g., usability, privacy, etc.).

4.2.2 Scoping literature review

A scoping review was conducted in 2019 to identify the methods and measures that health intervention researchers had used to evaluate the impacts of mHealth apps and systems. While systematic and meta-analysis literature reviews focus on combining and curating outcomes of health studies, scoping reviews are meant to provide overviews for new or relatively new field, to provide better understanding of some aspect of that field, which mobile health is [209]. As noted in one scoping review of diabetes management and mHealth technologies, "Alternative study designs and more rigorous methodologies are needed" [196]. To provide a foundation of where current research is on this topic, we aimed to gather an overview of current approaches to measuring the impact of mobile health technologies.

We focused our search on the period 2015-2019 based upon the, at the time, the most recent update of the relevant FDA documents describing the expectation and information needs regarding mHealth evaluation [160]. We chose to explore a sub-section of mHealth intervention studies, i.e., those that employed always-available technologies intended primarily for patients' self-management of six major chronic conditions. In doing so, we could represent both the approaches to patient self-management of chronic illnesses through mHealth technologies as well as how researchers have approached the testing of mHealth technologies that did not fall within the purview of actively regulated medical devices by healthcare authorities and certifying bodies.

Table 6 describes the search strategy used to identify scientific literature describing the evaluation of the lower-risk, patient-operated mHealth technologies that were used for the self-management of chronic non-communicable diseases (NCDs). We searched PubMed, ProQuest, Medline, and GScholar for literature published between 2015-2019, in English.

Table 6 Scoping review search strategy

Database	Search terms (with formatting)	Database-specific filters	Results
PubMed and ProQuest	"mobile application" OR "mobile phone application" OR app OR smartphone OR wearable OR sensor OR "mobile phone" OR "cell phone" OR tablet AND Self-effic* OR self-assess* OR self-manage* OR self-monit*	- Abstract and title - Publication date: 01/01/2015-12/31/2019 - Language: English	N=1610 and N= 534
Medline	(Self-effic* or self-assess* or self-manage* or self-monit*) and ("mobile application" OR "mobile phone application" OR app OR smartphone OR wearable OR sensor OR "mobile phone" OR "cell phone" OR tablet)	- Ab,kf,ti - English language - Yr= "2015-Current"	N=1436
GScholar	"self-efficacy" OR "self-management" OR "self-monitor" OR "self-assessment" OR "self-manage" AND "mobile phone application" OR "mobile phone" OR application OR app OR smartphone OR wearable OR sensor OR tablet	- All in title - 2015-2019 - English	N=332
JMIR	"mobile application" OR "mobile phone application" OR app OR smartphone OR wearable OR sensor OR "mobile phone" OR "cell phone" OR tablet AND Separately: "self efficacy" (2) no protocols, "self manag*" (372- protocols 57, proceedings 12, non chronic NCD)		

Inclusion criteria were that studies described interventions that: 1) were intended primarily for adult patients to use for the self-management of their own chronic NCD, 2) allowed patients to register and review their data on "always available" devices, and 3) aimed to evaluate, test or assess an mHealth intervention.

Titles and abstracts were screened for information that met the inclusion criteria. We extracted information regarding which methods and measures were used to evaluate mHealth app or mHealth system interventions. Data extraction also included the name of the intervention (if applicable), included technologies, study design and duration, health condition, and the participants.

4.2.3 Analysis of literature reviews

For the grey literature review, two co-authors reviewed the identified documents and extracted data independently. Due to the observed heterogeneity of the identified documents, all co-authors discussed what would characterize similar frameworks and distinguish other frameworks from one another. Each identified framework was distinguished based upon the type of evaluation described, i.e. a framework for how to evaluate a system's readiness for mHealth implementation, for how to evaluate a single or groups of mHealth technologies, or how an organization performs evaluations as a service. Extracted data were then discussed, synthesized and organized into the agreed upon three different types of framework and then reported according to a structure agreed upon by participating researchers. Information regarding which stakeholder(s) each framework were intended to be used by (patients, researchers, developers, policy makers or healthcare professionals) was either explicitly noted by the authors of the framework or described within the evaluation tasks to be completed by stakeholder. As the terms used for evaluation criteria were largely homogeneous, these were simply noted and tallied for each framework.

For the scoping literature review, we intended to perform a descriptive analysis of the results, thereby giving an overall picture of how researchers are approaching mHealth evaluation, and which resources they are using to do so. Single device, e.g. app, interventions present a lower risk to patients than those interventions involving multiple data sources, technologies, and potentials for error, i.e. system interventions. Therefore, we compared those methods and measures used to evaluate "app

interventions" against those used for "system interventions". We also reported which methods were used to gather different measures as well as which combinations of methods and measures were used by the identified intervention studies.

As was described in another publication, the use of different terminologies by each author to describe the similar methods and measures, some of which have numerous different definitions, made the categorization of methods and measures difficult [211]. Therefore, it was our job when performing data extraction and analysis to structure information about what was measured in and evidence-based i.e. definition-based, way. While not included in the attachments of published Paper 2, Table 7 below details the connotations, based off definitions, where possible from the online Cambridge Dictionary, and descriptions of authors of reviewed literature, of each disputable measure-category described in the appendices for Paper 2. The intention of highlighting discrepancies between these categories is that there is much heterogeneity within definitions and specific information can be used differently. For example, efficacy, effectiveness, and efficiency are sometimes included under the definition of usability. However, measuring how quickly someone can perform a task, i.e. efficiency, may not be someone's intention behind their assessment of a device's usability, and by grouping of all of these concepts under one definition can misrepresent the measured impact of an intervention and make it difficult for the accurate comparison of study outcomes.

Table 7 Explanation of the connotations for each category of measure used in the scoping literature review (Paper 2)

Category of measure	Explanations of definitions and connotations
App features and/or quality	App features refers to any description of included functionalities, display, other physical characteristics are included in the evaluation process of the mobile health intervention. The term "quality" with regard to the medical device industry has been defined as the following by the international organization for standardization (ISO), the degree to which devices "meet customer and applicable regulatory requirements" [212].
Efficacy/effectiveness	The degree to which a device is associated with a beneficial outcome [213], which can be defined differently based on who is being asked, e.g. satisfaction as perceived by the patient vs. clinical efficacy as determined by a medical professional.
Efficiency	How quickly, i.e. with minimal waste of time [214], users could perform tasks, i.e. interactions or use of a certain intervention or device functionality as prescribed, instruction or observed by the research team.
Engagement/motivation in self-management	Engagement relates to the level of which someone is involved with something, physically or mentally [215]. This can also be seen as a patient's actual behaviour or perspectives related to health compared to ideal or agreed-upon behaviour or perspectives internally, i.e. an agreement or goal for one's self to perform a certain way, or externally with another.
Healthcare utilization and impact	Indications or measures of a person's use of formal healthcare services.
Interactions (via app)	The number and/or type of physical interaction a user had with different functions of a device, e.g. button pushes, swipes etc. that caused the device to respond or change accordingly, which can also be to initiate or end data entry (i.e. patient-gathered self-management data).
Intervention experiences	First-person description or account, mainly represented in interviews or free-response options, of what or how something occurred between the participant and any aspect of the studied intervention.

Lifestyle	Specific to health-related habits, or activities or actions that a study participant performed, that were most likely part of a person's daily activities prior to the study start.
Patient-gathered self-management data (app)	Any information or data directly input into the app by the user or via a connected device that automatically measures relevant measures of a patients' health.
Patient-reported app-use (non app)	Any information about how and how often the user reported using the intervention or app that was not directly measured by analysing information within the app but instead via a questionnaire or verbally stated by the user.
Patient-reported health (non app)	Any information about health measures, symptoms or other indications of physical or mental health that were not directly measured by analysing information within the app but instead via a questionnaire or verbally stated by the user.
Patient-reported self-management (non app)	Any information about what activities, which were either prescribed or suggested by a reputable health information source specific to the management of their disease case, or how and how often these were performed and then reported by the user via a questionnaire or verbally stated by the user.
Perceptions, opinions, suggestions	Any subjective statements made by participants about the intervention itself or study.
Physical/clinical well-being	Measures taken by standardized protocols and/or medical tools related to a person's physical health, i.e. related to the tangible body [216].
Psychological well-being	Measures taken by standardized protocols, e.g. psychological diagnostic questionnaires, related to a person's mental or psychological health, i.e. related to their feelings or experienced emotions [217] related to their disease case.
Quality of life	A person's reported measurable perception of the quality of their life, especially as it relates to their health and disease case.
Security	The degree to which the intervention or any of its components can protect an entity, in these cases mainly of personal health information (PHI), from unauthorized/unpermitted access, abuse, manipulation or change of that entity by an outside party [218].
Self-efficacy	A measure of an individual's belief in their ability to perform a task [219], in this case use of an intervention or any of its components to ideally improve their health.
Study engagement	compliance , adherence to program, engagement (attendance) , intervention fidelity, number of sessions attended, number of participants who completed assigned intervention condition, fidelity (if having to do with intervention itself)
Task performance	The degree to which, or how well, a study participant completed a task, i.e. interactions or use of a certain intervention or device functionality, compared to the ideal, i.e. research team-prescribed or instructed performance [220].
Usability/ Feasibility	The degree to which an intervention or any of its components were easy-to-use [221], possible, i.e. feasible [222], to use from the perspective of the user themselves. If pertaining to the expected usability or feasibility, for example by a third party, this can relate to the overall, theoretical and/or perceived ability/availability of an app to provide necessary aid.

4.3 Approaches to usage-log data analysis

With the aim of answering **RQ3**, usage logs from completed studies were explored to understand what information could be gained from what, how, and when patients choose to use a diabetes app for their self-management. For the purpose of this thesis, usage-logs refers to each interaction and piece of information that an individual chooses to register in their mHealth device. Most data collected in a study, including usage-logs, are compared based upon the patient's originally assigned intervention group, i.e., intervention 1 vs. intervention 2 or control. However, it is well established that each patient is unique in how they approach their self-management and, subsequently, app use.

4.3.1 Usage-logs from the "Tailoring Type 2 Diabetes Self-Management" project

This retrospective analysis was performed on app usage-logs data collected during the 6-month cross-over RCT, Tailoring Type 2 Diabetes Self-Management [223]. Two versions of an app were used, the regular and the tailored versions of the Diabetes Diary app. Those who were randomized to the control group (n=16) used the regular app for 3-months. Those in the intervention group (n=25) used the tailored version of the app for the full 6-months. Participants were able to record measures of BG, medication, nutrition, and physical activity. Along with demographic information, participants reported upon which topics their goals focused, with options corresponding to each registration type in the app. HbA1c was taken at baseline, 3- and 6-months at the clinic. Continuous and non-continuous number of months that the app was used was measured for each participant.

4.3.2 Usage-logs from the RENEWING HEALTH Project

Preliminary findings from the original study

This retrospective analysis was performed on usage-log data collected during the 12-month RCT study, RENEWING HEALTH [224]. The original purpose of the study was to determine how patients used the Diabetes Diary app for their health self-management, both with (n=50) and without (n=51) health counselling, compared to a control group that received normal care (n=50). The app itself allowed patients to register and review measurements of their self-management, i.e., BG levels, diet, and physical activity, as well as related goals and static information included with the app.

Originally, results reported measures taken at baseline, 4- and 12-months focused on reported aggregate change of HbA1c and total usage of the app within and between each originally assigned intervention group. This study and analysis was performed prior to this thesis. The results demonstrated no significant difference in the change of these measures within or between the groups [225]. Therefore, the retrospective analysis for this thesis was based on the usage-log data of participants who chose to use the app; of the 101 patients in the two intervention groups, only 79 used the app.

Developing and testing a novel structure for data analysis

In the scoping review conducted as part of this thesis (**Paper 2**), several studies reported collecting and analysing usage logs [226]. While this retrospective study did not allow us to change the methods of collecting the data, studies identified in **Paper 2** did provide us an understanding of the variety of approaches used to analyse the data. Some studies noted, for example, grouping all interaction data by week, including recorded values [227], or describing analysis based on rolling retention, return rate –

in other words, based on duration or use over time – as well as registration of own-gathered measures and navigation of certain functionalities [228].

Working from (close to) scratch, we performed a preliminary analysis to understand what was possible to gain from these data as well as how to develop an evidence-based structure for the comparison of the usage-logs. Our challenge was to determine a) if the original patient groups were appropriate for mHealth analysis, b) in what period of time to group the data, and c) how, if possible, to compare mHealth-gathered app data to clinical measures, such as lab tests.

Acknowledging that BG levels do not exist in a vacuum, we incrementally compared the other registered data that was available (physical activity and diet). We began by searching for theories that could help us understand individuals' health self-management choices and the time it took to establish a new habit so that we could group the data accordingly. We referred to relevant, yet previously un-consulted fields, reassessed assumptions about patient behavior during a study and in every-day life and established medical knowledge. Finally, we identified several theories that not only worked in parallel with one another but also provided a means to both structure and interpret the data. In doing so, we established one way in which we could learn more about how, and potentially why, health and behavior changes occurred during this study.

Usage-log data from this study consisted of registrations, e.g., recorded measures of BG levels, and navigations, i.e., how and when a participant used and interacted with the app. These categories of information identified and summarized for each participant. Data was structured in two separate ways based on i) duration and level of app-usage, e.g., long- vs. short-term users, and ii) emergent groups of patients characterized by their combination of usage-log types, i.e., registrations and navigations, via K-means clustering.

4.3.3 Analysis of usage-logs

Retrospective analysis of data from the Tailoring study focused on the relationships between baseline goals and use of the app as well as use of the app and change in HbA1c. Total number of measurements registered, for each type of data, were tallied and grouped by month. Correlation analysis was performed between the number and type of registered data vs. value and change in HbA1c at baseline, 3- and 6-months. Repeated Measures ANOVA was performed on the usage-log data within and between months. The number and topics of baseline goals were compared to the number and types of registered measures taken in the app during the intervention as well as to the duration of app use. Comparisons of these data were also performed between groups.

Retrospective analysis of data from the RENEWING HEALTH RCT was based on emergent app-usage groups. Clustering is the process of identifying groups based on similar outcomes, i.e. discovery of discover the natural grouping(s) of a set of patterns, points, or objects [229], in this case usage-log patterns based on which functions were most used by the participants. This followed Bayesian logic, as options for outcomes are identified based on the options that are offered. The specific analysis method of K-means clustering was selected by the invited statistician who consulted and helped perform the secondary analysis of the data based on the fact that this is a commonly used clustering method [229]. Our intention was to identify profiles of use via secondary analysis of previously collected RCT data on participants' use of the mHealth device. This means that by treating individuals' data within originally assigned interventions groups as the same is ineffectual; the results

would be too heterogeneous and therefore skewed to accurately determine a common impact of the device. Therefore, RCTs, which perform analysis based on originally assigned intervention groups, do not apply to interventions that base their findings off of mHealth usage-patterns. Repeated Measures ANOVA was performed within and between each emergent group to quantify differences and trends in app-usage patterns. Correlations were reported between emergent usage groups and change in HbA1c.

4.4 A mixed-method evaluation of an mHealth intervention for diabetes

With the aim of answering **RQ4**, a mixed-method feasibility study was designed with the aim of supplementing traditional methods and measures with mHealth approaches and resources. The aim of a mixed-method study is to select approaches, methods and measures from both quantitative and qualitative research in such a way that would provide a comprehensive and explanatory insight into an intervention's outcomes [230]. In combination, quantitative measures can explain what changes over time - with patterns of such measures explaining how these change - and qualitative measures can explain why they change.

4.4.1 Designing the mixed-method feasibility study protocol

This mixed-method protocol aimed to evaluate the impacts of an mHealth system, for sharing patient-gathered app data during diabetes consultations, on both patients and HCPs. Our objectives in designing the protocol were as follows: i) identified an intervention design that would meet the needs of the patients and HCPs, i.e., the duration, coordination of activities from recruitment and training to follow-up to using the data-sharing system during the intervention, ii) identified traditional methods and measures that would address the main possible outcomes, i.e., on the patient, HCP, and their relationship during consultations, ii) identified how mHealth approaches and resources are incorporated or supplement the traditional methods and measures.

The outcomes from the scoping review (**Paper 2**) and co-design workshop (**Paper 1**) revealed that while such mHealth resources as usage logs and patient experts are indeed being used to supplement traditional and clinical quantitative data to assess the impact of mHealth diabetes interventions, there are still unanswered questions and address needs of end-users. A literature review of mixed-method studies provided a more focused exploration of how quantitative and qualitative methods and data were combined in diabetes and mHealth research [196], e.g. how qualitative interview data were used to explain quantitative usage log data. These reflected the different analysis approaches, or rationales, described in the pragmatism paradigm, i.e. mixed-method approach [204]: exploration, complementarity, triangulation, and explanation. Because we aimed to thoroughly understand how mHealth and share patient data during diabetes consultations affected both patients and providers, triangulation was found to be the most appropriate means of analysing the quantitative and qualitative data, which is described in the analysis section below.

The intervention

The intervention itself involved patients using and gathering data in the Diabetes Diary app for 6-months. The intention was that patients gather data on any of the following measures: BG level, physical activity, diet, medication, weight, and personal goals. They would have the choice to share and discuss their gathered data with their HCPs during one or more consultations in the intervention

period. Depending on how much and which data the patient chooses to share, the web-based system displays graphs, figures, and summaries of, for example, the patient's registered measurements, progress toward their goals, and even relationships between their different measurements.

We invited diabetes specialists (endocrinologists and diabetes nurses) and GPs in the Troms and Finnmark areas to participate in the study and recruit patient-participants. Patients with both T1D or T2D, 18+ years, and willing to use an mHealth app were included.

Methods and measures

The structure of the intervention, methods, and measures chosen had to address clinical practice, individual self-management, patient-provider cooperation, and technology. Through the Diabetes Diary app, we had the opportunity to track patient-gathered self-management measures and users' interactions with the app. By focusing recruitment on HCPs, we aimed to ensure their engagement and thereby reliable collection of clinical measures. Our choice of such measures was based on the duration of the study, i.e., likely relevant biological changes that would change in 6-months. We aimed to identify patient-reported qualitative and quantitative methods that provided as much insight as to what, how, and why measures changed during the intervention, as opposed to only what had changed between baseline and study end, i.e., the Black Box of pre-post study designs (Figure 6). We used the list of standardized questionnaires that were identified in the scoping literature review (**Paper 2**), as a selection pool. Focus groups were also considered as supplements to these measures with the aim of elaborating or clarifying participant responses.

The intention behind the search for measures was that the clinical measures and patient-registered usage-log data could provide an overview of the quantitative changes over time, based on patients' choices, while psychological questionnaires and study-end focus groups would allow participants to specifically explain why they chose to register data and use the system in the way that they did. We chose standardized questionnaires and discussion guide questions that would not only provide an insight into the impact on patient self-efficacy and self-management habits but also related to concepts relevant to health authorities, e.g., usability and feasibility of the technology itself. Following our objective of encouraging interdisciplinary research, we invited researchers in the field of psychology to develop the discussion guide with us. Together, we aimed to inform the questions and activities with psychological theories and frameworks related to human behavior, motivation, and decision making. As a result, the order and content of the questions, as well as their eventual analysis, were based upon consensus reached between these researchers after several iterations [231]. In doing so, we could theoretically provide a more complete and comprehensive understanding of the impacts of mHealth than traditional methods and measures alone.

Study-management

For the study design, the efficiency of study management was a priority given the speed of development of mHealth technologies. There was also the challenge of ensuring complete data collection. As our location, Tromsø, Norway, proved a challenge for both recruitment and participant follow-up, a remote study-administration approach was taken. Previous experience with a remote study-administration platform (study platform) demonstrated the importance of participant follow-up and support, the role of goal setting, and the need to connect data collection databases so that data structure and analysis would be performed more automatically and efficiently [232]. These informed

improvements to ensure even more complete data-capture as well as dynamic and personalizable follow-up with our end-users during the FullFlow feasibility study.

The study platform provided access to the automatically collected usage-log data from the patients' diabetes diary apps, including an account of patients' continuous interactions with their apps, e.g., which functionalities were used and when, as well as their registered self-management measurements, e.g., BG levels.

4.4.2 Analysis of mixed-method feasibility study

For this mixed-method study, we plan to provide our experiences with the study administration platform, recruitment and HCPs' responses to the pre-study perception of the data sharing system, with a focus on the main outcomes of the study, i.e. descriptive comparison of the participants' experiences and perceptions measured before, during and after the study.

Information regarding HCPs' specialties as well as their unique and raw responses to the pre-study questionnaire on the perceptions of the data sharing system will be translated from Norwegian to English. To explain participant's experiences, we chose to present the three main interactions that were described in the study protocol, i.e. patient interaction with the app, patient-provider interaction, and user interaction with the data sharing system, as case studies. Case studies are often chosen as an approach to understanding a multifaceted or complex intervention [233]. As much of the data from healthcare providers and patients were collected separately yet pertained to a shared experience I believed it helpful to both illustrate and describe in text all of the relevant data for the three main interactions that occurred during the study. Figures allowed me to present both quantitative and qualitative information together and objectively. Analysis of standardize questionnaires were performed based on the protocols described by the authors of the standardized questionnaires: patients' perceptions of intervention usability (System Usability Scale –SUS) [234], own diabetes empowerment (Diabetes Empowerment Scale-Short Form- DES-SF) [235], own wellbeing (WHO-5 Wellbeing Index) [236], and the therapeutic relationship with their HCPs (Health Care Climate Questionnaire- HCCQ) [237]. We will illustrate, chronologically, each patient's and HCP's progress through the intervention. This will include usage-logs from patients' apps during the 6-months; the data patients chose to share through the Full Flow System and HCPs' post-consultation survey responses. We performed a qualitative analysis of the transcripts from the study-end focus groups. To demonstrate the feasibility of using these methods and measures to provide a comprehensive understanding of the impacts on the FullFlow System on both participant groups, for the purpose of this thesis, I analysed data related to two of the eight participants (n=1 T1D, n=1 T2D) and their respective HCPs.

5 Ethics

The FullFlow Project activities, including the co-design workshops, usage-log analysis, and mixed-method feasibility study and their associated preceding activities, were found exempt by the Norwegian Regional Committee for Medical and Health Research Ethics (REC), and instead acknowledged by the Data Protection Officer (Personvernombud) at the University Hospital of North Norway (**Appendix B**). The study administration platform followed the same regulatory approval process. We strived to reach gender equality during each study. Data was kept safely stored as per requirements by both REC and Personbernombud. All participants of these activities provided signed

informed consent forms prior to the start of each activity. They were informed of their right to withdraw themselves and their data from inclusion in the study and analysis at any time.

6 Results

6.1 What diabetes patients and HCPs need from mHealth

With the aim of answering **RQ1**: "What information, support, and functionalities do patients, general practitioners and specialists who work with diabetes, need and expect from mHealth tools?", **Appendix C** [238] describes the activities and results of the online patient survey and HCP workshop that informed the first prototype designs for the FullFlow data-sharing system. **Paper 1** [239] describes the results of the co-design workshops, including the suggestions for how a data-sharing system should function to respond to the information needs of patients and HCPs together in practice. Results from the co-design activities are all based on the concept of patients self-managing their diabetes with mHealth technologies and their choice of sharing that data with HCPs during consultations.

6.1.1 Patients' needs and perceptions of mHealth

Of those who completed the 2016 anonymous online survey regarding self-management challenges and ideal consultation discussions, 15 were diagnosed with T1D, and 9 had T2D [238]. The most commonly reported challenge between both groups was *motivation to exercise* (60% o T1Ds, 89% of T2Ds). However, those with T1D reported greater challenges with *eating healthy* (47%), and those with T2D reported more challenge with *reducing their weight* (67%). The most desired topic during a consultation discussion was *dealing with stress* (60%), amongst those with T1D, with the least desired topic of the *best exercise for me* (7%). Amongst those with T2D, the most desired topics were tied between *dealing with negative thoughts/feelings* (44%), *the best exercise for me* (44%), and *reasons for variability in their blood glucose levels* (44%). The least desired topic amongst those with T2D was *personal goals* (11%).

Four individuals with T2D participated in the 2017 co-design workshop, which also involved GPs. Five individuals with T1D participated in the 2018 co-design workshop, which also involved specialists in diabetes care [239]. All participants with T1D and T2D acknowledged that the availability of such mHealth devices that enabled them to take on greater responsibility, understanding, and control of their diabetes health. Differences between individuals with T1D and T2D were noted under each of the major themes: 1) patients' and providers' need for more specific and detailed information in diabetes care, 2) mHealth technologies' impact on patients and providers, and 3) data-sharing. These differences were consistent with the inherent differences between diagnoses. Overall, those with T1D are required to closely monitor and understand how to react to immediate changes in BG levels. However, most with T2D would benefit from recalling their historical actions, over a period of time, to explain symptoms that appear sometimes days after its cause. They also often have comorbidities that their GPs must focus on as well, which means less time during consultations to discuss each health issue. Differences in feedback during respective workshop sessions were reported; those with T1D focused more on detailed information and feedback whereas those with T2D were focused more on gaining motivation and understanding their general health trends. This accounted for differences in when those with T1D and T2D needed feedback, i.e. more immediately when issues arise vs. after data had accumulated to provide evidence of reoccurring

symptoms. Both noted that apps provide some of this feedback, which is especially appreciated given the participants' reported lack of support from HCPs when and where they needed it, i.e., in their every-day lives, when their symptoms arise. While the individuals with T1D and T2D were frustrated with this situation, they still noted their own inability to see all answers in their app data and highly valued their HCPs' ability to identify and explain unseen issues within their self-management habits and health measures. However, those with T2D did note that GP's understanding of diabetes was limited - understandably so- by their lack of time and specific training. Suggestions regarding alternative diabetes support services included diabetes nurses (DNs).

While they were independent in their app use and self-management, they were eager to share that data with HCPs. Both those with T1D and T2D wanted to share their data before consultations, believing that the HCPs would have more time to review it and then explain the patients' diabetes health to them during the consultations. However, they were unsure about which data the HCPs needed or wanted to see in order to provide such input.

6.1.2 HCPs' needs and perceptions of mHealth

One endocrinologist and two GPs participated in the 2016 HCP workshop that reviewed patients' responded to the online survey and provided ideas for how a system should present patient-gathered app-data during consultations [238]. Both agreed that HCPs function as guides to their patients in the diabetes care process, with consultations giving patients and HCPs the opportunity to learn from health and app-gathered data. However, the participants explained that there were main differences in their practice that needed to be acknowledged before designing a system to introduce any new data. The GPs were most concerned with gaining an overview of the patient's situation quickly (1-3 mins), given the GPs' need to cover not only diabetes but other health concerns as well during a shorter consultation. The specialist reported having more time, and therefore a priority, to discuss diabetes-related health issues in-depth. If patients shared their own-gathered data, the GP preferred to see summaries of the data and the patients' personal goals, while the specialist preferred to view detailed graphs and trends from multiple self-management tools. Both agreed that if patients intend to share their app data, they should come prepared with discussion points and any technology solutions to display that data should avoid data noise and overload.

Three GPs participated in the co-design workshop held in 2017, together with patients with T2D. Two endocrinologists and a DN attended the 2018 co-design workshop, together with patients with T1D [239]. These results were similar to those reported by the participants in the 2016 workshop, involving only HCPs. In the 2017 co-design workshop, GPs reported that the technology acts as a learning tool for individuals, with the potential to help patients see issues within their health habits and correct them without requiring consultation time from the HCPs. All participating HCPs (2017 and 2018 co-design workshops) saw their roles in diabetes care as guides or teachers, with the patient taking the most responsibility for the actions determining their health.

Both agreed that when presenting data, it should be summarized and structured in a way that highlighted patients' ineffective habits or reoccurring issues. HCPs main concern was being overwhelmed, on both the individual HCP and healthcare resource management levels, if the patients chose to send great amounts of data to the HCPs. GPs especially reported their incapacity to review data before each consultation, and only wished to see the data when something had changed, either in

the patients' self-management habits or as the result of changing, for example, medication. Without such a context, GPs did not view receiving data as useful for their case as HCPs.

While specialists agreed with GPs, that context is important; they were more specific in their preferences for data-presentation. They suggested that if a patient was to present a short period of intensive data-collection, it would be representative of a person's self-management routine and its effects on their health. While one specialist preferred to see "fluctuations over 24-hours" to identify specific issues that arose for that patient, another wished to rely on algorithms to indicate when an issue occurred and provide a suggestion as to why.

6.2 Methods and measures to mHealth evaluation

A grey literature review and scoping literature review aimed to answer **RQ2** from both the organizational level and research levels: "What approaches, methods and measures are being used to collect data for the evaluation of mHealth interventions for chronic illness self-management?", with a subsequent question being "are end-users' needs being addressed in evaluations?". The grey literature review (**Appendix D**) [240] included methods and measures that government and independent organizations are using to evaluate mHealth technologies. The scoping literature review (**Paper 2**) [226] described the mHealth approaches and resources that were used that supplemented or were incorporated into traditional methods and measures.

6.2.1 Government and organizations' mHealth evaluation initiatives

Three main categories of evaluation frameworks were identified: i) implementation frameworks (n=20), ii) assessment frameworks (n=28), and iii) service frameworks (n=13) (Table 8) [240].

Table 8 Descriptions of the three main types identified mHealth frameworks

mHealth Implementation Frameworks*	mHealth Assessment Frameworks	mHealth Service Frameworks
• Offers detailed suggestions, strategies and criteria to assess an environments' readiness for mHealth implementation	• Offers 2+ methods - for a series of evaluation measures - to assess an individual or group of mHealth technologies	• Describes an organization's own services and products for assessing mHealth technologies
• Often includes case studies or examples as well as practical tools, e.g. worksheets for the instruments to track and assess an environment for mHealth implementation	• Intended for use by mainly developers, clinicians, policymakers, and researchers	• Often includes a publicly published "Library", but the detailed processes used by the frameworks themselves are not often publicly available
• Intended for use by mainly policymakers and medical groups * Mainly include mHealth assessment frameworks		• Intended for use by independent organizations and available for those who apply for\request an organization's services

These frameworks primarily target health authorities, researchers, and mHealth developers, with few providing guidance for, or involving individuals or patients. Instead, app directories were the only resource for individual users. The most commonly evaluated topics were measures of privacy, effectiveness, usability, and data security. While comprehensive in relation to governmental regulations, most frameworks did not cover transparency, reliability, validity, and interoperability of mHealth technologies [240]. In other words, the identified topics represent some of the aforementioned priorities of stakeholders, but not those of individual patients.

Decisions about which methods should be used to provide evidence of mHealth's effects on individuals' physical and mental health, connected technologies, and the medical system were diverse. Information was not mentioned regarding factors mHealth technologies impact and whom they impact, and how to measure and report these impacts [169]. The scientific literature review demonstrated how health intervention researchers are attempting to answer these methodological questions.

6.2.2 Scientific evaluation methods and measures for mHealth interventions

The search identified 3912 records, which were narrowed by removing duplicates and applying our inclusion/exclusion criteria [226]. App interventions were described in 15 studies, and system interventions were described in 16 studies. One study described both intervention types. It was found that both traditional and mHealth-enabled methods, i.e., mHealth approaches, and measures, i.e., mHealth resources, were used together in mHealth intervention studies.

Most studies were also able to achieve their objectives, and in some cases, produce more information than expected because of their inclusion of mHealth resources, i.e., mHealth as a data-collection tool. Ten studies reported more than they intended [228, 241-249], three of which were able to do so through the use of mHealth as a data-gathering tool as well as part of the intervention [228, 245, 249]. One of these studies [250] was not able to produce the intended outcomes of cumulative time on an app due to technical errors.

The most common methods amongst both app and system intervention studies were the *Evaluation of usage-logs* (n=21) and *Standardized questionnaires* (n=18). *Ad-hoc questionnaires* were the third most common method used (in n=15 studies), which were often (n=14 ad-hoc questionnaires) based off of standardized questionnaires, or used in conjunction with standardized questionnaires but included questions that the standardized questionnaires did not cover. The least common methods used were *Download count* (n=1), followed by *Attendance*, *Medical record entries*, *Observational tests (in a lab setting)* with two citations each, and *Quality guidelines* (n=3).

Measures were gathered directly from patients 29 of the 31 studies. HCPs participated in many of the interventions and reported Perceptions, opinions, suggestions (n=4), and Usability/feasibility (n=4) most often. Interactions with the tested system were also reported by HCPs in two studies [251, 252]. Most quantitative measures were gathered from the intervention's app or system. mHealth, including the central app as well as connected medical and wearable devices, provided the platform for collecting data, e.g., Interactions (n=8 in app studies, n=11 in system studies), followed by Patient-gathered self-management data (n=6 in app studies, n=8 in system studies), for 3 of the 14 identified methods including *evaluation of usage logs*, *collection of additional device data*, and *download count*.

6.3 Analysis of app usage-logs

With the aim of answering **RQ3**: "Can usage-logs and patient-centered analysis be used to provide more evidence and information about what, how and why changes occur during an mHealth intervention?", analysis of the Tailoring project's usage-logs identified non-significant yet telling relationships between patients' pre-determined goals and use of app functionalities (**Appendix E** and **Appendix F**). Analysis of the RENEWING HEALTH usage-logs **(Paper 3)** [253] identified

relationships between HbA1c, a formal clinical measure, how long and for which functionalities participants chose to use the app.

6.3.1 Usage patterns of short- vs. long-term users

First, we differentiated those who did and did not use the mHealth app. Those that used the central app for three continuous months were considered short-term users (n=11). Long-term users were those who performed at least five interactions per month for three continuous months (n=61). There were 29 participants who did not interact at all with the central app during the intervention. There were no significant differences between these groups in terms of their demographics, including age, duration of disease, and education. However, while not significant, non mHealth users had a higher baseline HbA1c (8.4 mmol/L) than the short-term users (7.9 mmol/L) and long-term users (8.1 mmol/L), while short-term users had the lowest number of SMBG measures (5.5 per week) compared to the non-mHealth users (7.2 per week) and long-term users (9.4 per week). There was a significant difference between these groups related to HbA1c at baseline, four and twelve months between the non, short and long-term users ($F(2, 74) = 3.794, P = .027, \eta 2 = .093$), with long-term users demonstrating the greatest reduction in HbA1c (-0.86%), a clinically but not statistically significant reduction. However, none of the groups achieved the Norwegian goal of <7mmol/L during the study (Figure 8).

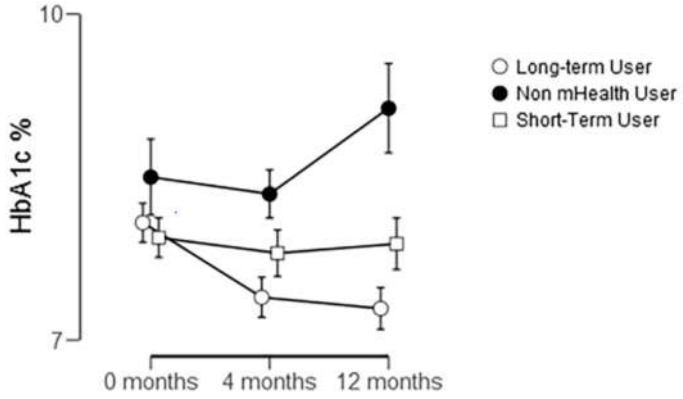


Figure 8 Changes in HbA1c between users grouped by duration of app use (Paper 3)

Among the 61 long-term users, there was a significant decrease in use after the first annual quarter, with a decrease of 64.91 interactions on average ($t = 9.234, P < .001$), with the greatest increase occurring after the first month of 212.25 interactions from 461.2 total interactions (($t = 5.022, P < .001$, effect size = .643). BG registrations were the most consistent app function used during the study, which was shown by the least difference in these interaction types between quarters.

Using K-means clustering, we identified two patient app-use profiles, i.e., their emergent groups or "clusters" based on the usage-pattern analysis. Cluster 1 was characterized mainly by Diet/exercise registrations and navigations (n=16), while Cluster 2 demonstrated mostly Blood glucose registrations and navigations as well as Navigations overall (n=40). Those that fell into two smaller clusters were not included (n=5). The two main clusters differed in all comparisons except BG navigations and Information navigations in total, over the 12 months and between quarters. For all participants in these two Clusters, it was found that there was a significant difference in change in HbA1c over time ($F(2, 110) = 5.043, P = .008, \eta 2 = .084$) (Figure 9).

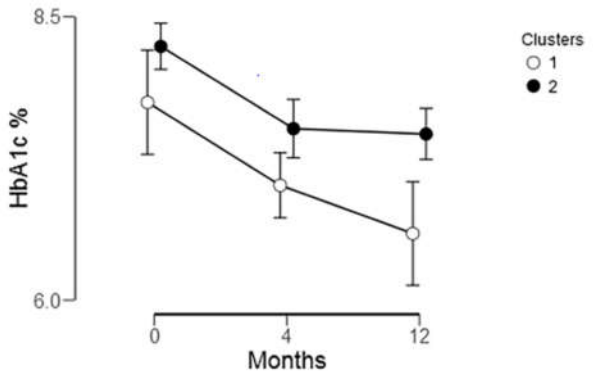


Figure 9 Changes in HbA1c of groups based on usage patterns (empty circle= diet/exercise users, filled circles=BG users) (Paper 3)

While not statistically significant, there was a medically significant change in HbA1c found between baseline and 12months for those in Cluster 1, but only between baseline and 4months for those in Cluster 2.

6.4 Comprehensive design of an mHealth intervention protocol

With the aim of answering the first part of **RQ4**: "How can mHealth-based data-collection and analysis be combined with traditional research methods and measures to produce more comprehensive information about what, how and why changes occur during an mHealth intervention?", **Paper 4** [254] describes a mixed-method study protocol. This protocol suggests a way in which an mHealth resource, app usage-logs, and mHealth approaches, e.g., the end user-driven structure of analysis, study, and intervention design, can supplement traditional methods and measures.

6.4.1 Intervention study design

The developed intervention was a system for sharing data between a patient's app and their HCPs during consultations. It was designed and chosen because it allowed for both patient and HCP understanding and use as well as characteristics of measurement for the potential of mHealth: impacts on patients, HCPs and consultation structure. We designed a 6-month mixed-method feasibility study to measure these impacts. Before the study start, patients were sent a questionnaire both to their email and the Diabetes Diary app. Patients were encouraged to use the central app to collect data about their BG measures, medication doses, diet, weight, physical activity, and goals, in any manner that they choose. Monthly reminders sent as set follow-up messages through their email and app related to possible app functionalities to use etc. The follow-up message at month 5 instructed patients to schedule a consultation, during which they were meant to share their choice of collected data. HCPs were instructed to complete a post-consultation questionnaire after each time a patient shared data with them. Patients were then sent a study-end questionnaire after the research team had confirmed the HCP post-consultation questionnaire had been completed, thereby confirming the patients' participation.

6.4.2 Integration of mHealth resources in measures chosen

We selected continuous and pre-post quantitative and qualitative outcomes that complement one another to be able to answer the questions: what, how, and why more fully. The complete set of measures, when they were taken and what each hoped to answer, are illustrated in Figure 10.

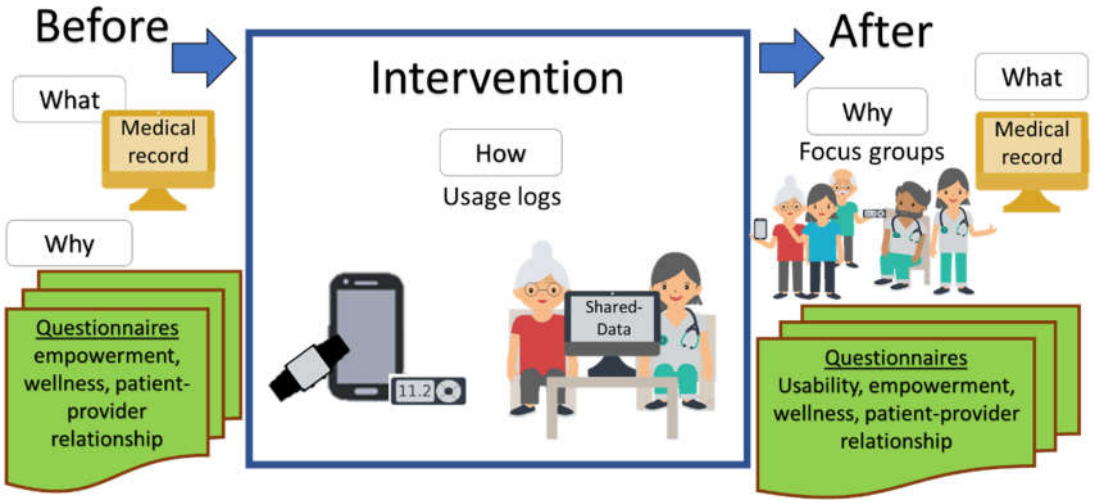


Figure 10 Illustration of what and when data was collected.

We chose the following standardized questionnaires, quantitative measures based upon a goal of measuring a balance of wellbeing, motivation, and health behavior change theories, and technological possibilities. Standardized questionnaires distributed at baseline (**Appendix G**) and 6-months (**Appendix H**) measured patients' perceptions of intervention usability (System Usability Scale –SUS) [234], own diabetes empowerment (Diabetes Empowerment Scale-Short Form- DES-SF) [235], own wellbeing (WHO-5 Wellbeing Index) [236], and the therapeutic relationship with their HCPs (Health Care Climate Questionnaire- HCCQ) [237].

Study-specific questionnaires allowed us to gather information that was specific to our research questions but were not part of the included standardized questionnaire. Appendix F includes the study-specific questions for patients at baseline, which were distributed with the aforementioned standardized questionnaires. To measure the impacts of the data-sharing system on HCPs, we asked them to complete a pre-study survey (**Appendix I**) related to their impressions and expectations of the data-sharing system. After each consultation with a patient participant, we also requested that they complete a survey of which shared-data was discussed, which of the system's functionalities were used (**Appendix J**).

Quantitative changes in patients' health were measured by comparing the HbA1c and BP levels available in the medical records from lab tests. Usage-logs provided quantitative information about both what had changed by collecting own-gathered measures of health and self-management tasks. These also demonstrated how these data had changed by demonstrating longitudinal patterns throughout the intervention in the logged data.

Study-end focus groups provided a means to collect more information about how participants acted during the intervention and why they chose to use the technology in the manner that was recorded via the usage logs. We invited both patients and HCPs to separate sessions. The meetings were designed to allow participants to elaborate on their questionnaire responses and provide more context for their perceptions of and actions during the intervention. The focus group discussion guides were the result of a joint effort of FullFlow Project team members and three psychology researchers. Questions were based upon psycho-social theories of behavior change that were not available or being used in

comparable studies (**Appendix K**) [231]. Questions were chosen that addressed the following: the traditional measure of technology interventions, i.e., user-experience, as well as users' intentions, perceptions, and motivations related to using mHealth for sharing patient-gathered data during consultations, as well as patient-HCP collaboration (**Appendix L** and **Appendix M**). These were audio-recorded, transcribed, and translated from Norwegian to English for analysis.

6.4.3 Use of the mHealth study-administration platform

While it was possible for this platform to perform nine functionalities (**Appendix N**) [255]: 1) recruit, 2) send and collect informed consent, 3) randomize participants, 4) send and receive questionnaires, 5) track and 6) follow-up participants as they moved through the study, 7) gather and 8) provide basic summaries of data and 9) perform study closure. However, for this project, patient recruitment was performed through HCPs, who were themselves recruited in person, and randomization was not part of the study design.

Users within the research team would be able to access project information through a secure web-based interface. From here, it was possible to track participants as they moved through the study from informed consent to the reception of follow-up messages to the delivery and reception of questionnaires. We initially created one follow-up message for each of the six months of the intervention as well as a study-end "Thank you" to ensure engagement and support was provided to participants. Each of these was sent and tracked manually through the platform.

It was then possible to access collected data from three data-sources: LimeSurvey [256], the app data server, and Piwik (now called Matomo [257]) for usage-logs. LimeSurvey also allowed us to create questionnaires for both patients and HCPs in the study. Within the FullFlow data-sharing system landing page, the HCPs could access the post-consultation questionnaire. Piwik automatically uploaded participants' interactions with the app regularly, when they were connected to the internet. The coordination of these platforms is illustrated in Figure 11.

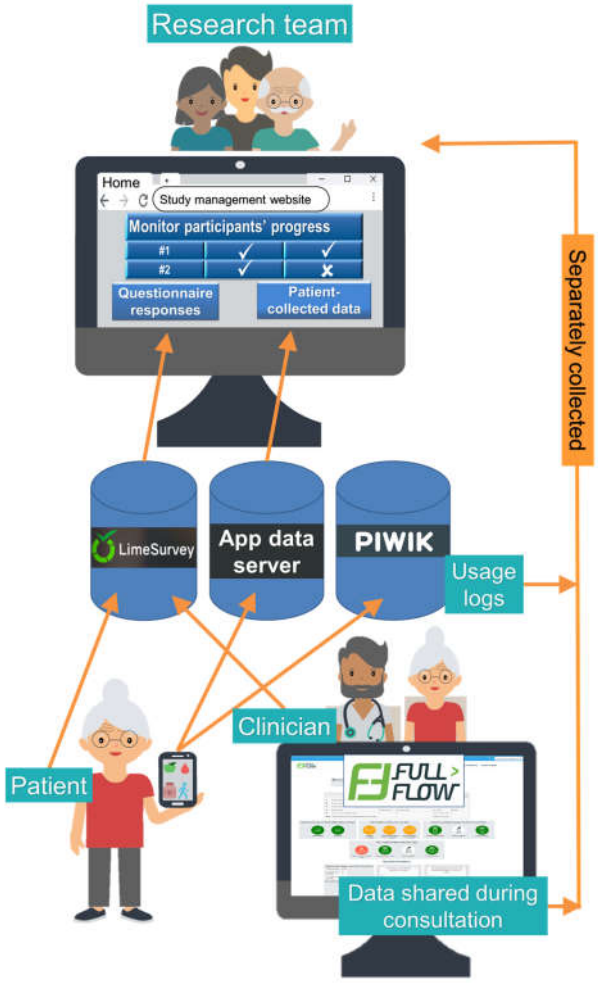


Figure 11 Illustration of the flow of data from the participants to the research team using the study management platform in the FullFlow mixed-method study.

6.5 FullFlow mixed-method study: preliminary results

With the aim of answering the second part of **RQ4**: "How can mHealth-based data-collection and analysis be combined with traditional research methods and measures to produce more comprehensive information about what, how and why changes occur during an mHealth intervention?", the mixed-method study results demonstrated the information that was gathered from the selected traditional methods and measures, with supplemental mHealth resources. While these results have not yet been published, examples of this analysis are presented below. In general, it demonstrates the feasibility and potential of using such an approach.

6.5.1 Study admin platform

Three researchers were provided unique and secure usernames and passwords to coordinate these activities: the principal investigator to oversee all activities, myself to assist in creating follow-up messages and to manage their deployment throughout the study and a researcher who focuses on programming to coordinate and structure data collection between the three main data-sources.

Both predefined and ad-hoc follow-up messages were required for participants experiencing different issues including not updating their app to the version required for us to collect data, not answering a questionnaire or scheduling the necessary consultation with their HCP, or when we saw a participant had not used the app in some time. **Appendix O** [258] describes the lessons learned from using this platform during this study.

6.5.2 Recruitment

Recruitment began in October 2018 and ended in June 2019. The principal investigator contacted and held information sessions to educate the HCPs on the system. All HCP recruitment efforts for the feasibility study are presented in Figure 12. The research team contacted a total of 26 offices and organizations (first column in Figure 12) to inquire about their interest in joining the project. We requested times to present the project and introduce interested HCPs to the intervention, i.e. including a walk-through of the system's functionalities (yellow circles in Figure 12). Often, the research team had to initiate contact and follow-up several times throughout the recruitment period to, for example, provide more information, recruitment material or check on the status of patient recruitment.

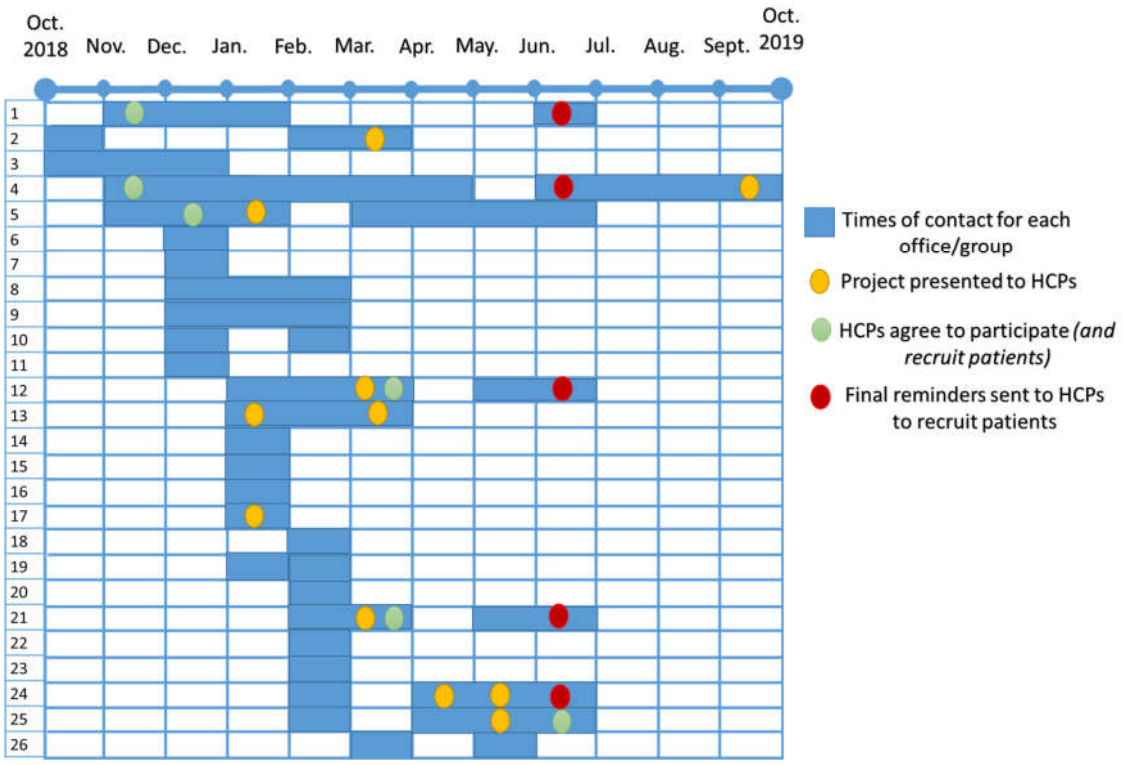


Figure 12 Illustration of the main HCP recruitment efforts for the FullFlow Feasibility study, i.e. initial contact (blue rectangle), presenting the project (yellow circle), agreement from HCPs to participate (green circle) and final reminders sent to HCPs.

At offices #13 and #24, one HCP in an office would recommend we present the project to colleagues, in which case more than one project presentation was made (multiple yellow circles in a row). More than one HCP agreed to join at office #12 and #21. Study presentations concluded with a survey inquiring about their expectations of how the system could function with their patients. Seventeen (n=12 GPs, n=4 DNs, n=1 nutritionists) completed a pre-study survey, agreed to enter the study, and inform their patients with T1D or T2D about possible participation. Reasons for not being able to

recruit patients to the study included not having time to participate in an information session about the project, having too few patients who they thought would be eligible, and having too hectic a schedule to follow-up during the study.

Eight patient participants with T1D (n=4, n=2 Female) and T2D (n=4, n=2 Female) entered the study. Participants with T1D were between 38 and 65 years old, had been living with diabetes for between four and 23 years. Of the four participants with T1D, two used five or more medical and commercial mHealth devices (e.g., apps and insulin pumps). Those with T2D were between 54 and 74 years old and had been living with diabetes for between one and 15 years. Of the four participants with T2D, one used a paper diary in addition to two or more mHealth devices before the study.

6.5.3 HCP's pre-study perceptions of the FullFlow system

All 17 of the HCPs (n=1 nutritionist, n=4 DNs, n=12 GPs) participated in the pre-study survey after being given an hour-long session to introduce them to the FullFlow data-sharing system. **Appendix O** [259] summarizes these results, and Table 9 details the free-text results.

Table 9 HCPs' perceptions of the data-sharing system after pre-study information session

Respondent # and profession	Will the system be useful to share data during consultations? Explain.	Additional comments
1. Nutritionist	Yes, • For those with android phones. • For those who are interested in the technology.	• Correlation between insulin and carbohydrate intake. • Associate the "Carbo and Insulin" for carb assessment in food, as a supplement to the Food Table
2. Diabetes nurse	Yes, • For those who already use the app.	• Does the patient have the opportunity to enter the type of carbohydrate they eat (the number may not always be enough). • This system can be good for everyone but especially for patients who live more remotely.
3. Diabetes nurse	Yes, • The Diabetes Diary app can replace written diaries. • Many of our patients use other apps and we are familiar with relating to these.	• Under carbohydrates, does the patient have the opportunity to write down what they eat?
4. Diabetes nurse	Yes	• Note from the consultation (short note) that could be entered in the Diabetes Diary app.
5. GP	Yes, • For those who are preoccupied with their diabetes.	• Must use the system for a while before re-evaluating.
6. Diabetes nurse	Yes, • Depends on the patient entering enough data	• In addition to the information provided by the patient, would liked to have seen the distribution of slow and fast-acting insulin • Different colors on the columns that are slow-acting insulin. • In the overview: include a separate section for blood sugar values above 15 mmol / l and a separate section for severe values/symptoms (below 2.8 mmol / l).
7. GP	Yes	• Desire to add lipids
8. GP	Yes	

9. GP	Yes	• As much as possible, to allow automatic registration directly on Strava, blood glucose meter, insulin pen, etc.
10. GP	Yes	
11. GP	Yes	
12. GP	Yes, • Can be motivating for both the doctor and patient.	
13. GP	Yes	
14. GP	Yes	
15. GP	Yes	• Should support Apple phones • Should there be separate apps for type 1 and type 2?
16. GP	Yes	
17. GP	Yes	• Integrated in EHR, e.g. Noklus form. • Highlight changes, that can also be "journal-note-friendly". • Information [from the EHR] can be copied and adapted to the app so that measures are generated for the patient (can be followed up at the next consultation)

All believed that that the presented system would be useful during consultations. One diabetes nurse though that it would be particularly useful as a replacement for the paper diaries, recognizing that most of their patients use apps and other technologies. Another DN believed this system would be more useful for patients who lived at a distance than those who lived more centrally. GPs' suggestions for improvement included the desire to enter a note after the consultation, automatic registrations from medical devices. Nurses were more interested in specific outputs of information, such as cases of severe hypo- or hyper-glycemic events and correlations between insulin boluses and food consumption in order to more accurately understand each patient's particular metabolism of food in response to insulin. The responses of two participants, in particular, i.e., a DN and a GP, are presented in detail below in use case 1 and use case 2, in combination with their associated patient-participants.

6.5.4 App interactions, patient-gathered data, and pre-post questionnaire responses

Eight participants completed the first questionnaire set, with five completing both questionnaire sets. All participants provided usage-logs, which included patient-gathered data, i.e., physical activity, BG values, calories/carbohydrates, and medication (e.g., insulin, oral medication), and the number and time of interactions with the app. Two attempts were made to recruit HCP and patients. Four patients (n=1 T1D, n=3 T2D) participated in the study-end focus group meeting. One nurse participated in the corresponding healthcare personnel focus group meeting. However, this nurse did not see any of our patient-participants.

To demonstrate the ability of the measured outcomes to provide a comprehensive understanding of the impact of the mHealth app and FullFlow System, I chose two use cases (one with T1D, one with T2D) including patients' app usage-logs, demographics, and pre-post questionnaires and the healthcare personnel's responses and focus group results. These quantitative and qualitative data will be illustrated together, for each patient participant, in three diagrams: one diagram will depict data associated with the user's health, app-use and self-management, one depicting data related to the

users' perception of their patient-provider relationship and one diagram depicting the patient and HCPs' reported experiences using the system for data-sharing during the study consultation. After each diagram, a brief text will summarize how the data was analysed to give a more complete understanding of each of the three main impacts: i) users' health, app-use and self-management, ii) the patient-provider relationship and iii) use of the FullFlow data-sharing system.

Use case 1: Qualitative and quantitative data related to a T2D user and his HCP

T2D user's health, app-use, and self-management

Figure 13 illustrates the variety of participants' data, i.e., demographic and reported self-management data, usage-logs, changes in self-efficacy via the DES-SF [235], changes in reported wellbeing via the WHO-5 Wellbeing Index [236] and quotations from the focus group meeting about their use of the app for self-management. Major trends within the usage-logs are pointed out in the graph. Based on these data, we can see what parameters this individual focused on as well as begin to understand how these changed during the intervention and some explanations for why this individual chose to engage in the manner that he did and why some parameters changed. Note that HbA1c for this participant was not inputted correctly and is, therefore, missing from this dataset.

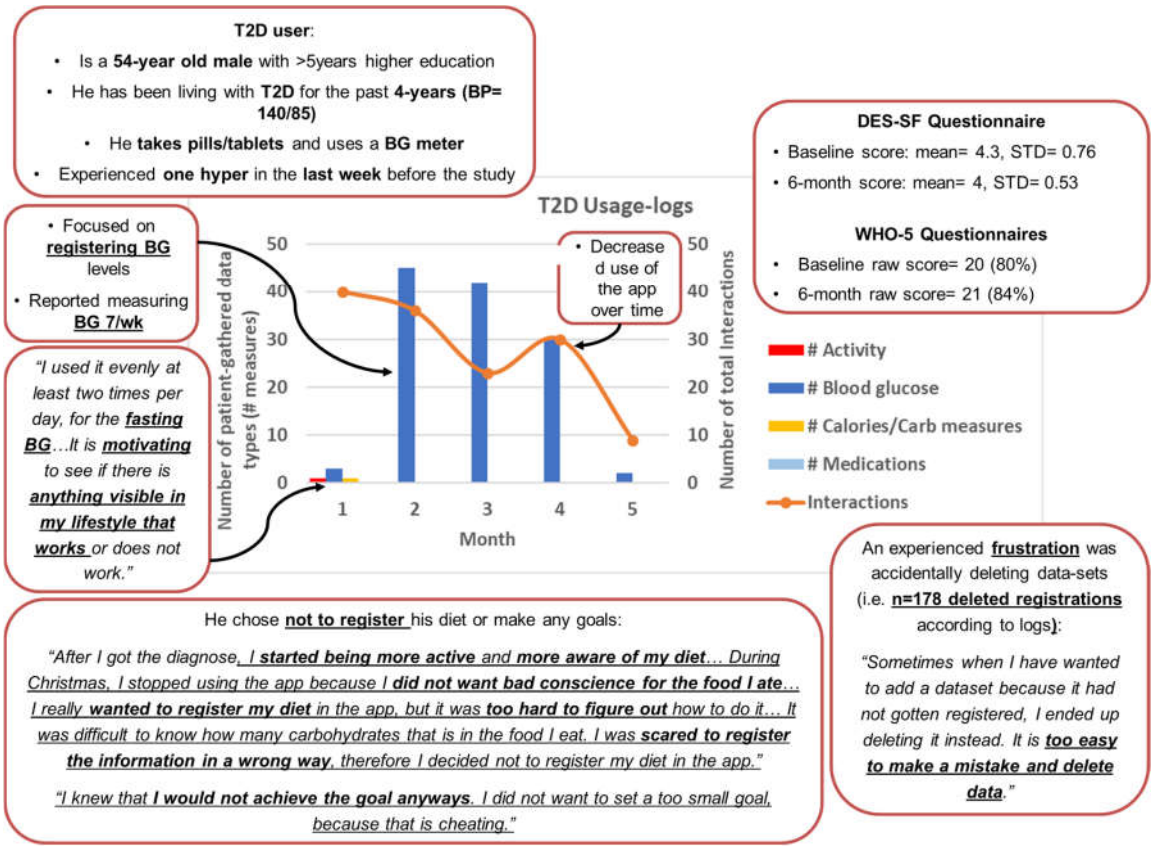


Figure 13 Quantitative and qualitative data related to T2D user's health, app-use and self-management

This T2D user focused on measuring his blood glucose using a BG meter and oral medication to self-manage, but not goals. His motivation behind his focus on BG was reportedly to see how his lifestyle affected his BG levels. He chose not to set goals because, as he explained in the focus group meeting, he felt that goals were "unachievable" from the start. It appears that the user registered activity, BG,

and diet a few times during month #1 but showed a significant increase in his registration of BG values during month #2 and then a decrease until the BG registrations and interactions stopped after month #5. While there were no physical activity and a few diet registrations made in the app, this user explains that he exercised more and became more aware of what he ate. However, he expressed that he felt shame for eating poorly and, therefore, for example, during Christmas, would not register food. It is unclear why he performed so many more interactions at month #1, yet had few parameters registered. However, technical difficulties may have played a role; he reported that it was too easy to delete his data, including his diet, which may explain the large number of deleted measurements (n=178) in his usage logs. By comparing questionnaires collected at the beginning and end of the study, we can see that he felt more refreshed after waking up and calm after the study (WHO-5 Wellness questionnaire) and experienced some improvement in his self-efficacy, including ways to overcome barriers and to stay motivated, with the exception of creating and accomplishing goals (DES-SF questionnaire).

Patient-provider relationship: T2D patient feedback

While the HCP responsible for meeting with this user did not attend the healthcare personnel focus group meeting, Figure 14 illustrates the patient's report about what changed in their patient-provider relationship via the HCCQ questionnaire and more in-depth explanation of his preferences and frustrations with the HCPs shared during the focus group meeting, i.e., how and why he perceived changes in their patient-provider relationship.

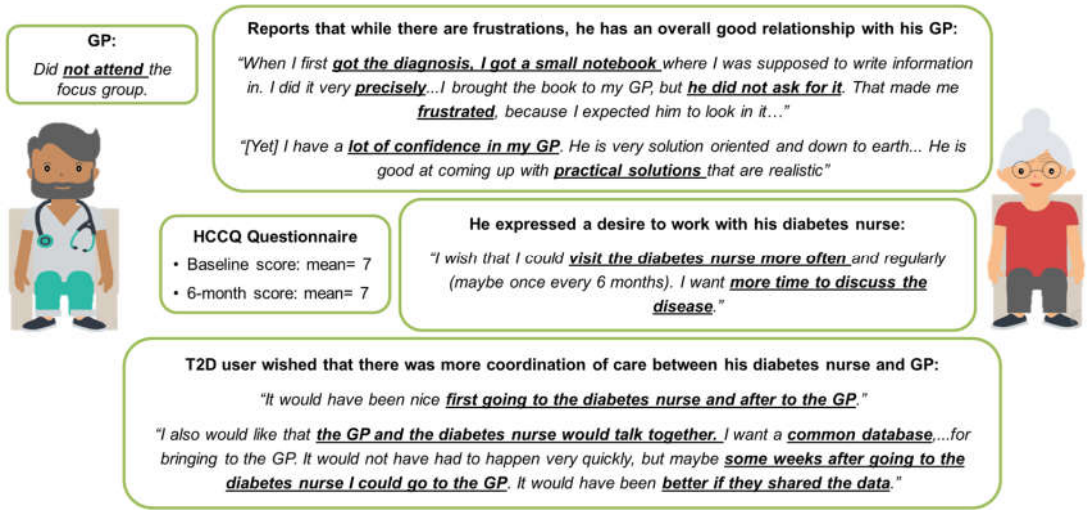


Figure 14 Qualitative data from the patient related to patient-provider relationship

Based on his responses to the HCCQ, the T2D patient's relationship with his GP did not change, except that he did perceive that his GP showed less confidence in his ability to make health changes. The patient was frustrated when he was first diagnosed because although he was diligent in using a paper diary to track his measurements, the GP did not spend time to look at it. However, he also reported that he has confidence in his GP because the GP gives him realistic self-management recommendations. He expressed how he would rather experience healthcare, i.e., by visiting his DN first to discuss the details of his disease and then to the GP and having a common database whereby his HCPs could coordinate his care. He also explained that he spent more time discussing the details of his diabetes and collected app data with his DN.

Use of the FullFlow System: T2D patient and HCP feedback

Figure 15 illustrates what occurred during their use of the FullFlow data-sharing system during their consultation. The HCP reported discussing health measures with the patient as well as how they recall using the system and its effects on their clinical practice via post-consultation questionnaires. During the patient focus group meeting, this participant reported their experience with the system as well as how it was for them to share and discuss their data with their HCP and some explanation as to why these may have occurred.

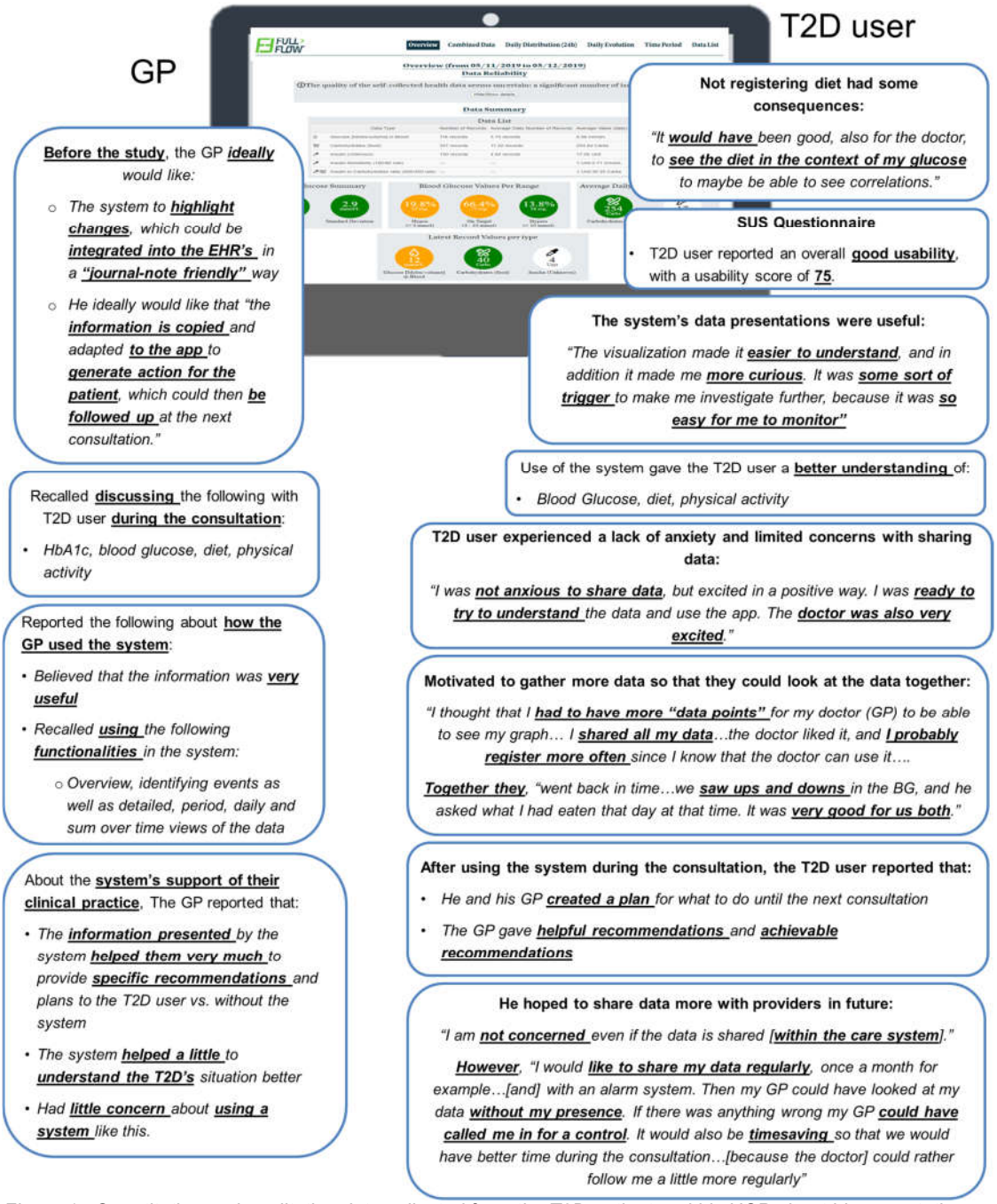


Figure 15 Quantitative and qualitative data collected from the T2D patient and his HCP about his expectations and use of the FullFlow data-sharing system

The HCP reported using five of the six main pages of the system. However, he would ideally have liked to integrate the data into his EHR system. He found that he understood more about the T2D's situation after using the system, and it allowed him to provide the T2D patient with more specific recommendations.

Use case 2: Qualitative and quantitative data related to a T1D user and his diabetes nurse

T1D user's health, app-use, and self-management

This case describes how a T1D user experienced the app, system, and relationship with his HCP during the 6-month study. Just as with the T2D user, we will explore these data to see what parameters this user-focused on as well as begin to understand how these changed during the intervention and some explanations for why this individual chose to engage in the manner that he did and why some parameters changed (Figure 16). Note that HbA1c was not input correctly and is, therefore, missing from this dataset.

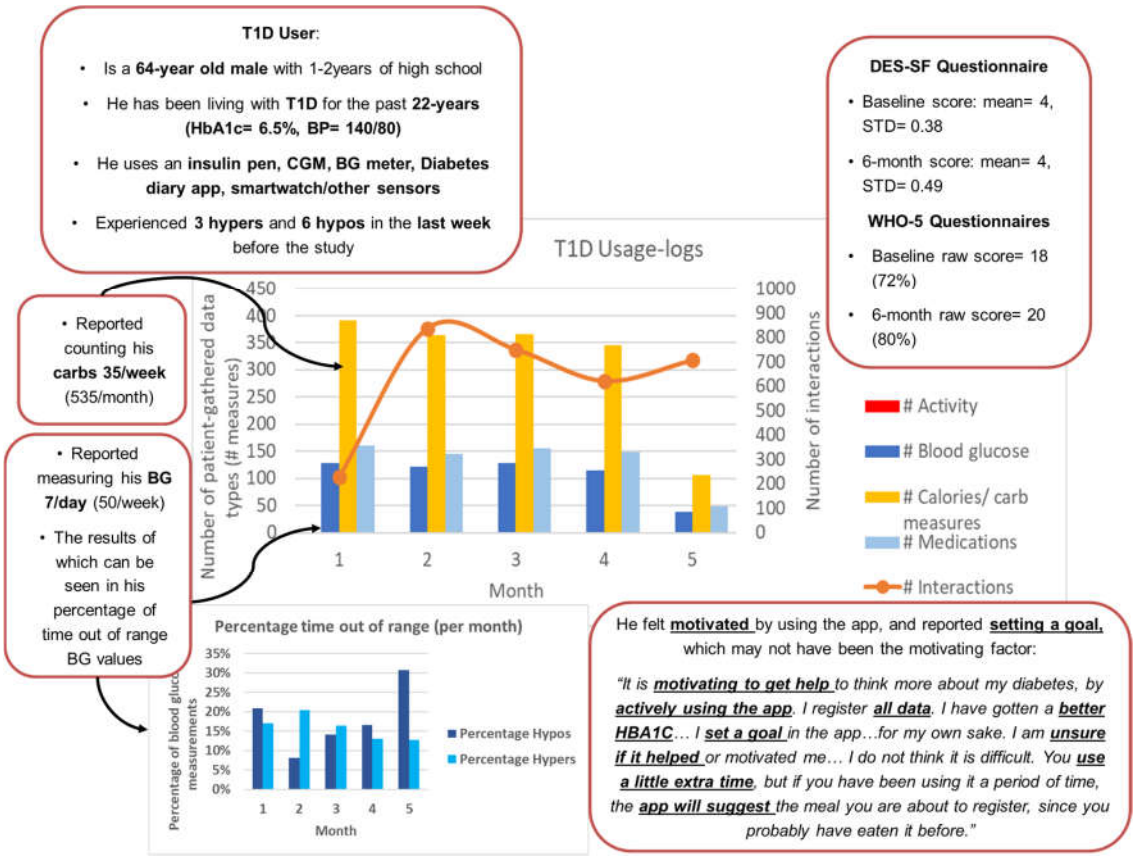


Figure 16 Quantitative and qualitative data related to T1D user's health, app-use and self-management

This T1D user focused on measuring his BG, diet, and insulin, using a combination of medical and mHealth devices. While it was not possible for the CGM to transfer BG values to the app, the BG values that were registered gave a relative view of the percentage of time this user experienced hypos and hypers, since he mainly recorded those values. His registrations and interaction with the app appear consistent throughout the study, with the exception of month #5—his reported being motivated by the app – associating a better HbA1c with its use. The user expressed that while it is easy to use the

app, one does have to invest time to record enough data so that the app can have a useful level of information to help you decide, e.g., how many carbs were in your meal. By comparing questionnaires collected at the beginning and end of the study, we can see that he felt more refreshed after waking up and more active after the study (WHO-5 Wellbeing Scale) and experienced little change in his self-efficacy – only a decrease in his understanding of which parts of his diabetes he is dissatisfied with (DES-SF). Data was gathered for five months instead of six because data-collection and structuring was not finished for this participant by the time this analysis was performed.

Patient-provider relationship: T1D patient feedback only

As was the case with the T2D user, this patient's HCP did not attend the healthcare personnel focus group meeting. Figure 17 illustrates the patient's report about what he typically experienced during his consultations via the HCCQ questionnaire, how he felt during the consultation, and why.

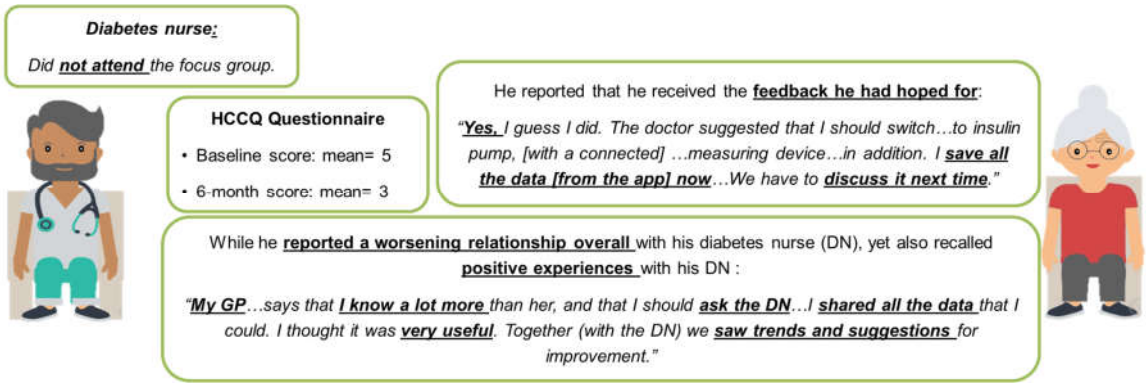


Figure 17 Qualitative data from the T1D patient related to patient-provider relationship

The HCCQ questionnaire showed that the T1D's relationship with his HCP worsened; he reported that the DN gave him fewer options, showed less confidence and encouragement toward the patient, and as a result, understood less about how he (the patient) felt about his health. While he did report positive experiences with his DN, because they were able to explore the data together, it was unclear which HCP he was referring to in the HCCQ, i.e., GP or DN. These negative experiences may be because, as he mentioned, the GP demonstrated little knowledge about his self-management and app use and, therefore, should rely more on the DN.

Use of FullFlow System: T1D patient and diabetes nurse feedback

Figure 18 illustrates what both expected from the system prior to their consultation vs. what they actually experienced, as well as how the system was used and perceived and what contributed to their perceptions.

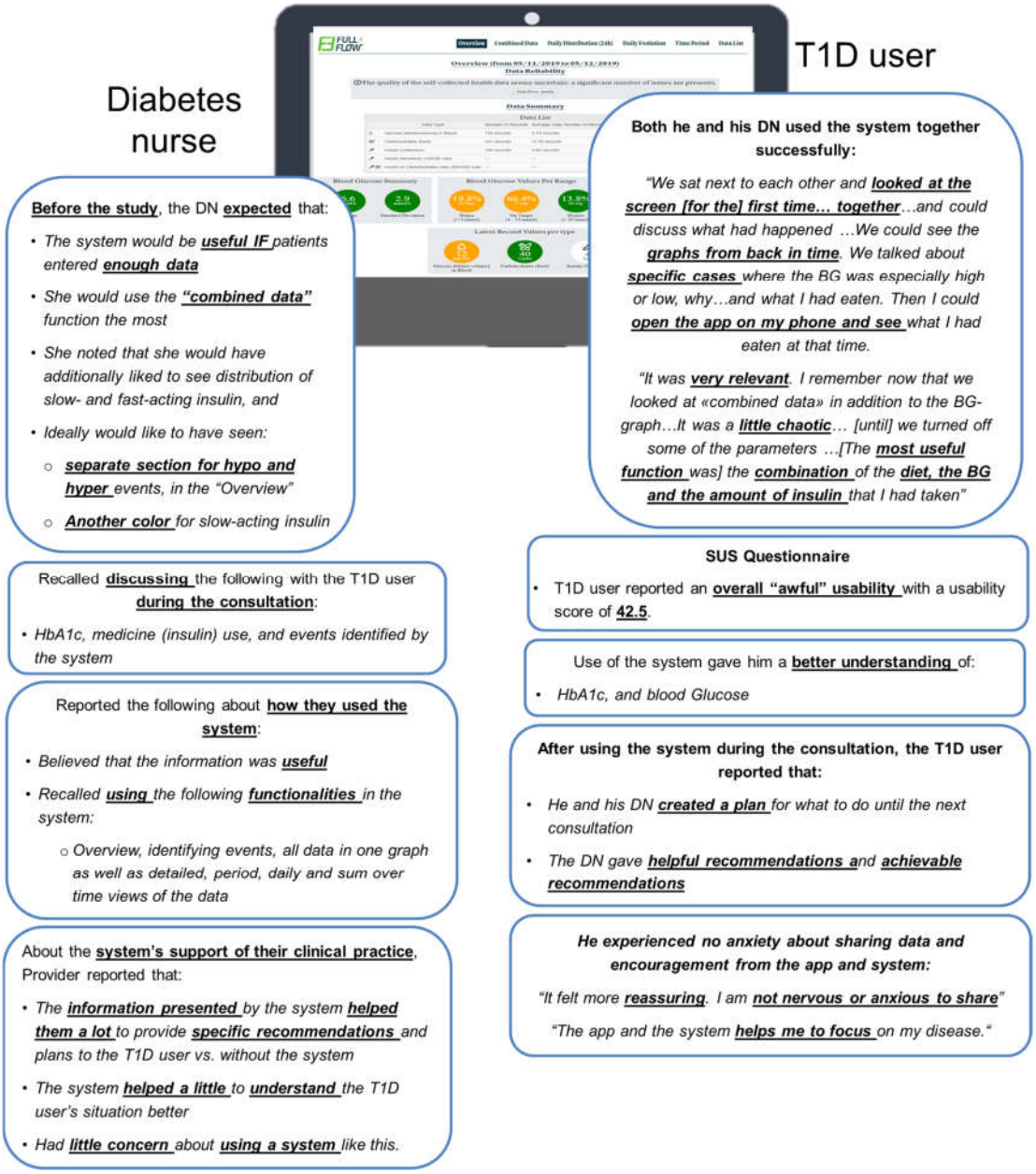


Figure 18 Quantitative and qualitative data collected from the T1D patient and his diabetes nurse about their expectations and experiences.

While the T1D patient-reported gaining a better understanding of his HbA1c and BG, not feeling anxious sharing his data, and improving his focus on his disease and discussion of specific cases with his HCP, he also reported a very poor usability score for the system. Specifically, he believed the system was too inconsistent and cumbersome and slightly agreed that he would have benefited from learning more before using the system. On the other hand, the DN said that the system, including the presented information, was very useful and noted using all of the pages of the system. She (DN) said that compared to before, this system helped her to create more specific recommendations.

7 Discussion

The aim of this Ph.D. was to explore (**Papers 1-3**) and then test (**Paper 4** and the mixed-method study) a combination of both traditional and modern mHealth approaches and resources with the aim of providing a more comprehensive understanding of how mHealth technologies affect patients and HCPs. The lack of methodological standards for how to structure mHealth intervention studies is a blessing and a challenge. As such, we have the opportunity to evolve how we approach and conduct research – we can be more relevant, more user-oriented, more creative, and more comprehensive in how we produce knowledge.

This thesis has taken an exploratory role within the research evaluation of mHealth interventions. In addition, I would like to take the opportunity to dive into the potential impact or implication of these works – from the limitations of outcomes from pragmatic research to the generalizability of lessons learned about study administration. This chapter is separated into sections. Section 7.1 summarizes the outcomes of each of the studies and describes the limitations unique to those studies, while 7.2 discusses the limitations to generalizability of the overall FullFlow Project and thesis outcomes. Section 7.3 then discusses what is generalizable, or useful information and insights, for fellow professionals working with mHealth technologies for diabetes intervention research and the like.

7.1 Insights and outcomes summarized

7.1.1 How mHealth data-sharing can address patients' and HCPs' needs

RQ1: "What information, support, and functionalities do patients, general practitioners, and specialists who work with diabetes, need, and expect from mHealth tools?"

The results of the HCP workshop, which was informed by the online patient survey, responded to **RQ1** by providing insight as to what patients wanted out of a consultation, i.e., their ideal consultation discussions, that could include their app gathered data. As both activities were conducted in 2016, the HCPs' feedback about the needs for EHR-integration of the patient-gathered data (**Appendix C**) was still a focus on many stakeholders, including the research team of the FullFlow Project. Perhaps the un-reported assumption of the HCPs was that patient-gathered data could inform clinical decisions. This perception shifted during the project duration, as EHR-integration lost its appeal and feasibility. This shift also matched the sentiments of our vendor partners in the project, as this ambition of the EHR integration of a mHealth data-sharing system was too far ahead of the practical possibilities of the time. The loss of appeal of EHR-integration for some HCPs could be seen during the joint co-design workshops of 2017 and 2018 (**Paper 1**); as HCPs, especially GPs, had over time became more aware of the details of mHealth, the potential breadth of data that patients could gather, they became more concerned with data-overload and the liability of trusting erroneous data. However, in another published work, we describe how time also played a role in HCPs' readiness and willingness to accept mHealth app data. HCPs began to see a different potential to use patient-gathered data to understand their patients and recommend more tailored self-management recommendations, with no mention of how they would change their clinical recommendations (**Appendix P**) [260]. HCPs' cautious optimism about relating to PGD during consultations was reiterated during the joint-co-design workshops.

One major outcome of the joint co-design workshops was the breadth and depth of information that was known and suggested by both our patient and HCP participants. A significant point that was made by both was that mHealth information is out there, but limited to a few stakeholders. Our specialist and DN, in particular, had experienced different patients coming with different mHealth devices, such as apps, and asking the HCPs to interpret the data or even help with technological errors. This was certainly not included in their medical training. HCPs noted that the only information about patient health devices that they receive semiregularly is from device manufacturers, who are often large corporations contracted with that clinic. These cover clinically approved devices such as insulin pumps and CGMs, not apps. This later informed the mixed-method study design (**Paper 4**) by highlighting the HCPs' need for a thorough training session prior to the study start, as they would not have gained enough knowledge or understanding of an mHealth data-sharing system elsewhere.

The joint co-design workshops responded to **RQ1** by also producing an outcome related to the structure of the participant sessions. Choosing to involve both patients and HCPs together proved to be a greater benefit than challenge, despites concerns about this arrangement. Participants were able to resolve or correct assumptions that either group had - there and then. As observing researchers, this provided us with concepts for the designs of both our FullFlow data-sharing system and mixed-method feasibility study, that were agreed upon by both end-user groups. In other words, we were able to move forward with concrete, realistic and common ideas for the intervention as opposed to trying to coordinate misunderstandings and erroneous comments from both sides. For example, in the joint session of T2Ds and GPs, by discussing patients' assumption that HCPs could review all of their data before the consultation, GPs were able to comment that this was unrealistic and alternatives should be sought to meet the patients' needs of specific and thorough responses. In fact, in the T2D session, patients demonstrated their ingenuity and understanding of both the GP's limitations when they suggested seeking answers from DNs, or others who know more about the technology and specific situations in diabetes.

As patients are becoming their own experts in mHealth and self-management, we have to ask, "s research answering to the needs of our primary mHealth end-user, patients?", "Are we looking at all of the information or using all of the resources that we can to provide evidence?" Patients are now asking HCPs such detailed questions based on their data as, "how did this specific combination of foods, while I was hiking two days ago, affect my blood glucose today?" or "why am I so tired all of the time, with swinging blood glucose levels, even if I follow the recommendations that you, my doctor, gave me? Here, can you look through my data to tell me why?" and "what information should I be gathering that is relevant to you, my doctor so that we can discuss my situation more effectively? Similarly, HCPs' questions were, "how are we, or anyone in healthcare services, expected to provide these kinds of answers given such unstructured data and little to no evidence of this app's reliability and effectiveness?" As researchers, we have to ask, "can we help HCPs feel more comfortable with these data?" The answer – partly. We cannot immediately change the EHR and other proprietary systems to be more open and accessible, but we can listen to our end-users when we develop something new and perform any research on their behalf.

We can develop the most innovative technologies, taking advantage of advancements in connectivity, wireless technologies, sensors, and artificial intelligence, but if we do not answer to the needs of our end-users, these technologies will essentially be useless. We need to address more specific questions and take into account the broader environment in which patients use mHealth and other available

health resources. Our research team also conducted a related work whereby we compared patient reported-needs to what information was being produced by mHealth app and social media interventions. The results showed that research is producing general information, e.g., about usability and feasibility of these technologies, but not necessarily the specifics that patients are asking for, e.g., what resources are available to effectively support personal self-management (**Appendices K and Q**) [231, 261]. The results of these co-design workshops also support the conclusion from the scoping literature review (**Paper 2**), i.e., it is not feasible for one group to produce all of the information, and collaboration is needed. Patients need to be part of study designs and the selection of methods and measures to ensure that their needs are being addressed and valued when it comes to producing evidence of mHealth's effects on them and their overall lives.

Limitations of the co-design workshops

While much preparation and theory was put into developing the discussion guide questions and activities, participants reported being confused by some of the more introspective questions, and why it was suggested that they write their answers on post-it notes prior to discussing their answers. The sessions with patient participants were also held in Norwegian, led by the project manager, while I observed the best I could, with limited Norwegian language proficiency. Coming from an American style of research, with the tradition of more formal and, perhaps, over-detailed explanation of activities to participants, I saw an opportunity not taken to explain more thoroughly before the start of the workshops. There was also a lack of balance between men and women in each of the workshops, i.e., more men than women. As HCPs vary in their practices, and individuals differ in their self-management and lifestyles, I would have preferred to have more specialists and female patients.

7.1.2 How mHealth evaluations are being approached

RQ2: What approaches, methods, and measures are being used to collect data for the evaluation of mHealth interventions for chronic illness self-management?

The grey literature review responded to **RQ2** with evidence of the mHealth technology criteria that governmental and independent organizations were focusing on in their evaluation efforts. These criteria aimed to cover categories of apps or an mHealth system for regional or national integration. The evaluation processes that are described are largely publically available and concrete. In other words, they are published in such a way that others can use them. With the exception of evaluation services, which aim to generate profit for their services, governmental reports, guidance, and frameworks are intended for hospital systems, regions, or entire countries to follow in order to understand the impacts of mHealth at scale. Processes described ensuring not only the success and feasibility of the technology in and of itself but also the readiness of the medical facility and network in question to ensure the sustainability of the technologies' practical integration. Like traditional medical systems, these evaluation approaches are meant to offer an explanation for how these mHealth technologies can deliver the most positive impact to the most people.

Whereas the grey literature review described the broader, more publically-facing approaches to evaluation, the scoping literature review provided an overview of evaluation efforts in controlled and clinically informed structures, looking at specific questions about mHealths' impact. The scoping review paper (**Paper 2**) aimed to answer **RQ2** by collecting information about what researchers' intentional study approaches were and how they chose to evaluate patient-operated mHealth

technologies. Unlike the grey literature review, the research processes described in the scoping review are controlled and are meant to be built upon with additional evidence from fellow researchers.

By comparing traditional vs. mHealth approaches and resources, we discovered that these two categories are not mutually exclusive. Researchers are using a combination of traditional and mHealth approaches to explain, more comprehensively, how mHealth technologies affect patients and HCPs. In doing so, they acknowledge that each category of information alone has its own strength and weakness, but together they form a more complete picture.

While usage-logs and patient-expert feedback are valuable and informative, we still have a way to go when it comes to validating such mHealth-related resources and measures. Researchers demonstrated much creativity regarding how they collected, structured, and analyzed these data within the reviewed studies. However, these strategies were unique to each study, making them difficult to compare, form a meta-analysis, and thereby provide reliable and useful evidence.

There have been attempts to create evaluation frameworks, scales, and scoring systems for these technologies. The WHO and the mHealth Technical Evidence Review Group's (mTERG) mobile health evidence reporting and assessment (mERA) checklist, represents a research-facing strategy for identifying information about an mHealth app or system [262]. It urges studies to produce results on topics ranging from the financial impact, user feedback and accessibility, clinical impact, and delivery at scale, among others. But have these studies followed these strategies? Partly. Unintentionally or intentionally, researchers have, of course, covered the user-facing and medically-related outcomes that such checklists call for. However, to the best of our knowledge, there is little to no solid evidence in the scientific literature that researchers have been able to, or choose to, produce business and operational evidence.

Limitations of the scoping literature review

As was pointed out by our reviewers, we could have included more types of NCDs. While our narrowed selection of intervention types was based on public trends in mHealth and up-to-date regulations posed by health authorities regarding mHealth evaluations, we could have included a broader selection of technology and intended uses. For example, we could have included interventions based on SMS, an established and effective means of providing self-management support, especially in more limited socio-economic areas.

7.1.3 How usage-logs can illustrate what is happening during an intervention (inside the Black Box)

RQ3: Can usage-logs and patient-centred analysis be used to provide more evidence and information about what, how, and why changes occur during an mHealth intervention?

Finding a balance between the mHealth resources that we now have access to, the patient voice, and the clinical interests of HCPs seems like a pipe dream. Yet, this is what we tried to illustrate in **Paper 3** by analysing patient participants' mHealth app usage patterns, from a year-long RCT study. With data that told us when users interacted with the app, which screens they accessed and which health and behavior data they entered, we had the opportunity to provide more information about how patients chose to use the app for diabetes to meet some of their own self-management needs, during an intervention. If that sounded like a long, complicated task, and sentence, then you would be correct.

In health studies, the typical approach to data analysis is to compare results before and after the intervention, between pre-assigned intervention groups and control groups. The traditional analysis of these study groups represents differences in the assigned intervention groups, not differences in the individuals. This is an example of Weinstein's criticism – back in 1974 - that clinical trial methodologies "obscure, rather than illuminate, interactive effects between treatments and personal characteristics" [263]. The analysis presented in Paper 3 proposes a more patient-driven approach at data analysis by structuring analysis, only after it was found that there were no significant differences between intervention groups, on how patient-participants chose to use the mHealth app. In doing so, we acknowledge that patient-choice has more of an impact on the outcomes of app usage than assigned groups. Focus on these emergent groups contested the traditional pre-post evaluation of health intervention studies and acknowledged patients' choices of app usage just as much as clinical outcomes. Justification for this approach came when we saw that there were no significant differences between control (n=50) and intervention (n=51) groups (in app-use or health outcomes), yet there was much heterogeneity amongst those who chose to use the apps. Some focused on physical activity and diet behaviors and data entry (Cluster 1), whereas the other main group focused on BG and reviewing previously recorded events (Cluster 2). By comparing the usage-logs in addition to traditional clinical measures, between these two groups, we found that these two app-use strategies did have an impact on how much their HbA1c changed; Cluster 1 lowered their HbA1c more than Cluster 2. We also noticed that there was a relationship between how long patients used the app and clinical change – not after an entire year as one would expect, but instead after 4-months. This suggests that perhaps individuals did not have to use the app for a long time to experience benefits; perhaps it mattered more how they used an app, not how long.

The outcomes of this analysis demonstrated that not only do end-users have a greater impact on the outcomes of a study than the group assignments made by the researchers; they also demonstrated how usage-logs provide context and some explanation for changes in before-and-after studies, using traditional and clinical measurements, such as HbA1c and self-efficacy. This was a test of a new way of structuring data for analysis and has the potential to help HCPs and researchers structure patient-gathered app data for future practice and health interventions to answer questions about patients' self-management strategies and impacts on their health. Had we only depended on the original analysis, based on comparing intervention groups, we would have been forced to accept the results of "no significant differences, i.e., no significant impact, was found" and a conclusion that, simply, "more and different forms of research are needed"– something we find in very many of the research papers in this field. With the new approaches that we tested, we not only produced more information about the impacts of the intervention and which factors were at play, we also produced more actionable questions for future research. Instead of a general call for "different forms of research," we were able to generate questions such as, "what impact did motivation play, or why did they choose to use the app in that way?", "what other services or guidance would support patients to make more effective use of the app, given their collection of these data sets, e.g., what kind of help could an HCP add?", "how long do patients really need to use an app, and in what way, to achieve physical or psychological changes – and what kind of changes are these?" Not only has mHealth technology and patient-driven research provided us the opportunity to understand what changes occurred during interventions, but we can also continue to explore why and how they changed.

Limitations of usage-log analysis

Due to the K-means clustering method, used to identify similar usage patterns amongst participants, resulting clusters that were compared had few individuals included in the analysis. Also, five participants were excluded from the analysis due to their irregular or dissimilar usage patterns. Similarly, we did not include short-term users in our analysis. It has been proposed that individuals may not have to use an mHealth intervention sustainably or for long periods to experience benefits. As proposed by a specialist participant in the co-design workshops, intensive use of an app to record detailed self-management habits and health changes could also be very informative to the HCP but also to the patient-user. The short-term users may have chosen to use the app as more of an informational tool or to answer a specific question about an issue they were experiencing within their self-management. It would not necessarily require more than three months of use to gain the answers and support they needed –usage logs from whom could also be informative.

Bias in clustering

This analysis method was selected by the invited statistician who consulted and helped perform the secondary analysis of the data based on the fact that this is a commonly used clustering method [229]. Our intention was to identify profiles of use via secondary analysis of previously collected RCT data on participants' use of the mHealth device. Clustering is the process of identifying groups based on similar outcomes, i.e. discovery of discover the natural grouping(s) of a set of patterns, points, or objects [229], in this case usage-log patterns based on which functions were most used by the participants.

Clustering has been used to identify and make decisions related to, for example, "natural classification" such as those used to classify similar biological organisms into phylum. It should be noted that this is different from a case-control study in which controls and cases, e.g. disease exposure, are matched based on a common features, e.g. age, sex or education, and then retrospectively compared to identify if there are inherent differences that could have contributed to their different outcomes, i.e. no disease exposure vs. disease exposure; in k-means clustering, the individuals are being treated as a group because of their similarities and their usage-logs are described to gain a detailed understanding of what those patterns include, e.g. ratios between different functions used, duration of use of these functions, when the device was more or less frequently used. In the case of this usage-log analysis, it allows us to interpret the results from a participant-driven perspective, based on their decisions, not our third-party, and observably incorrect, presumptions that all use the technology in the same amount or way. However, there are biases related to the following parts of the "partitional" approach to clustering, i.e. the K-means cluster analysis: i) the researcher decided on the cut-off number of 5 individuals as this would allow for more meaningful statistical comparison between groups, ii) "hard assignments" of a data point to one group or another do not, by definition, allow an individual to be part of more than one cluster at a time, even though could share a low level of similarity to another cluster than the one they were assigned to; while this eases statistical comparison between emergent groups, it does not allow for interpretations of just how similar individuals are between the "hard assigned" groups just that they are "different enough" to be assigned to different groups, iii) identification of the emergent clusters and decision that a data point, or participant, is more similar to one group than another is somewhat subjective based on the researcher's interpretation and decision, which is often difficult as cluster clouds can be different and vague in terms of density, size and shape [229], and iv) clusters were assigned based on a certain set of data,

without consideration of age, gender and other potentially relevant factors. We can therefore not form conclusions related to differences in usage patterns between older and younger individuals who may have used similar functions but in different variations within an assigned cluster, which again was based on the most commonly used functions. Differences between people within the assigned clusters based on these factors were not explored and therefore should be considered upon future analysis of, ideally, larger participant populations.

7.1.4 How mHealth can be used as a resource for traditional health evaluation methods and measures

RQ4. How can mHealth approaches and resources supplement traditional methods and measures in a protocol describing how to measure impacts of an mHealth intervention on patients and HCPs?

The design and the test of the protocol answered the first part of **RQ4**, related to how mHealth approaches and resources could be used to supplement and complement the traditional methods and measures. Combining standardized pre-post questionnaires – measuring both psychological and physical wellbeing and patient-provider relationships – with usage-logs, focus group feedback, and usability questionnaires from both patients and HCPs. We believed that these combinations of measures would allow us to answer not only what had changed during the intervention for both patients and HCPs, but also how and why. However, these results only demonstrate, not prove, the possibility of mHealth as a resource for health intervention research. While we have the opportunity to broaden research's perception of what is relevant and what impacts the medical community, we do have to take these results with a grain of salt and take into account before our next studies that both mHealth and traditional research have their strengths and weaknesses.

Traditional methods and measures are specific, validated, and make it possible to replicate studies and build upon the same evidence as others in the field. However, they attempt to measure cumulative change reported at a single moment, such as the Healthcare Climate Questionnaire (HCCQ). The responses may fall victim to memory error or mood that day for the patient, which may not accurately reflect their experience during the whole intervention. This may have been the case with the second case (T1D) analysed as part of the feasibility study, in which the participant responded that they felt as though their DN had less confidence in him, even though they both reported positive effects of using the system together. Situations during an intervention, especially interpersonal ones, are much more complex than can be measured by one method applied only a few times during the study, typically 2-3 times. While our focus group meetings helped to elaborate on the T1D patients' side, it was not possible to clarify any miscommunications from the DN's side, as she was unable to attend the HCP focus group meeting.

mHealth technologies reinforce and facilitate the concept of patient-centred and patient-driven research. mHealth for self-management puts individuals in the driver's seat of their own health decisions. When we acknowledge patients' decisions in our research activities, e.g., usage-log analysis, we are also forced to acknowledge that individuals use apps differently – just looking at the heterogeneous data of the RENEWING HEALTH study demonstrated that one size does not fit all. It forces us to rethink our questions, our interpretations of the data, and our assumptions of patient needs, priorities, self-management practices, and barriers to doing so. With the help of mHealth technologies and empowered patients, we can more effectively expand the impact of research by expanding the conversation and focus of healthcare practice to include that of the patient.

As demonstrated by the mixed-method feasibility study, usage-logs can also be complementary to traditional measures. These logs refer to each interaction that a user has with an app or other mHealth device [264]. Researchers can refer to "usage patterns" to describe a patient's journey through a study, e.g., their engagement with the intervention as well as participation in the study or when they were most and least engaged [265]. By comparing these data to other data collected during a study, we could theoretically begin to explain why these changes in usage patterns occurred. We can also begin to ask more questions than we have been able to measure before, e.g., when did that user change which type of data they collected and used in their self-management routines? These could be followed by more qualitative questions that elaborate or explain these responses. Analysis of usage logs and usage patterns is also a very new concept in medical and health research, with most cited studies occurring in the last 2-3 years. As such, the same questions apply to this form of data as patient-generated health data, e.g. how to structure the data, how trustworthy and reliable these are etc.

The results of the feasibility study demonstrated that the mHealth-focused resources and measures helped to explain why and how the experiences, relationships, and wellbeing changed during the intervention period. For example, focus-group input explained some patient participants' motivations behind not only collecting but also sharing data. Patient participants seemed to give honest and direct feedback about technical errors that they had with the system and frustrations with the healthcare system and their HCPs that were correlated with, e.g., missing data for the T2D user, and T1D's decreased satisfaction with his patient-provider relationship.

mHealth could provide an approach and the resources to conduct studies that lead to more in-depth and foundational questions about not only what but also how and why patients, and even HCPs, engage with an intervention in the manner that they do. Perhaps by using mHealth approaches and resources, the future publications of our research works could conclude with concrete suggestions for what information needs to be explored next, as opposed to the very popular phrases "more research is needed to…".

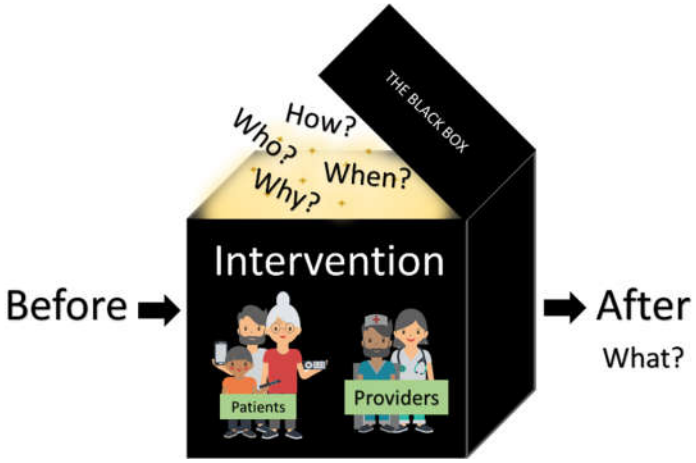


Figure 19 Illustrating how mHealth can help to open the "black box" of health intervention research.

We can continue to ask: what information should we aim to produce, for whom, and how should we go about this for mHealth intervention evaluations? In doing so, we can use mHealth to open the "black box" of research interventions and identify not only what has changed but also how and why

these changes occurred during an intervention using a practical case, diabetes self-management interventions (Figure 16).

However, patient-generated data, such as usage logs, are prone to technological and human error. The analysis for these data has not yet been standardized and therefore are difficult to replicate and validate. Case and point, while the structure of the usage-logs for analysis was based on interdisciplinary theories, this process has only been performed a few times; it has not been performed or validated outside of the present research team, i.e., during the Tailoring and RENEWING HEALTH projects, and therefore requires more validation and, of course, data.

Reflections of the pragmatism paradigm in the study design and administration

Loudon et al. provide a means to assess the level of pragmatic approach that a study has built into its design and performance [266]. Based on 9-domains of a study design and performance, the study could be scored from 0 (explanatory, positivist and evidence driven) to 5 (pragmatic and knowledge driven). I performed this analysis on the FullFlow feasibility study will benefit from recalling Figure 20.

Figure 20 PRECIS-2 Score for the FullFlow Feasibility Study

I provide detailed explanation for how I concluded on these scores for each PRECIS-2 domain, based on specific decisions made in the protocol and administration of the FullFlow Feasibility study, in Table 10 below.

Table 10 Explanation of the FullFlow study's scores for the 9 PRECIS-2 criteria

Domain	Score	Explanation
Eligibility	**3**	• Individuals who were 18+years, with T1D or T2D, lived within the Troms/Finnmark areas, interested and willing to try to use the intervention were considered eligible • Providers were identified based on our own research network and colleagues' contact within the Troms/Finnmark areas • Because this excluded those who were not interested in mHealth technologies, from both the patient and provider side, or those who lived outcome of the Troms area, scores of 4 or 5 were not justified • However, no limitations were placed on HOW the intervention would be used, only described the possibilities of the various ways in which it could be used, so use-related decisions were meant to be based on participating users' level of technology interest and ability, which justified a score of 3
Recruitment	**4**	• All patients with T1D or T2D were recruited through their providers, who had already agreed to enter the trial • Recruitment materials were given to those who attended an appointment at the clinic or mailed to those whom the provider perceived as potentially interested • A score of 4 is justified because, outside of eligibility, the process of recruitment used existing workflows and protocols, which did not require much more work than a provider would normally perform to contact patients
Setting	**4**	• Part of the intervention occurred in the typical setting of a consultation for the purpose of diabetes care between the patient and their normal provider in their office setting • While the research team encouraged patients to schedule these in order to try to use the intervention, it was unknown which of these were regular appointments or which were scheduled because of the study, which is why the score of 5 is not justified
Organization	**3**	• Patients were not trained but were provided with access to online resources to assist them in deciding how they would like to use the system • The system was made available online so that anyone anywhere could access the patient's data (including themselves) as long as the patient provided the access key and initiated data transmission. Therefore, this could be made available during normal clinical consultations as long as the secondary user had access to the internet and consent from the patient (the ideal and hoped-for setting of our study) • Participating providers were trained on the system for 1hour, which would, the in real world, require outside support and technical assistance • Additional assistance is a rather large barrier to real world use, which is why the score is only 3 and not a 4 or 5

Flexibility: delivery	**5**	• Participating patients were encouraged to schedule an appointment with their provider to discuss their data after a 6month period of time (via a message sent to their smartphone app and on e-mail) • Patients decided when and if they would indeed do this and follow-up reminders were provided only twice if they did not decide to do so (data limitations were expected to result) • Providers were instructed to click the link in the intervention system, which automatically led them to a questionnaire page associated with the consultation of the individual who shared the data, after each consultation to provide research feedback so that the experience was fresh in their minds and it would reduce the need to remember later. • Patients were sent the link to a 6-month questionnaire about their consultation via a message to the intervention's app on their smartphones and on email • Patients and providers drove the conversations together and questionnaires only asked what they talked about instead of dictating what they should talk about or how they should use the system • While the research team did encourage use of the system, the freedom provided to patients and providers justifies the score of 5 for this criteria
Flexibility: adherence	**3**	• Researchers sent follow-up messages each month to encourage and inform participants of the different functionalities that were available on the app • However, these messages did not direct the patient about how to perform self-management or what information to record, only encouraged them to explore the possibilities of the technology that they believed would be useful for them (tailorability) • More administrational follow-up messages included instructions for how to participate, i.e. up to 2 reminders for the start-up registration of their device to the research system so that we could remotely collect their data, baseline questionnaire, 6-month consultation scheduling and post-consultation questionnaire • These would not be available in real life, which is why this is not a score of 4 or 5.
Follow-up	**1**	• As mentioned under "Flexibility: adherence", we performed significant efforts of follow-up after each consultation throughout the duration of the study and provided email support whenever they needed. • The score for "Follow-up" is low because such support would not be available in the real-world setting. We did not expect healthcare providers to be able to do so given their already overwhelmed schedules, and if they would like to include this in their practice, they would most certainly have to hire additional and technologically trained personnel, especially to help those experiencing tech issues.
Primary outcome	**5**	• Outcomes were largely based on the previous studies (described in the Methods and Results sections), provided by both healthcare providers and patients • To ease reporting by patients, outcomes were gathered by response offered via a link in a message from us to their smartphone app/email to a set of questionnaires. Usage-log data was remotely captured (which did require some effort from the individual participant who had to enter a code in order to allow our system's access to their logs) • Patients and providers were also invited to study-end focus group meetings, through which they could express their experiences, frustrations, and overall perceptions of their experience and the intervention's impact. • Because outcomes were based on end-user input and the flexibility in which they could be reported was based on the user's decisions, the score of 5 for this criteria is justified

Primary analysis	**5**	• We did not exclude or limit the data available if the participant stopped using the device, did not complete questionnaires or did not schedule with their providers. we simply viewed these as results reflective of real-world situations • Missing data were seen as valid results of either the participant's experience in the trial or use of the intervention (although we did not know which one), which is why the score of 5 is justified for this criteria

Limitations of the feasibility study outcomes

The main limitations of the feasibility study as a whole included geographical location, recruitment, and technological challenges. Because this study focused on collaboration between patients and HCPs, we needed HCPs to be engaged, and therefore we needed to recruit prospective patient-participants through them. The Troms and Finnmark regions occupy a large geographical area, with a small potential participant pool from each clinic. As a result, we were only able to recruit eight patients. This led to the inability to comment on the statistical change or comparison of the usage-logs or questionnaire responses within and between patients during the study. There were also limitations regarding the amount of quantitative data we could gather through the app due to the connectivity challenges with not all users being online 24/7. As such, we also have limited ability to comment on the usage data of app interactions. As a result, we would not have continuous interactions and patient-gathered measures data to provide insight into behavior change during the study. However, all patient-registered measures were recorded and will be included in later analysis.

Due to the risk of participant burn-out, known as respondent or participant fatigue [267], we were limited in the number of standardized questionnaires we could include. While the patient focus group meeting did provide more understanding of their situation, we may have improved our ability to understand the responses more thoroughly by reflecting their questionnaire responses in the discussion questions that were asked in addition to basing questions off established theories.

The patient study-end focus group, fortunately, was held before city closures were enacted due to the COVID-19 crisis [268]. Unfortunately, only one HCP – a DN who did not participate with a patient in the study, and used a system called Diasend [269] instead of the tested data-sharing system – was willing and able to attend a virtual interview. The rise of the COVID epidemic only highlighted an existing research challenge - recruiting HCPs. While we did pay GPs for their time, these HCPs do not have the same funding and flexibility as hospital staff to participate in research. Therefore, the only understanding of how the HCPs who met with patient participants felt about the use of the system was based on questionnaires.

7.2 Limitations of the Pragmatism Paradigm

In addition to the practical study-specific limitations that affect the generalizability of this thesis, as was mentioned in the background section, the pragmatism paradigm comes with its own perception of generalizability that must be discussed.

COVID-19: prime example of how a global change affects generalizability

Circumstances change how we perceive and respond to our environments. As we can see from the world's ongoing experience with COVID-19, perceptions and realities evolve with time and are highly

affected by the tangible and intangible factors that surround individuals. In one of our own articles (Appendix P) [260] we noted that while clinicians' willingness to support their patients' use of mHealth and receive patient-gathered data had increased between 2013-2017, healthcare authorities had not provided sufficient daily recommendations for how to successfully and safely accomplish this. Today, the need for healthcare services despite social distancing measures of the pandemic have forced healthcare authorities such as the CDC to offer official guidance and recommendations about how healthcare providers and facilities should react [270], and even provide information regarding insurance coverage, something that mHealth technologies have not yet achieved [271]. These changes happened over a matter of months in response to the rapid spread of COVID-19. There are also the intangible influences such as the stress of being isolated and defeated during the pandemic, i.e. COVID or Pandemic Fatigue, for everyone and/or the exhaustion and anxiety of being a healthcare provider. These symptoms of mental stress can manifest in many different ways from frustration with simple tasks and short tempers, to depression and loss of occupational productivity [272, 273]. While these may not seem to affect the use or perception of mHealth think of how frustrated we can normally get when our phones or internet is not working – an overly simple example yet one we can all relate to. Now add the stress of needing to connect online, perhaps with your doctor about some worrying symptoms you are experiencing from your diabetes, and not being able to. If we had the capacity to interview the HCPs and individuals with diabetes who participated during the FullFlow Project, it is within reason to expect that their perceptions of mHealth and/or the need to share patient-gathered data in-person would have changed. The functionalities of the system that we developed during the presented project would then also need to change to support social and "medical distancing" where possible.

Self-selection bias

The generalizability of our findings is also limited by a common bias – self-selection bias. This is exactly how it sounds; while recruitment information may have been made public via pamphlets or social media etc., individuals who choose to enter a study inherently skew the data that are recorded because they are willing and able to participate. As such, they may not represent the larger population. The negative impact of self-selection bias can be larger or smaller given the study design and purpose. In the FullFlow Project, we aimed to build upon existing and used mHealth technologies for diabetes and therefore the purpose of our findings not only expected but relied on self-selection; we aimed to recruit and analyse the specific needs of those who have or were willing to have experiences with diabetes apps and data-sharing. Our recruitment activities reflected this need by posting recruitment messages on our research group's Facebook page (Diabetesdagboka), via our research app and through healthcare providers themselves, who had a population very specific to the geographical region. However, the danger of selection-bias for this project is evident in the interpretation and application of these findings to other circumstances. Factors, such as prevalence of smartphone use and internet coverage, accessibility of health information and support prior to study-start, could have influenced individuals in the described studies to present as more or less motivated or have greater internal locus of control than other populations. These results cannot be compared to or expected to appear, if the same intervention were used in a geographical area with less access to useful information and other support. A systematic review also noted self-selection bias as a challenge of interpreting results from mHealth studies [274]. An example from the FullFlow project is the secondary analysis of an mHealth intervention's usage-log that was performed as part of Paper 3. The results are highly biased because the use of the intervention technologies was entirely up to the

individual participants, i.e. as part of our secondary analysis, they self-selected their groups by using the app for shorter or longer periods of time and using different combinations of functionalities. As an RCT, individuals were assigned to a control, intervention or intervention with counselling group; while these factors and other measured demographic data were possible to account for in the statistical analysis of the usage-logs, the behavioural component within was not part of the original plan. In the primary results of the study, it was reported that there was no significant differences between groups or within groups over time [225]. Upon review during our secondary analysis, based on use-duration and clustering, we observed that n=29 participants did not even interact with the app, i.e. introduced non-response bias which has similar effects as self-selection bias; these participants' usage-patterns pulled the averages and other measures of use down. Due to small group sizes, the lack of identified significant differences between these self-selected groups as part of the secondary analysis (Paper 3) [253] cannot be taken at face value. Similarly, the statistics show a change over time and difference between groups associated with HbA1c, these numbers cannot be generalized to other individuals or cohorts. This is because comparisons were the result of k-means clustering. As mentioned above, clustering is highly affected by the statistician's interpretation, which is influences by underlying biases like background, previous knowledge of the intervention, disease and cultural influences that affect perceptions of study participants' behaviour.

Other limitations to generalizability: technology and geography

The activities described in this thesis do not address all types of mHealth, nor will they answer all of the needs of mHealth evaluation. In order to improve upon these works and direct future studies, we must acknowledge the limitations of the described thesis activities with regards to what mHealth intervention evaluations can tell us.

This thesis uses patient-operated mHealth technologies as a use case. Evaluation of these technologies assumes that patients' use of these technologies, and thereby their health impact, are equally dependent upon the patient's daily self-management decisions as much as those of the HCP's clinical judgment and recommendations. However, there are health technologies that can still be described as mHealth that are used by HCPs to monitor their patients. In these cases, use is prescribed, and patients may not have access to their data. Therefore, an evaluation may not need to rely as much on understanding the patients' varying motivations for using the technology, their health literacy, nor their diverse patterns of use, as these are directed by their HCP. In addition, there is a slew of other types of mobile technologies that are not included in the "patient-operated mHealth" category, including short-message-service (SMS) and consultations via Skype. As such, the findings in this thesis may not be as applicable to those who live in lower-income areas and/or only have access to SMS-based services and/or video conferencing tools.

The mHealth technologies chosen for most of the thesis activities, i.e., the Diabetes Diary app and FullFlow data-sharing system, are in-house developed and tested technologies that we use as a research platform. As a research platform and not a commercial product, we do not have the funding or capacity required to pursue extensive development, e.g., those who pursue connectivity, advanced computational abilities, and functionalities. In addition, due to timing and policy constraints during the course of the FullFlow Project, our original aim to incorporate patient-gathered data into HCPs' EHR systems was not reached. As many HCPs in our previous works have expressed the desire to have data incorporated into the patient record in a clinically informative way, this may have affected recruitment

of participating HCPs as well as their ability to use yet another electronic system to meet their patients – an addition that they have specifically said was undesirable.

This thesis' generalizability is also limited by geography. In Norway, residents have relatively high access to healthcare, good health, education, disposable income, as well as a low prevalence of reported unmet needs in healthcare. This means that participants in these presented activities represent highly educated individuals and HCPs with the access and disposable income needed to receive treatment as well as preventative and palliative care when it is indicated. While this may be comparable to some other medical systems and countries that have fully or partially socialized medicine, this is a unique situation compared to other high-income countries, such as the US, without socialized healthcare, not to mention low-income countries.

7.3 Contributions to the field of mHealth diabetes intervention studies

This thesis focused on how to approach studying the impacts of mHealth on patients and providers related to diabetes care. My intention was to explore and understand the concepts related to study design, methods, what and how to measure these impacts whereby the purpose of the outcomes of each study being to indicate the depth and breadth of knowledge and understanding that could possibly be generated by these approaches. Therefore, while the specific results of research based on the pragmatism paradigm may hold little potential for generalizability, there are elements of these research activities that contribute to the relatively new and largely unknown field of mHealth.

As described in the background, many intervention studies involving mHealth for diabetes describe limited outcomes and often end in the conclusion that further research is needed to, e.g. better understand the impacts of other factors that make "it difficult to demonstrate the efficacy of apps" [109]. The importance of exploratory research efforts (e.g. those performed during the FullFlow Project using a sequential exploratory strategy) in a burgeoning field is to identify what more needs to be known, e.g. compared to health technology intervention research, what can be known and how it can be known.

Building upon previous knowledge: the pragmatist paradigm and pragmatic research

In the 1970's, qualitative methodologies were found to be necessary to build upon, contextualize and/or explain quantitative findings; for such chronic illnesses as diabetes, researchers and healthcare providers acknowledged that a patient's understanding and behaviours related to their diagnosis was just as impactful to their health as was the biological impact of medications. What we are seeing today, i.e. identifying what can be known about the new field of mHealth using traditional and largely pragmatist approaches vs. what more is needed to know in order to optimize its use, parallels the shift from quantitative to qualitative methodologies in the 1970's. Research into mHealth interventions for diabetes self-management requires a shift from a dichotomous approach of performing separate qualitative and quantitative research to the dialectic pluralism approach of the pragmatism paradigm. This means holding both positivist, quantitative methodologies and constructivist, qualitative methodologies as equally important and often mutually dependent. As described by the HCPs in the co-design workshops (present in the transcripts but not included in publication), continuous glucose monitors are considered the gold standard in Norway for those with T1D. However, they are more effective if they are worn continuously; in reality, individuals often have interrupted and inconsistent

use patterns. Using this as an example, the evidence of the CGM's efficacy (established via positivist quantitative methodologies [275]) is not feasible in the real-world unless used optimally, which means we need to understand why individuals take breaks in using these tools. In other words, by applying constructivism and qualitative methodologies, we can begin to understand barriers and reinforce facilitators that contribute to the optimal efficacy of, e.g., CGMs.

While CGMs have a protocol for how best to use them – whether it is used correctly or not – mHealth in general has no such guidelines; downloaded diabetes apps for self-management can be (and are) used in almost uncountable different ways. This means that outcomes from most studies that aim to prescribe a certain type of use are not as generalizable as other health technologies studies, such as those for CGMs. Theoretically, to understand the impacts of mHealth (well enough to judge its safety and efficacy to the point of, e.g., CE-marking and FDA approval), we as researchers would have to set up studies that mirror the "almost uncountable different" uses of mHealth for diabetes self-management. I think we can all agree that this is unrealistic. Applying the pragmatism approach to the study of mHealth interventions for diabetes self-management can help us narrow down the factors that should be measured and explained; emergent factors and ideas that impact one's use of mHealth technologies point to the next question to be asked in future studies. As demonstrated by the outcomes of the PRECIS-2 assessment of the FullFlow feasibility study's administration, we can systematically identify which parts of a study can be more or less expected in the real-world application of an intervention – a criticism of quantitative outcomes that led to the popularity of qualitative approaches. It is also important to note that the factors that were measured, i.e. the primary outcomes and primary analysis which were given a score of 5 on the PRECIS-2 assessment in the FullFlow feasibility study, were generated from smaller studies which produced understanding of end-user needs and priorities through the sequential exploratory strategy of mixed-methods research.

Using pragmatism paradigm in the thesis: a best fit for mHealth diabetes mixed-methods intervention research?

The activities of this thesis followed a sequential exploratory strategy within a pragmatism paradigm: each study informed the design and provided the research questions for the subsequent studies, with a focus on reflecting and understanding real-world situations. Figure 21 illustrates how each separate study was dependent upon preceding studies. The blue diamonds represent the thesis activities, the dark blue rectangles represent the outcomes of these activities (either published as a conference paper, poster or publication), the green rectangles represent the questions that arose upon completion of the previous outcomes, i.e. the questions that prompted subsequent activities (i.e. the blue diamonds). Activity outcomes (dark blue rectangles) also generated ideas (orange rectangles) that would help design and perform the mixed-method feasibility study.

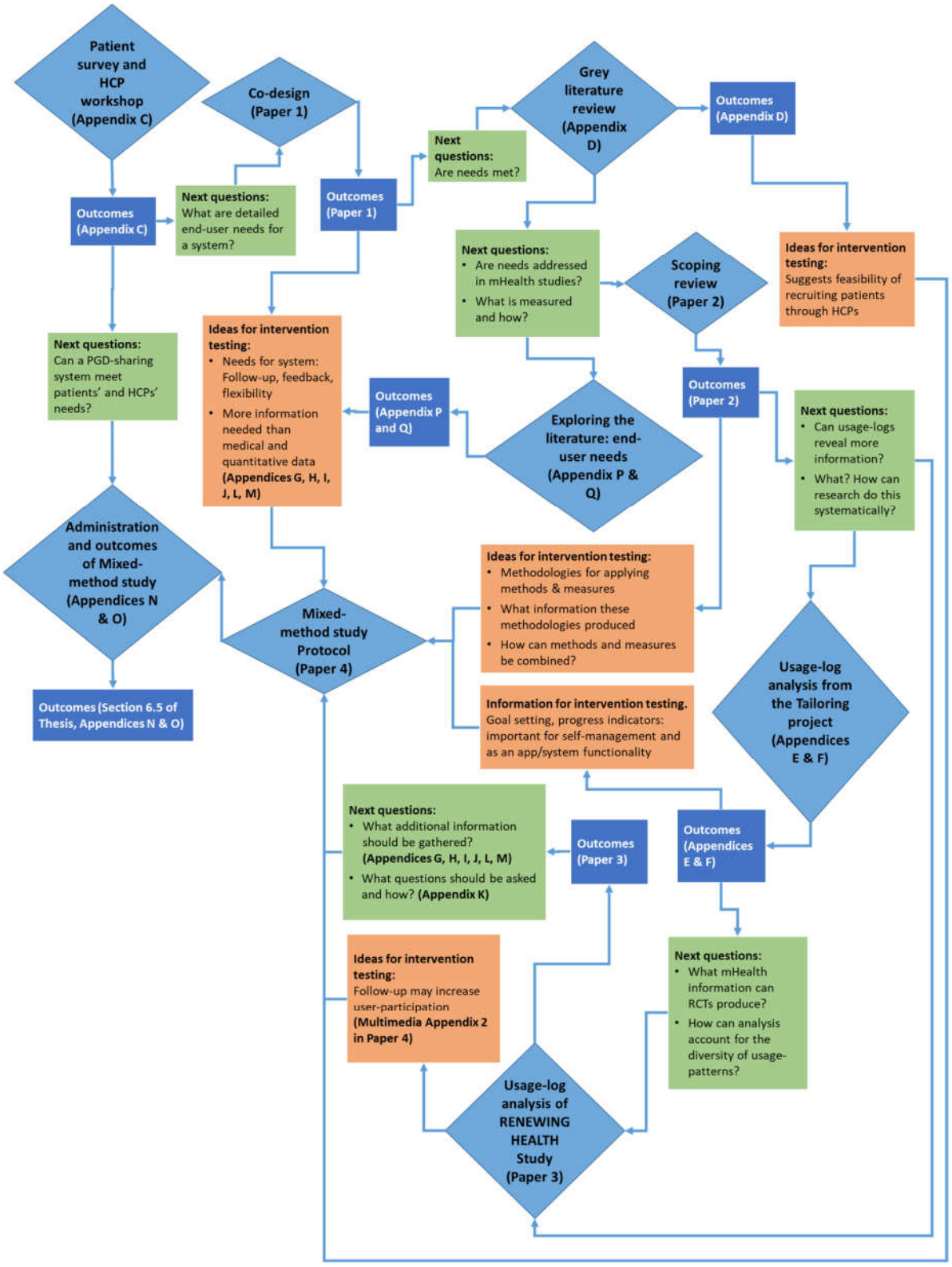


Figure 21 Overview of the relationships between activities, outcomes and subsequent questions in this thesis' pragmatic sequential exploratory strategy

7.4 Implications of the Pragmatist FullFlow Project for future research

What I have learned from participating in FullFlow Project activities, the expressed needs of different stakeholders in the care of chronic conditions, as well as my own experiences with healthcare services, has impacted how I intend to pursue a career in research, described in details in the sub-chapters below.

7.4.1 Does mHealth call for a new paradigm or just a new way to measure impacts?

Rapport and Braithwaite provide a description for the shift in thinking, or paradigm shift, as a lens through which we can view these changes in the diabetes research environment. In their 2018 paper, Rapport and Braithwaite introduce the concept of a shift between the "Third" and a proposed "Fourth Research Paradigms" in medical and health research, which build from the "First" or quantitative positivism paradigm and "Second" qualitative constructivism paradigm [276]. The Third paradigm of research embraces mixed-methods research, i.e. a combination of both quantitative and qualitative approaches and methods. It is important to note that what Rapport and Braithwaite mean by "a shift in paradigms" is not really a pure shift but an evolution; it builds upon the advancements in understanding that came before, but does not seek to replace them. This Fourth paradigm is described as being one that is distinctly different than the Third paradigm; while the Pragmatist Third paradigm still uses established and standardized methods and measures, the Fourth acknowledges the need to incorporate the more continuous, real-time gathered data into research (Figure 22). However, they do not answer "how" we as researchers can achieve this in practice.

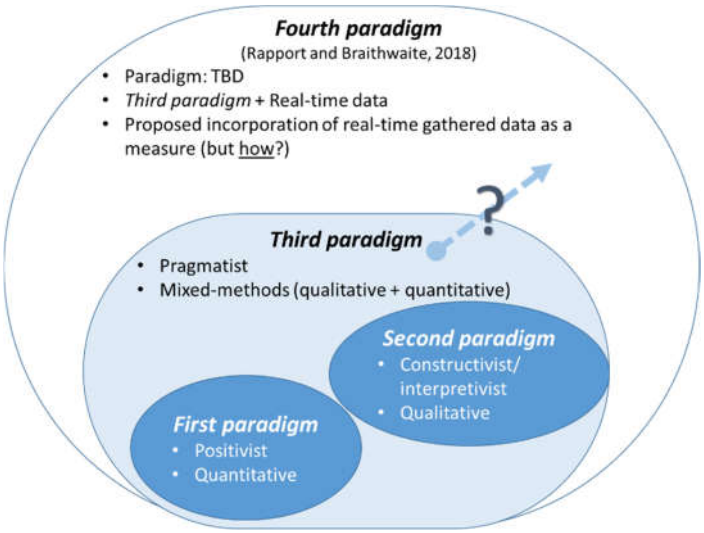


Figure 22 Illustration of Rapport and Braithwaite's [276] proposition of the ongoing evolution from the third to fourth paradigms of research, with the question of how to achieve this evolution practically.

While this is a newly proposed concept, with few references, the point they make is sound and one that this thesis supports, in part. The way in which the Pragmatism paradigm applies qualitative and quantitative methods, as well as interprets these outcomes, is in a more flexible manner than that of Positivist and Constructivist approaches. However, the methods and measures themselves are still consistent with those used in these other two paradigms; Pragmatists still rely quantitative measures that are validated, established and structured and qualitative measures that are collected and analysed

in established ways, e.g. semi-structured interviews and analysis via identification of themes by researchers, independently, within a team. However, Rapport and Braithwaite point out that mHealth data presents different characteristics that are beyond those of established methods, i.e. patient-gathered data is continuous, unstructured, arbitrarily gathered by individuals. But do mHealth data call for a shift in paradigm or simply a way in which to capture, structure and perform analysis on collectable data? I argue that this thesis supports the proposal by Rapport and Braithwaite, but only in part, because a paradigm is built from more than just a new method or measure. The Pragmatist paradigm already addresses the axiology, epistemology and ontology that mHealth embodies. Even the "Reality Cycle" proposed by Maarouf [192], to describe how knowledge is generated and evolves in a cycle, is comparable to the "Experiential model of learning" for health self-management – the foundation for Diabetes Self-Management Education - which describes how a person can learn from previous experiences to improve upon previous actions or maintain their habits to achieve health. So, I suggest that what we, additionally, need to explore further and eventually decide is how we could, or should, perceive mHealth data.

As demonstrated in Paper 3, usage-logs can be quantified and analysed similarly to measures taken from the Positivist perspective. Part of the positivists paradigm is the belief that even emotions, feelings or motivation can be measurable, e.g. standardized questionnaires about self-efficacy or wellbeing. The frequency, duration, type and amount of interactions can all be perceived as, of course not standardized, but distinctly measurable accounts of a person's self-management habits and, in turn, possibly their health foci and progress. The main divergence from this paradigm is the interpretation, which is more in line with the Pragmatist approach. Usage-logs reflect a single reality - living with diabetes-, which calls for at least some of the four primary parameters to be measured. However, usage-log analysis in this study also acknowledged that individuals do not perceive or act upon that reality in the same way. Especially when compared to the qualitative feedback from the study-end workshop, we were able to interpret the usage logs through the lens of the individual's preferences and capacity. As is the purpose of science, the way in which this measure is analysed and interpreted depends on the research question and intention of the researcher. Future research should explore the lengths to which mHealth usage-logs and patient-gathered data can be treated as either qualitative or quantitative measures of the impact of mHealth, patients' self-management, engagement or otherwise.

7.4.2 The importance of collaboration and multidisciplinary approaches

This process has opened my eyes to the heterogeneity of those living with chronic illnesses. Most of us have become familiar with the phrase "one-size-does-not-fit-all" in relation to fashion and other commercial industries, politics, education, and health care. Especially for the medical system, and we as researchers who aim to provide evidence for practice, this ideal of tailored care has yet to be realized at-scale [277]. Research is traditionally set up to describe cohorts or groups of people who demonstrate relatively similar characteristics. What research is not as prepared or set up to doing on a large scale, is combining comprehensive data sets to describe each person as their own cohort. We have, to a large extent, been educated and trained to specialize – to focus on either qualitative or quantitative methods, to focus on clinical changes or psychological impacts, to base our approaches on one or just a few fields of knowledge. As such, we are limited in our ability to bridge the gap between the ideal of personalized care and the reality of generalized research approaches and outcomes. Specialization historically allowed societies to grow, each group focusing solely on their skill with a limited understanding of other fields [278]. While it is true that one group or person cannot do everything, specialization has met its limits in today's age of research where more involved

connection, collaboration, interoperability, and interdisciplinary endeavours are favoured [279]. While it is important for groups, e.g., HCPs, patients, health authorities and device manufacturers, to have their unique competencies, it is now more important than ever to find common grounds and objectives in order to achieve the ideal of personalized, empowering and clinically effective health interventions.

7.4.3 Challenging the common terms: changing the language can change perspectives

Words have meaning. They can confuse or effectively educate. Here I will describe two situations in which a common set of terms could have facilitated a more unified, open perspective and common understanding, and thereby, more efficient and effective work. The first is from the overall project, through which this Ph.D. was conducted. The second is a more widespread use of phrases related to "patients," users or individuals living with a chronic condition in research and healthcare settings.

The first situation was at the research project level. In the FullFlow Project, our team was comprised of those with clinical, engineering, programming, and marketing backgrounds. When it comes to collaboration between groups, we continuously experienced the challenges of, for example, agreeing on what "usability" meant. These differences were also experienced in other projects, e.g., developing a global framework for mHealth assessment [280]. It was difficult to move forward through the project stages because we were speaking, effectively, different languages. We spent hours, over the course of days, to agree upon how to proceed based on our background and understanding of relevant terms. However, after we agreed, and in some cases, agreed to disagree on minute (inconsequential) details, we were able to collaborate to design a working prototype in each of these projects.

The second group of situations is more systemic to the healthcare environment. The use of the words "shared" and "centred" in terms such as patient-centred, shared decision-making, adherence, and hard-to-reach patients, may lead us to believe that individuals are treated as equals in their involvement. However, it often means that the assumptions of patients' needs are addressed. The words "diabetics" and "patients" imply that a person is –or at least is largely - their illness, while "adherence" and "hard to reach" imply a negative judgment on individuals, i.e., that they are not meeting others' expectations. What these phrases have in common is that they often describe events that lack patient input and perspectives. These phrases are commonly used to describe different aspects or groups of people in research and healthcare practice. I, too, am guilty of this habit; it has always seemed easier and universally understood. However, these words strongly affect our perceptions of the individuals whom we aim to help; they apply the stigma of the fault and propagate the inaccuracy of our involvement of individuals in medical and health research. We have become numb to using these words, but now, with the advent of mHealth and patient-empowered movements and societal foci, it is time to stop using these phrases and instead try to use more inclusive, non-judgemental and open-minded words to describe those who are living with chronic health conditions.

Just as medical services and approaches to the care of chronic conditions have been turned on their heads, so too have research approaches. People living with health challenges have become partners in research as well as decision-makers in their own health care. Methods that originated from other fields, such as business and marketing, have been incorporated into intervention design and development in order to address all end-user needs, not just those with an official acronym.

7.4.4 Changing perspectives can lead to the spread of equal collaboration and empowerment in healthcare

We can and should challenge our assumptions and perspectives of one another. Not just within healthcare but in society. This brings to mind a quotation from the movie *Finding Nemo* in which the predators, the sharks, are in the process of changing their perspective of their prey, the fish:

> *"I am a nice shark, not a mindless eating machine. If I am to change this image, I must first change myself. Fish are friends, not food" –Bruce, the Great White Shark [281].*

The same must happen in healthcare: "patients are people, not symptom clusters." Just as the sharks are fighting their instincts, we have to fight our formal education. While we in research and healthcare, of course, do not set out to view people as such, our training and education urge us to embrace the more objective and emotionally distanced practices of care and research. The aim of this approach is not to be callous or unfeeling, but to be effective to the greatest number of people – of those whom we serve in the medical system. Instead, I argue that by embracing what mHealth encourages, e.g., empowering the individual to become experts of their own health, and personalizing heterogeneous health solutions for chronic conditions, we, as equal stakeholders in the healthcare system, can be more informed, communicative and effective.

When we acknowledge one another's competencies, we can enact more strategic change. We need to challenge the assumptions that we make of one another. For example, one of our HCP participants in the co-design workshop expressed that he believed patients were not interested in discussing the specifics of their health. This implied an end to this conversation, as there were no alternatives provided. Alternatively, those in the patient co-design group described that they understood GP's limitations in time and schedule to be able to answer their specific questions related to technology and mHealth-aided self-management. Instead of ending the conversation, this allowed for further discussion that could address these specific limitations, and several participants ended up suggesting alternatives.

To change our assumptions, our perspectives, we need to ask questions and communicate between groups. By treating individuals as equals in true, shared decision-making practices in healthcare, and as partners in the design of research endeavours and intervention evaluations, we have the opportunity to produce knowledge, devices, and practices that are relevant, useful, and sustainable for patients and HCPs.

Ultimately, to achieve greater understanding and provide the basis for correcting assumptions, we have to communicate. However, the platforms through which different stakeholders communicate are generally very much separated. This is especially where having field-specific vernaculars limits understanding across fields.

7.4.5 Tailoring communication to spread knowledge: "the democratization of knowledge"

As the results of this project and other research have demonstrated, most patients living with chronic conditions want to know more – about their condition, about options, and even about research or developments in the pharmaceutical and medical device fields. Unfortunately, they are not always able to access this information. Relying on scientific publications to disseminate research knowledge is not

ideal if the aim is to educate all relevant stakeholders. The Norwegian government, among other authorities throughout Europe, have made disseminating research results in a more publically accessible way a primary goal [282].

Just as the traditional hierarchy of medical care is coming to an end, so is the habit of collecting health knowledge in scientific silos, such as scientific journals. While, yes, having a medical and health researcher agree with a programmer on what the finite points of "usability" means, may hel p those in the scientific community communicate, those outside of these fields are not interested in the specifics of words. They want to know what "usability" means for them. The trend toward "the democratization of knowledge" is a consequence of progress in information and communication technology (ICT), such as access to information on the internet [283]. Individuals no longer have to wait for a book on advancements in diabetes treatment to be printed in order to access it. However, they do have to know which online platform to look in.

Unfortunately, most results of these innovative and to-date studies are secluded in research journals. Outcomes of tested technologies or new strategies for health treatment are mainly published in literature via subscription-based forums, in a scientific vernacular, and directed to our peers. However, the accessibility of online information has contributed to the greater focus on open-access literature and even popular science articles to reach all, not only some, of the interested parties [284]. Everyone has a right to knowledge. Popular science articles are accessible, direct (to-the-point), and focused on informing a general audience about advancements in health care knowledge. Only when we have interdisciplinary collaboration, transparency, and truly accessible knowledge can we hope to produce a complete set of mHealth impacts that can effectively inform decision-making in research approaches, clinical practice, and self-management.

As those who develop and produce knowledge, we have to consider more diverse options for dissemination. Popular science, social media, blogs, and newspaper articles address the masses [285]. Professionals in the healthcare fields have begun to take advantage of a more inclusive and accessible language and a more direct voice used on these platforms to appeal to a more socioeconomic and educationally diverse audience [284, 286]. By continuing to do so, we have the opportunity to come full circle -- to facilitate patient-empowerment, self-efficacy, and health literacy, which will, in turn, enable people living with health challenges to be informed and active participants in their own health care process.

7.5 Future research

As the results presented in section "6.5 FullFlow mixed-method study: preliminary results" only focus on two of the eight participant cases, our research team will focus on publishing not only the usage logs, questionnaire and focus group results and analysis, but also the method in which we designed the study-end focus group meetings.

One major limitation of not only mHealth intervention research but also medical and health research, in general, is who we are able to recruit. My experience as a researcher in the field of mHealth, patient engagement, coupled with my recent works of this thesis, has opened my eyes to those who are and are not, engaged and represented in medical research and care. The focus on patient-empowerment and personalized care grows, and with it more detailed and comprehensive understanding of those who participate in research studies. However, these participants are seldom representative of individuals

living with chronic illnesses who need the most help and support. The public is told, by organizations such as the WHO, that there are large percentages of those in the population with chronic illnesses, who are underserved and/or remain undiagnosed. No matter how well we, as researchers, HCPs, and health authorities, prepare, explore and discover how to improve healthcare outcomes, if we are unable to reach those who would benefit the most from this knowledge, then our efforts eventually hit a glass ceiling. Those who are not reached and experience poor health experience high costs – physically, mentally, socially, and financially - and eventually require unnecessarily costly and resource-heavy healthcare treatment. Whether it be socioeconomic disparities, gender, differences in priorities, or disinterest – I am interested in why individuals choose not to or cannot engage in their health. We know that the tradition of one-size-fits-all has been, and continues to be, challenged. By identifying if such factors as limited resources, lack of motivation or incapacity, play a role in those who experience poor health and are unengaged in their healthcare, we can begin to understand what we need to add or adjust within interventions or how we as researchers and HCPs can adjust our practices to reach these individuals. I aim to apply for a Post-Doctoral research grant in order to study these factors in the coming years. In doing so, the lessons learned and insights gained from such works can further inform our exploration of both those who are already engaged, yet are unable to achieve their ideal health, as well as those who are not yet engaged but would benefit from more personalized health interventions.

8 Conclusion

Evolution is inevitable. How we perform research is no exception. The intention of these thesis activities was to continue discovering using pragmatism paradigm to research as a scaffolding. Two important parts of this were i) using new and relevant resources that have more recently become available , i.e. mHealth tools and services and ii) constantly asking questions that build upon the knowledge base of previous research and dig deeper into concepts that could provide more actionable insight into clinical practice, in our new situation where use of mHealth is increasing rapidly.

These Ph.D. activities describe some of the research means that we have at our disposal for use in mHealth intervention evaluations. The literature reviews and usage-log analyses described the breadth and depth of what kind of information can be provided by traditional and mHealth resources. These activities responded to two of my research questions (**RQ2** and **RQ3)** by forming a sort of library from which I proposed methods, measures, analyses, and intended outcomes for the mixed-method feasibility study. While not the primary focus, the different study structures also demonstrated the breadth of information that was possible to collect. Study administration, e.g., participant follow-up and reducing the efforts needed to participate, also seemed to play a significant role in the efficacy of the methods and reliability of the outcomes based upon end-user engagement and decisions in how they used the intervention tools. This was confirmed in our experience during the mixed-method feasibility study.

The integration of end-users in the design of the intervention technology, as well as their input into the formation of the associated feasibility study, responded to my two other research questions (**RQ1** and **RQ4)** by demonstrating the depth and breadth of contribution patients and providers can have in research. Without this input, our selection of features for the data-sharing system, questionnaires, or discussion guide questions may not have responded as directly to end-user needs or answered more about the rationale and motivation behind patients' use of mHealth or the patient-HCP use of the data-sharing system. However, these outcomes have to be taken with a grain of salt. They do not concretely

answer how these mHealth technologies should be used to ensure the greatest impact, only how the Diabetes Diary app and FullFlow data-sharing system were used by this small group of patients and providers. While the HCPs who participated in the co-design workshops and pre-study survey suggested that they would use patient-gathered data more to inform their recommendations for changes in self-management or lifestyle, not clinical changes in, e.g., medication. While these outcomes are situationally limited, they do demonstrate the depth, breadth and complementarity of the quantitative and qualitative data gathered throughout the thesis studies.

The complexity of diabetes care networks calls for diabetes intervention studies to be flexible. The addition of mHealth technologies and concepts that have been newly introduced to these networks only services to support this call. By acknowledging the added opportunities for data-gathering and analysis that mHealth brings, we as researchers can combine our knowledge from different backgrounds, and utilize mixed-methods to determine how to best coordinate the use of these novel resources and structure the analysis of their impact. As summarized in Figure 21, we have demonstrated that the necessity, ability and feasibility of research to structure mHealth diabetes intervention studies in such a way that allows us to adjust our focus, questions and methods to fit the ever changing needs of mHealth for diabetes. As such, the sequential exploratory strategy of performing mixed-method studies through the lens of the pragmatic paradigm is an appropriate way of combining the strengths and benefits of traditional, positivist, quantitative approach to research with those of the constructivist, qualitative approach to research.

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Paper 1

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RESEARCH ARTICLE Open Access

How mHealth can facilitate collaboration in diabetes care: qualitative analysis of co-design workshops

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Abstract

Background: Individuals with diabetes are using mobile health (mHealth) to track their self-management. However, individuals can understand even more about their diabetes by sharing these patient-gathered data (PGD) with health professionals. We conducted experience-based co-design (EBCD) workshops, with the aim of gathering end-users' needs and expectations for a PGD-sharing system.

Methods: $N = 15$ participants provided feedback about their experiences and needs in diabetes care and expectations for sharing PGD. The first workshop (2017) included patients with Type 2 Diabetes (T2D) ($n = 4$) and general practitioners (GPs) ($n = 3$). The second workshop (2018) included patients with Type 1 Diabetes (T1D) ($n = 5$), diabetes specialists ($n = 2$) and a nurse. The workshops involved two sessions: separate morning sessions for patients and healthcare providers (HCPs), and afternoon session for all participants. Discussion guides included questions about end-users' perceptions of mHealth and expectations for a data-sharing system. Activities included brainstorming and designing paper-prototypes. Workshops were audio recorded, transcribed and translated from Norwegian to English. An abductive approach to thematic analysis was taken.

Results: Emergent themes were mHealth technologies' impacts on end-users, and functionalities of a data-sharing system. Within these themes, similarities and differences between those with T1D and T2D, and between HCPs, were revealed. Patients and providers agreed that HCPs could use PGD to provide more concrete self-management recommendations. Participants' paper-prototypes revealed which data types should be gathered and displayed during consultations, and how this could facilitate shared-decision making.

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Conclusion: The diverse and differentiated results suggests the need for flexible and tailorable systems that allow patients and providers to review summaries, with the option to explore details, and identify an individual's challenges, together. Participants' feedback revealed that both patients and HCPs acknowledge that for mHealth integration to be successful, not only must the technology be validated but feasible changes throughout the healthcare education and practice must be addressed. Only then can both sides be adequately prepared for mHealth data-sharing in diabetes consultations. Subsequently, the design and performance of the joint workshop sessions demonstrated that involving both participant groups together led to efficient and concrete discussions about realistic solutions and limitations of sharing mHealth data in consultations.

Keywords: Patient-gathered data, Data-sharing, Co-design, mHealth, App, Health care providers

Background

As a medical society, we have increased our knowledge about diabetes beyond managing the cornerstones of self-management: blood glucose, physical activity, medication and diet. We have recently unmasked the effects of less well-known factors as sleep, stress or even temperature, on blood glucose levels [1]. While it is theoretically ideal to understand all factors that affect a disease, in order to effectively treat it, it also inadvertently puts added pressure on healthcare providers (HCPs) and patients to not only track these factors but also understand and react to them. In fact, it was only 50 years ago, with the invention of the first commercial glucose meter, that patients were given the ability to check their blood glucose at home [2]. Since then, medical devices for diabetes have been developed alongside the necessary systemic changes to the medical system that are required to effectively use such new technologies. However, this trend has shifted as commercial technology, such as mobile health (mHealth) apps and devices, now offers patients the ability to easily track all of the indicated disease factors that are expected of them, often without oversight from medical professionals [3].

Lately, the use of mHealth technologies has become common practice for diabetes self-management [4]. For example, by connecting one's smartphone app to a blood glucose meter and wearable activity tracker, one can automatically combine blood glucose levels with how physically active they are as well as manually entered food and medication intake. Such measures are considered patient-gathered data (PGD) and allow a user to track how their self-management activities affect their health outcomes [5]. With this stored history, the next time an individual chooses to undergo a similar combination of activities, they could easily identify, for example, how they chose to eat or what dose of insulin was effective or not for that situation. However, this information is only effective if used correctly; not everyone is able to process and make connections for all of this information on their own. Therefore, while mHealth provides clear potential benefits, there is only so much most individuals can understand without the complementary medical knowledge of the disease itself. This is where the potential of sharing one's own data from their mHealth tools with HCPs can benefit both the patient's understanding of their own health and the provider's understanding of how to best practice personalized and evidence-based medicine.

Unfortunately, when it comes to introducing mHealth and PGD in the clinic, both parties have differing ideas as well as concerns and unanswered questions. Providers have noted concerns about data overload and how to relate to the data for clinical decision-making [6]. Patients are concerned with how providers can effectively use this information to give personalized health recommendations [7]. Despite a growing effort to research these technologies, most research focuses on exploring the topics of technical possibilities, feasibility, usability and policy issues [8], with little focus on how both patients and providers can use PGD together. This is not only due to the concerns and questions mentioned above but also because the gap in disease knowledge between patients and providers has traditionally been too great [9].

This gap has lately been shrinking thanks to mHealth, which adds a new dimension of diabetes management – enables greater self-efficacy, disease understanding, especially among technology savvy people. In fact, in the field of mHealth, patients' have become vastly more knowledgeable, and are even considered "experts" by some [10]. By gaining insight into their own disease self-management, patients are now more capable of bringing this understanding and PDG to consultation discussions with their healthcare providers [11, 12]. Therefore, there is a need for data-sharing systems to be able to transfer, structure and present this data in a way that facilitates collaborative discussions and shared decision-making in diabetes care. Previous studies in the field of health technology have provided knowledge regarding the needs of data integration and patients' and HCPs' expectations and their needs from data-sharing technologies. The majority of these studies have gathered information from patients [13] and providers [14] separately. However,

other studies also show that when both end-user groups were engaged together in development discussions, more concrete and realistic solutions can be identified [15].

Experience-based co-design (EBCD) (hereby referred to as co-design) allows patients, and providers to impose their collaborative insights on the design and development of the tools and services that they are eventually meant to use [16]. "Happenings become experiences when they are digested, when they are reflected on, related to general patterns and synthesised" [17]. This describes the general use scenario of those who use mHealth technologies for chronic illness self-management; recording, reviewing or reflecting and synthesizing an understanding of their health experiences. Unfortunately, many "patient-centred" research efforts do not always involve patients or other end-users in such design, and/or development [18, 19]. By considering patients as "experts" in their own self-management and providers as, of course, experts in the disease mechanics, we acknowledge that both parties can bring complementary knowledge and skills to diabetes care. Ideally, this is considered the process of shared decision-making, which is characterized by providers and patients collaborating to make decisions about the patient's health, with a balanced focus on both hard clinical evidence as well as the patient's priorities and values [20]. This suggests the necessity of engaging both main end-users in co-design to design and develop the technology that they will use, together [21].

In this paper, we present the qualitative analysis of transcripts and paper-prototypes from two co-design workshops involving both patients and HCPs regarding the design of a system to share patient-gathered self-management data during diabetes consultations. These workshops were conducted as part of a larger research project to create and test a system for sharing PGD between patients and providers, called the "Full Flow of Data Between Patients and Healthcare Services" project (2016–2020) [22]. Previous workshops within the same research project reported the differences in self-management foci and challenges between those with T1D and T2D, as well as differences in how specialists and GPs meet their patients and their clinical practice needs. These results were published elsewhere [23]. In this paper, we build upon this knowledge, and the input from co-design, to design a system for sharing PGD during diabetes consultations. We focus on our end-users' intentions for the use of, needed functionalities, ideal discussion and collaboration that can and should be generated from sharing PGD.

Objective

By arranging two co-design workshops, where patients and HCP together discuss expectations and design ideas for an mHealth data-sharing system for diabetes, we aim to understand how a system can present patient-gathered mHealth data and be used effectively by both parties to facilitate shared-decision making and collaboration in diabetes care.

Methods

Two co-design workshops ($N = 15$) were conducted with the aim of inviting both stakeholder groups to discuss the concept of sharing and using patient-gathered self-management data during diabetes consultations. The first involved patients with type 2 diabetes (T2D) ($n = 4$) and GPs ($n = 3$) (2017) and the second involved patients with type 1 diabetes (T1D) ($n = 5$), diabetes specialists ($n = 2$) and a nurse (2018). The workshops were held in Norwegian, the participants' native language.

Recruitment

Participants were invited to attend the workshops at the Siva Innovation Centre in Tromsø, Norway. Convenience sampling was used to expedite recruitment and draw from a population with experience or interest in the particular field of mHealth for diabetes self-management. Patients were recruited by messages sent through the Diabetes Diary app [24], which is available on Google Play app store. At the time of recruitment, there were approximately 7000 downloads of this app in Norway. Patient participants had to be 18+ years with either T1D or T2D and be willing to travel to Tromsø, Norway for the workshop. All who expressed interest and met inclusion criteria were invited to participate. All participants presented a signed consent form prior to the workshop. HCPs, who currently see patients with diabetes, were recruited via e-mail requests. Participants were given the option to withdraw their participation at any time.

Discussion guides and workshop activities

During each daylong workshop, patients and clinicians were split into their respective groups in the morning. Following a common lunch, all participants took part in a joint session in the afternoon. The intention of joining both groups was to allow participants to present their views to each other and to discuss and correct assumptions and expectations regarding mHealth technologies and data-sharing during consultations. A moderator used a semi-structured discussion guide, which was developed by the co-authors (see Additional file 1).

Two story-boards, describing T1D care and T2D care, were split into three main sections illustrating the following: experiences and topics surrounding patients' own self-management, the healthcare providers' clinical practice and experiences, and the consultation between

both patients and providers, which was used only during the joint session. In both of the separate patient and provider sessions, participants filled out post-it notes in response to questions, presented them orally to the group and then placed the notes on the story-board that corresponded to each of the three situations. This allowed them to form their own opinions before engaging in group discussions. During the joint session, participants were asked to create, and then describe how to use, his or her own paper-prototype of an ideal data-sharing system. Paper cut-outs that represented functionalities and features of the system's interface were provided. These included cartoon representations of data sources, such as mobile phones, wearables and sensors, data types, such as blood glucose and physical activity, how to display data, such as graphs, arrows and scales, and computer screen, through which the system is meant to be accessed.

Thematic analysis

After each workshop, single-page summaries were made by the research team, within a month following each co-design workshop, and sent to all participants. Participants were encouraged to correct these reports, comment or ask any additional questions before further analysis was performed.

All sessions were audio recorded, transcribed and translated into English by a native Norwegian speaker, and de-identified. As not all in the research team were present during all sessions, before more detailed analysis took place, narrative summaries for each of the six co-design sessions were created. Co-authors discussed the summaries to ensure collective understanding of the transcripts, e.g. what was produced that was directly related to the research questions and what unexpected yet relevant additional information was provided. To identify patterns within and across the participants' feedback while also addressing the research questions, a thematic analysis was used. As it is difficult to separate one's self from their research experiences and background knowledge, this thematic analysis included iterative use of deductive and inductive reasoning to structure and report the transcripts, i.e. an abductive approach [25]. The deductive approach first generated themes, based upon discussion guide questions that participants responded to, from a small selection of the transcript, which are described as "analytic inputs" by Braun et al. [26, 27]. These themes then direct the combination of emergent salient concepts, i.e. the inductive approach; while emergent concepts were identified and grouped as primary and secondary codes, relevant codes were selected and combined into sub-themes and assigned, based upon reasonable association, to agreed-upon themes [28]. An example of this process is provided in Table 1. Quotations will be formatted with brackets indicating omitted words, e.g. "it", "they", that are replaced with the words to which these articles refer.

Results

Demographics

Seven individuals attended the first co-design workshop, related to T2D (Fig. 1), and eight individuals attended the second workshop, related to T1D.

While it was not required for participants to offer these information, as the focus was on development of the data-sharing system, some did offer some personal information when asked introductory and ice-breaker questions. The available details are provided in Table 2. HCPs offered only basic information about themselves before offering their opinions of mHealth and data-sharing (Table 3).

Main themes identified

Across the workshops, the following three main themes were identified: 1) patients' and providers' need for more specific and detailed information in diabetes care 2) mHealth technologies' impact on patients and providers, with subthemes concerning a) both groups' use of patient-gathered data and b) roles and responsibilities, and 3) data-sharing, with subthemes concerning a) expectations of sharing and receiving PGD during consultations, b) what and how to share PGD, c) electronic health record (EHR) integration and d) concerns. Because each session focused on allowing the participants to drive the discussion, each theme and sub-theme varied in the amount of feedback participants' provided. Therefore, for the themes and sub-themes that generated lengthy and diverse feedback, tables are provided for each-sub-theme to summarize and differentiate between responses of each group. Additional quotations from the transcripts, and details about responses for the sub-themes, are provided in Additional File 2.

Theme 1: patients' and providers' need for more specific and detailed information in diabetes care

At the beginning of each workshop, participants were prompted to describe their overall self-management and clinical practice, respectively. Responses about sub-theme 1A: What and how information is needed are exemplified in Table 4.

Both those with T1D and T2D had similar experiences with healthcare providers – lack of specific feedback and information. Differences in self-management and care of T1D and T2D were evident in the details, for example, when individuals needed specific support from their healthcare providers. For those with T1D, support is needed when a challenge or symptoms arise because their symptoms and challenges occur more frequently

Table 1 Abductive approach to analysis process of categorizing quotable text from the transcript into codes, followed by the grouping of codes into progressively higher-level themes

Deductive Analysis →		←Inductive analysis			
Narrative summary for joint T1D session	**Example of agreed-upon theme**	**Codes grouped under concept/ Sub-theme**	**Secondary codes**	**Initial codes**	**Example from transcript**
• Research questions asked • Impressions of major topics and concepts presented in the transcripts by both patients and providers	Data-sharing system	Concerns	• Which data to share/look at • Time capacity of consultations	• Question: how much data can incorporate into consultation? • Preference to see selected/relevant data	"Could you possibly assimilate so much data?...How much data can you incorporate into a [15-min] consultation?" (Specialist2)

and immediately. However, those with T2D experience more delayed symptoms, making it difficult to identify the cause leading them to need to accumulate information over time and then seek guidance or answers about how those decisions affected their health. GPs and specialists agreed in the importance of specifying their recommendations based on a patient's situation, but noted that this also requires patient engagement. Specialists mentioned that mental health and a patient's knowledge and skills affect their expectations of their patients with T1D and how they approach diabetes care. The participants' background with diabetes care allowed us to identify potential needs for mHealth and data-sharing support for both individuals and healthcare providers during consultations.

Theme 2: mHealth technologies' impacts on patients and providers

As one participant stated concisely, "diabetes doesn't happen in a container. There are other things around it." [T1D_P3].

Subtheme 2A: purposes of, and challenges related to, mHealth and patient-gathered data Participants were promoted to discuss how they used mHealth technologies and patient-gathered data for self-management and during clinical practice. Both groups of T1D and T2D participants used their own-gathered data to find patterns by comparing their self-management actions to their resulting blood glucose levels. However, differences emerged regarding what kind of information they aspired to understand, how much data, and over how long a period, these comparisons were made. Responses about sub-theme 2A: Purposes of and challenges related to mHealth and patient-gathered data are exemplified in Table 5.

Those with T1D tend to look at information related to daily experiences. In contrast, T2D requires less frequent measures, which is consistent with both patients and GPs' focus on longer-term health control and expectation of less data. These differences between patient groups point to how much information either group would gather and possibly present during consultations as well as their driving health goals. It was also evident

Fig. 1 Story-board and post-it notes generated during the first co-design workshop, illustrating the T2D patients' and GPs' situations and their expectations of a system for sharing patient-gathered data

Table 2 Demographics of T1D and T2D patient participants in both co-design workshops

Diabetes type _Patient#	Gender	Age range (yrs)	Duration of diabetes (yrs)	Reported technology used	Reported self-management foci
T1D_Patient#1	F	40–50	N/A	N/A	N/A
T1D_Patient#2	M	20–30	2	Apps, insulin pen	Physical activity, BG
T1D_Patient#3	M	50–60	30	Insulin pump, CGM, app	BG, physical activity, insulin, carbohydrates
T1D_Patient#4	M	40–50	38	Insulin pen, app	BG, insulin
T1D_Patient#5			N/A	Insulin pen, app,	BG, physical activity, sick days, insulin, diet
T1D_Patient#6	M	60–70	8	Smartwatch, insulin pen	Physical activity, insulin, BG
T2D_Patient#1	M	60+	12	Paper diary, app	BG, physical activity, diet
T2D_Patient#2	M	60+	N/A*	BG meter, insulin pen, paper diary, app	Diet, medications (non-diabetes related), insulin, physical activity
T2D_Patient#3	M	60+	3	BG meter, apps	Diet, physical activity, well-being
T2D_Patient#4	M	60+	N/A**	BG meter, paper diary	BG, input from doctor

*Participant stated "a good amount of time ago"
**Participant stated that they were "in the introduction phase" of their diabetes

that the ability of those with diabetes to collect much data has affected what healthcare providers expect of their patients.

Subtheme 2B: roles and responsibilities Within the formal healthcare setting, those with T1D and T2D note that the value of healthcare providers is based upon their ability to understand the patients' everyday reality of living with diabetes. They also share similar frustration with healthcare providers' lack of such specific knowledge and answers, when the patient needs it. However, during consultations, the role of authority figure is different in either case (Table 6).

Those with T1D appeared to place themselves in the role of authority and decision makers. In these cases, healthcare providers – mainly diabetes nurses - are seen as sources of suggestions and information about unique situations that an individual may face in their daily lives, yet the individuals are the ones to use of the data and make the final decisions about their health. This division of responsibility and roles within T1D care also seemed unanimous and expected amongst healthcare provider. Specialists stated that outside of the consultation, patients were expected to be active in using and understanding the data they generate. While, in the previous sections, those with T2D established that they value mHealth and its ability to help them to better understand their health, in the formal healthcare setting, individuals with T2D place more authority in the healthcare providers. Also, they make a distinction about which healthcare provider is better prepared to answer their specific questions.

Table 3 Demographics of participating HCPs in both co-design workshops

Provider#	Gender	Age range (yrs)
Specialist#2	M	50–60
Specalist#1	F	60–70
Nurse	F	30–40
GP#1	M	50+
GP#2	F	30–40
GP#3	F	50+

Theme 3: The data-sharing system

Subtheme 3A: expectations of sharing and receiving PGD during consultations With regards to their expectations of sharing data with their healthcare providers, participants with T1D and T2D were similarly concerned with receiving specific and relevant answers. Just as with the theme of roles and responsibilities, differences between expectations of those with T1D and T2D centered on the level of detailed feedback from their providers, who to contact and overall goal of the consultations when sharing data (Table 7).

Participants had experienced the expected benefits of sharing their own-gathered data, i.e. more personalized self-management recommendations. However, even with data, others experienced the limitation of interoperability problems of healthcare technologies. Participating specialists expect that those individuals who use health technologies, including both medical and mHealth devices, pre-digest the data to identify self-management problems before coming to the consultation. However, specialists also explained the diversity of experiences and expectations in their clinical practice, including the fact that many either do not use these technologies or do not use them optimally.

Table 4 Summary of responses about what and how information is needed by patients' and providers' regarding diabetes self-management and clinical practice, respectively

Groups	Codes	Summary	Example quotation
Participants with T1D	What information	Answers about specific challenges in their self-management	*"[What is important is] not what we struggle most with on average but what we need to do in specific situations and individual days that stand out as being difficult" (T1D_P2)*
	How information is or should be shared	Answers in the form of recommendations from HCPs about why specific self-management challenges occur and how to respond to them	*"[Most healthcare providers] too far away from the specific situation … You get answers after a day or two … but that is not when I am in the situation … I don't want to disturb doctors and nurses with my small problems, but maybe they are not so small if we acknowledge what they really are" (T1D_P3)* *"More appointments more frequently … and maybe get more continual information … since the [diabetes] situation changes" (T1D_P6)*
Specialists	What information	• To differentiate patients based on situation and needs • To understand patient's mental state to effectively guide them	*"For example, I cannot expect this one man to get a perfectly controlled diabetes. I would be happy if his hba1c came down to 9%, whereas another patient who is themselves a doctor, I can expect him to have an hba1c around 7% or even below 7% without hypoglycaemia" (Specialist2).* *"Separate the patients in two groups - the ones who have hba1c higher than 8.5 or 9 who are the higher risk ones, [and] the ones with lower than 6–8% who still have problems … different problems" (Specialist1)* *"A person's mental state and resources, of course … gives you a background for what kind of targets you can expect" (Specialist2)*
	How information is or should be shared	It is the responsibility of the patients to collect and share information as well as provide explanation of their situations.	*"[Patients must] take the responsibility [themselves]" in order for the HCP to be able "to understand diabetes and insulin and how all these things function together" (Specialist2)*
Participants with T2D	What information	• Motivation, • To understand how lifestyle choices affect health (i.e. BG)	*"I was better in the starting phase to note down drinks and food … but it has faded, and I don't today. Need more motivation" (T2D_P2)* *"I have injured knees and shoulders, so motivation is lacking" (T2D_P1)* *"I kind of feel like I don't self-manage because … I think it goes a bit slow when I test my blood sugar. It's usually high and it doesn't really change much … I can't see what is happening" (T2D_P1).*
	How information is or should be shared	Disease-specific knowledge from HCPs	*"[Healthcare providers] could be more specific. They are pretty diffuse and say "you can do this", but they need to be more specific and say "you need to do this", and then tell me the things I need to be doing" (T2D_P2)*
GPs	What information	• Information about specific challenges, • To understand and treat all of a patient's health challenges	*"If [the patients] have reliable information, we use that more than medical history because things happen along the way" (GP1)* *"Patients don't just have diabetes. Many are mixed with a lot of other things and I feel that can be confusing because they high blood pressure, maybe are overweight, maybe have low back pain, maybe a lot of other things" (GP3)*
	How information is or should be shared	Health measurements and patient recollection/ evidence of challenges to then discuss together	*"Things I find important focus on how it has been since last time. Any hypos? Are they in okay shape? Anything wrong? Sometimes I check blood pressure, but not always. I usually check hba1c … then we make an appointment and discuss the plan" (GP1)*

The expectations and experiences of those with T2D and GPs reflected a different dynamic between individuals, the technology and their providers than those with T1D and specialists. While those with T2D did want specific answers, they were first and foremost concerned with the concept of communication and responsibility; when to communicate and with whom, in order to receive the type of answers they wanted. Participating GPs also acknowledged the challenge of providing specific feedback to their patients in the absence of data. Like those with T2D, GPs were also interested in communion but more specifically, shared decision-making and believed that specific data would lead to specific and realistic goals for the patients.

Table 5 Summary of responses regarding purposes and challenges experienced by patients and providers when they encountered or used mHealth devices or patient-gathered data

Groups	Codes	Summary	Example quotations
Participants with T1D	Purpose	• To identify similar situations • To identify relationships between parameters, e.g. BG and diet	*"Similar situations … I rarely eat ice cream so I can go back and look at how much insulin I took then and how my blood glucose was after" (T1D_P5)* *"Seeing patterns about what I ate and did in relation to my blood glucose" (T2D_P2).*
	Challenge	Lack of support/guidance to interpret data	*"The lack of support from the healthcare system", asking "where is the course where I can learn as a patient? I take more responsibility for my own health when using mHealth tools … [and get] a better overview … But even though I know a lot … I want to know more and I want to do better" (T1D_P1).*
Specialists	Purpose	For technology to support patients' self-learning	*"Use of technology needs to create patient action … We want these sort of [patient-gathered] data to be self-learning technology" (Specialist1).*
	Challenge	Limited capacity	*"The number of consultations in our out-patient clinic has increased steadily during the last years. And I remember when I started there almost 20 years ago we had so much more time for patients" (specialist2).*
Participants with T2D	Purpose	• To understand long-term effects of lifestyle choices on diabetes health • To spend less time worrying about their health and more time living	*"[I look for] the results for stress level, drinks and such … to find the causes for high blood glucose" over "days, sometimes a month sometimes three months, between the evaluations" (T2D_P1).* *"spend less time and energy on self-management" (T2D_P2)*
	Challenge	• To understand relationships between parameters, • To trust in technology to function properly, • Cost (in some cases)	*"I document blood glucose in the Diabetes Diary app. Plus, I have it on paper too. I don't trust electronics. I do double" (T2D_P1)* *"I stopped the electronic way because I was abroad and it cost a lot. But I record manually" (T2D_P2).*
GPs	Purpose	*Not specifically stated*	*N/A*
	Challenge	Inconsistency in and lack of patient-gathered data	*"They just test three days before, but then stop testing for half a year, and then come back with three lost test-days. Some are testing every day, four times a day … Some have blood pressure monitor at home, that they show me" (GP3)* *"I rarely see [paper] diaries with lots of measurements … many of them have Fitbit but I haven't seen the results from them" (GP2).*

Subtheme 3B: what data to share and how to display it Referring to their own developed paper prototypes during the joint session, participants were able to explain how their ideal system would function to generate a discussion (Table 8). For quotations that detailed both what and how the data should be displayed, cells within the table are merged.

Participants' comments converged on the end goal of information exchange - generating discussions. Both patients and providers acknowledged that each had relevant and desired information to exchange, and an opportunity to do so with mHealth, that was not commonly used at the time. A comment from one specialist summarizes what all seemed to hope for from a data-sharing system – to facilitate information exchange; "One thing is data sources another thing is information. Because the information is generally the communication with the patient at the site there and then" (Specialist1). However, both those with T1D and T2D independently identified a challenge that should be addressed within this type of information exchange.

Suggestions from both patients and providers were similar in that they would like a system that summarized the PGD, with the option of choose which data to explore further, if trends or outlier points were identified. Those with T1D wanted answers about specific challenges that they experienced and documented. Those with T2D wanted an overview of their progress and feedback about how to progress. One GP expressed the value of a diverse data-set while another expressed that, for some parameters, exact values were not as important as bringing correct and representative data. Figures 2, 3, 4 and 5 illustrate examples of paper prototypes designed by the participants.

Subtheme 3D: electronic health record integration Specialists and GPs preferred different ways of accessing and integrating the data into their everyday practice (Table 9).

Subtheme 3E: Concerns.

Despite participants' optimism and the potential that they saw with sharing PGD, providers consistently noted their concerns (Table 10).

As mentioned above, specialists were specifically concerned with healthcare service priorities and resource management. Specialists were also concerned with how and where they should go to learn how to use these technologies, because they lack the time and support to

Table 6 Summary of which roles and responsibilities patients and providers perceived of one another given the introduction of mHealth into diabetes care

Groups	Codes	Summary	Example quotations
T1D participants	Own role	Have control and responsibility for own health	*"You have to take responsibility for the things not being done by healthcare … you have to follow up yourself" (T1D_P3)*
	Specialists' role	Nurses support patients with answers to specific questions	*"[Want] more specific answers on situations and questions when I am meeting with the nurse. I sometimes have questions about different situations … and two similar situations can become two completely different ones. [And the nurses] never has any good answers" (T1D_P5)*
Specialists	Own role	• Advisors • To distinguish between what kind of support different patients need	*"Task is to be advisors. We can't change anything, we can just give advice. The data by itself needs to help the patients to do the best thing" (Specialist1)* *"We have to start differently and expect differently from our patients. This is about individualization of treatment" (Specialist1)*
	T1D patients' role	• Have responsibility and are decision-makers for own health • Must be the one to initiate contact with HCPs when needed	*"To make the appointments, and to bring some own generated data" (Specialist2)* *"Be prepared for the consultation. Because we have so little time" (Specialist1)*
T2D participants	Own role	Informed data-collectors	*"My role [in sharing data] could be to be more exact in documenting information, such as diet, physical activity … that can help the GP confirm where I am in the process" (T2D_P2).*
	GP's role	• Interpret patient-collected data • Authority figures, but GPs may not be the best HCP to answer diabetes questions	*"It is interesting … with input from doctor from more examinations and closer follow-up... I miss that, and I am uncertain" (T2D_P4)* *"[GPs] really lack the knowledge in which we diabetics struggle with [because they] do not have enough education to cope with those specific health issues" (T2D_P2).* *"There are also diabetes nurses … they can maybe give more input about what you should do and not do … let the doctor take the more serious, while nurses help along the way" (T2D_P1).*
GPs	Own role	• Teachers of patients • To give advice	*"[Patients] are our pupils, and we are their teachers so when they do homework, of course I want to see what they've done. And then … I can begin to give some advice" (GP3),*
	T2D patients' role	Have main responsibility for health	*"You take care of your own disease, not me. I will help you on the way. It is your responsibility, and you have to have some sort of a motivation for it" (GP2).*

engage with these types of new medical and mHealth devices technologies. Those with T1D shared the providers' concerns of data-overload. Both healthcare providers and patients expressed a desire to share relevant and discussion-worthy information during diabetes care, but these barriers highlighted reasons that some are reluctant to integrate PGD from both medical and mHealth devices.

Discussion

System design

The co-design workshops focused on options for integrating mHealth as a supportive tool for diabetes care – designing a system for sharing patient-gathered mHealth data during consultations. Common design features that were identified included a) the presentation of PGD in a summary on the first screen of the system, with the option to select more detailed views and combinations of information on subsequent screens, b) graphs and charts were popular choices for visual representations, especially when comparing different data types, c) visual indications of change such as arrows or symbols related to each data type based on desired and undesired clinical values, e.g. blood glucose values in high (yellow), acceptable (green) or low (red) ranges, d) presentations of data that is relevant to the patient and e) efficient to use. While both those with T1D and T2D believed that sharing data remotely or before the consultation would allow them to receive answers and guidance during challenging situations and save time for both patients and providers, most providers were sceptical of this idea noting that patients must be present during the discussion in order to share and explain their data effectively. With these design features, both parties would be able to choose which data to look at, and then agree upon feasible solutions together.

These design features support the concept of "shared-decision making". While this term was meant to refer to patients and providers discussing and sharing the responsibility of deciding the best course of action for both self-management and medical treatment options together [20], much of the literature refers to HCPs making the final decisions in a "paternalistic model" [29, 30], have cited the challenges of or referenced the lack of

Table 7 Summary of patients' and providers' experiences and expectations of sharing patient-gathered data during consultations

Groups	Codes	Summary	Example quotations
Participants with T1D	Experiences	• Without data, feedback is too generic • With data, discussion is more practical	*"[Without data], often I feel like the meetings I have with them, it's like – "how do you feel" and [I say] "I feel its fine". I don't get that much out of [the consultation]" (T1D_P2).* *"[I get] specific tips with things [the doctor] extracts through the data which I don't feel like I saw myself. I've gotten advice that works" (T1D_P2).*
	Expectations	• More specific feedback based on own-gathered data • Interoperability will limited HCPs in their ability to interpret data	*"[Healthcare providers could] Interpret data with the knowledge they have and then give specific tips and feedback about the data" (T1D_P2)* *"Maybe [HCPs] can help me more if they see that there's a reoccurring problem … if I'm high during the evening...we can try to talk more specifically" (T1D_P3).* *"The [insulin] pump has all this data, so when I come to the nurse she puts the pump into the computer then she runs through and program and sees everything, and … it doesn't turn into much … with having a lot of data … [its] because of the tools [the HCPs] use" (T1D_P3).*
Specialists	Experiences	• Not all patients use, or want to use, these technologies • Some patients do not use the technology as HCPs would like • Those who understand the potential benefit of the technology use it correctly • CGMs and pumps are the most common technologies seen, few apps	*"They can come with all sorts of data, because it's automatic. But they haven't made a diary or sort of explained why was it like this, why did I get a hypoglycaemia … saying "oh these are my measurements" and "ohh no, I haven't looked at them" then it's so useless" (Specialist2).* *"They check a lot of blood glucose and they actually write it down for me because they realize that when they come with their small booklet then we can talk about it together and see" (Specialist1).* *"When we are talking about new technology, it's mainly based on CGM. Because that's the new technology the past 10 years" (Specialist1).*
	Expectations	• Patients will pre-digest data before consultations, then present it to HCPs • Patients who use mHealth are adept enough to use it correctly • Too difficult to understand all of the diverse health technologies	*"Patient X comes in and she has her measured blood glucose … on her device, whether it's a telephone or not. You get it on the doctor's screen … and then you see if it's high in mornings and so on, and you see how much insulin you use. You have the patient already before the consultation – trusting in her responsibility and her interest in doing better" (Specialist1).* *"[Use of mHealth] requires some technological insight and of course some intelligence in a way or - you understand me - stamina" (Specialist2)* *"Less than 50%" of their patients bring their own data to the consultations, either written in a book or* via *an app...[and] I don't know how many of my patients would like to use the Diabetes Diary app - maybe 5–10% - because it's too much!" (Specialist2).*
Participants with T2D	Experiences	Frustration with GPs not being able to answer specific diabetes questions	*"GPs are busy with work, so … it would be better to get an appointment at the hospital with a diabetes nurse, maybe once a year, and discussed your case with your data. And if you are way off with your values, you could also discuss with a doctor and then come to a conclusion" (T2D_P1)*
	Expectations	Perceives that the GP wants patients to come to consultations with an agenda/questions and corresponding data	*"I think what doctor expects is that you bring your blood glucose measurements, at least from the last week [with] notes about diet, physical activity, [if I] ate too much or drank too much. Compare my own measurements" (T2D_P2).* *"As I see it with the GP, you go to them when you have a specific problem. If you have [an annual check-up] with diabetes, [you are not going because of] a specific problem" (T2D_P3).*
GPs	Experiences	• Without specific questions or data, the consultation discussion is "boring" • Wishes for the patient to explain their situation in more detail	*"I think it is a bit boring. "This doesn't look pretty good, go home and be better". We need to know how you have been doing, what has happened. That's what's going to start a discussion" (GP2).*
	Expectations	• That the patient-gathered data must be easy to understand, will save time and result in specific and realistic goals for patients • Patients and providers will discuss data together	*"[It is possible] if the patient comes with [PGD] and it is easy to understand" (GP2)* *"[Patients need to] understand how to get there. To say getting HbA1c down by doing X. Very specific. In that case, say "you won't have blood glucose under that and that, and you will walk 5000 steps each day". Specific feasible goals from day to day"*

Table 7 Summary of patients' and providers' experiences and expectations of sharing patient-gathered data during consultations *(Continued)*

Groups	Codes	Summary	Example quotations
			(GP2). *"What happened to that resulted in these data? What has happened here? Good and bad. Why is it like this?" they could "make a plan to reach a goal - make a decision together … because it is the patient who has to go through with it and follow it up, regardless of what we write... it has to be feasible" (GP3).* *"I think you go through data in together. Look at it together, both and points and trends, both hard data and stories … specific information will save us time, instead of trying to make people tell us" (GP1).*

specific suggestions for how to achieve this ideal [31, 32]. Even when shared-decision making is used in its truest intended way, it still faces challenges such as patients' lack of understanding of their disease and the providers' unwavering focus on clinical measures [33]. The results of these workshops suggest that patients and HCPs see that potential collaborative point between their areas of expertise – providers' medical knowledge and the patients' mHealth self-management experience an PGD– can lead to true shared-decision making and, subsequently, feasible health goals for individuals.

Collaboration and understanding

The shared aim amongst patient and healthcare provider participants of displaying these data was to facilitate discussion and shared decision-making. Patients and providers independently and consistently described the value of discussions, exchanging valuable and useful information and for improved communication, not just about the data itself but about expectations and intentions. For example, both those with T1D and T2D wanted to know which data healthcare providers were interested in or needed in order to provide specific feedback and recommendations. While patients hoped that providers could relate to and interpret PGD, providers were quick to explain that it is an unrealistic expectation because the healthcare system does not provide resources to teach providers about how to discuss the various mHealth technologies in care practice.

Participants also expressed an understanding of their counterparts' situations within diabetes care in general. For example, those with T2D understood that GPs may not be the only, or even the most knowledgeable, source of answers for their diabetes-specific questions. This was expressed with empathy, not judgement. Instead it prompted discussion about realistic alternatives such as going to visit hospital nurses or reputable internet sites. Specialists were particularly concerned with understanding the unique situations of their individual patients. While in some cases their comments were not directly related to the question being asked, it forced us to take a step back in the discussion and understand the reality of diabetes care. For example those with T1D, where one specialist urged us to keep in mind that treatment is about the individual person and their specific situation - a concept which should be more prominently addressed in our mHealth research; addressing those with T1D as a group is not actionable given the unique needs of each person. The other specialist emphasized that providers need a comprehensive understanding to effectively guide an individual, i.e. understanding their mental state, resources and intentions in order to generate a realistic goal for their diabetes. A participant with T1D also reinforced this from the patient perspective by explaining that they would rather have a conversation with their HCP about which data to share in relation to a certain situation so that the consultation could be more productive and targeted.

It is also important to note that the participating individuals with T1D portrayed the need for data-sharing as very straight forward – seeing the situation from the perspective of someone who already is familiar with, and uses, medical and mHealth technologies; i.e. they present their data and the healthcare provider can identify patterns. However, participating specialists made it clear that their perceptions and expectations of sharing data during consultations is much more complex. While some patients can come with a well-prepared agenda, providers also have to prepare to relate to those who only use paper diaries as well as those who try, but do not manage to use the technology as specialists would hope.

Data sharing and information exchange

Specialists were very aware of the impact of accurate and complete data sets because collecting data is useless if the user is unable to determine meaning from what they measure. They expressed several times that each decision about a patient's case not only had to be informed by their sense of the individual's personal

Table 8 Summary of patients' and providers' ideals about what and how a data-sharing system would present patient-gathered data during consultations

Groups	Codes	Summary	Example quotations
T1D participants	What data to share	• Indications of specific problems in their self-management • Concerns about what data to share	*"We could get a sign on the graphs … maybe statistics on how the blood glucose is … in the evenings or afternoons" (T1D_P5)* *"What I need is different than what you need as a doctor" (T1D_P4)*
	How to share patient-gathered data	• Summaries • Graphs, e.g. showing trends during different times of day • Symbols to indicate change of a data type over time • Provide specific data as requested by healthcare provider	*"Summaries of my every-day [data] in such a way that we together can discuss where the problems are" (T1D_P4).* *"I have a lot of data and my ideal situation is that I get a mail from my nurse saying I want your data, or a reminder. Or I upload my data in my program and share with my nurse and then I get the question "Can you note this week what you put of insulin in the given period and then I get the data from you" (T1D_P3)*
Specialists	What data to share	• Fluctuation and trends • Indication of what patient's problem/challenge is within the data • Representative data-sets	*"First, I would like to see the fluctuation [of blood glucose] over 24 h - it's the most important for me. Then have a look at some data because there was something special going on" (Specialist1)* **(**Fig. 2**)**. *"An intensive period [worth of data], maybe some days or weeks before they come to me, because I want to see variation. And document pretty carefully … Then we can see the context … So these very like, these short, tiny, detailed periods is very valuable for me even if it's not representative for the long life" (Specialist1).* *"The last week or 14 days … where you can see meals, calibrations - to see that you calibrate correctly - physical activity and illness … to explain why you are high the whole night, and of course insulin doses. Additionally, if the algorithm can pull statistics and say "ok, you are always low after correcting extra" or such things" (Specialist2)* **(**Fig. 3**)**.
	How to share patient-gathered data	• E.g. algorithm or statistics • Ability to choose which comparisons to make within the data provided	
T2D participants	What data to share	• Overview of own situation • Status of self-management habits, i.e. each data type gathered • Concerns about what data to share	*"Having summaries of the data, and then [you can] click on blood to get [more details] … what you've done that day and time and all. Everything in a submenu of the main" (T2D_P2)* **(**Fig. 4**)** *"I can collect irrelevant data - I can gather data about my own situation that may not be relevant for doctors" (T2D_P4)*
	How to share patient-gathered data	• Diagrams or graphs with colours or indications of change • Comparison of self-management habits vs. goals • Ability to choose which data-types to explore from a summary	*"You have green and red and yellow zones. I might not need all the values, but you could see if you are safe or not. Like the weight it is pretty much too high all the time. Physical activity is maybe not so good.... And then you could choose, and get out the exact values, as a table" (T2D_P3).* *"A diagram with levels - level for goals, level for what was completed.... With remarks and blood glucose data and diet" (T2D_P2)* *"A bar-graph … plotting blood glucose, exercise and wellbeing. Nothing more" (T2D_P4).*
GPs	What data to share	• Challenges or issues within a patient's self-management habits • Detailed data for challenges	*"I tried to get in everything at once [to] see a correlation if you have [different PGD] together … You won't bother to plot it every day, but rather have a marker of some sort if it was something special...like if [the situation is] suddenly changing- the values go up or down, their health situation is getting worse or something- it could be okay to have more values, to see what is actually happening" (GP1)* **(**Fig. 5**)**.
	How to share patient-gathered data	• Summary via, e.g. Graphs • Indicators to show if "something special" (challenges) happened • Correct and representative data	*"Type of compressed summary...Instead of having to look at a thousand measurements" (GP3)* *"If you get graphs and stuff it is easy to relate to and you can get quick glance of what has changed. But if you get the whole [data set] in reverse and just scroll and scroll, then it's not very useful" (GP2).* *"With physical activity, having it correct, so maybe step counter for example. It says something about changes. Useful if you have these watches. They are not necessarily very reliable, but it says something about your development. Instead of you saying you went for a walk, or half an hour, which doesn't really tell me much" (GP1).*

situation, e.g. other responsibilities in their life and well-being, but also the accuracy of the representations of their diabetes health, e.g. blood glucose levels in relation to insulin doses. GPs, however, were not as concerned with where the data came from as expected. While they did emphasize that the data was representative of the patient's situation, because, as some explained, they did not intend to alter medication or clinical treatment plans based on this data, the exchange of information was more important. Instead they believed that they could use PGD as an indicator for the patient's progress and a basis for which patients and providers could together develop self-management recommendations.

A significant distinction between the meaning of "data" and "information" emerged from these discussions. Data is useless on its own. Individuals need to

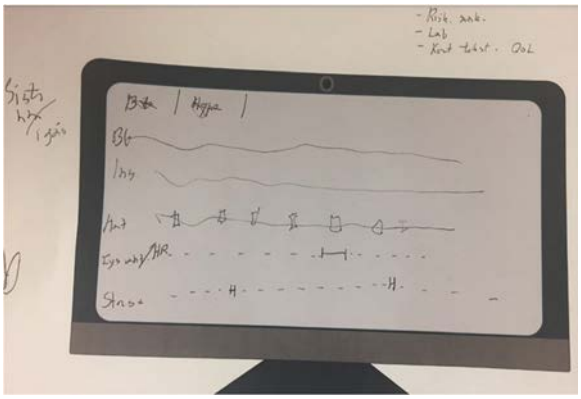

Fig. 2 Specialist 1's paper-prototype for an ideal data-sharing system display

have a purpose, intention and questions in order to direct what data to collect as well as how much and what information, evident from the whole collection of data types, can be identified and presented to their healthcare provider. Healthcare providers may be interested in specific data points when "something special is going on". However, again, participating providers believed that individual data points, or even a collection of one data type, are useless without context.

Issues that data-sharing can and cannot solve

By comparing participants' backgrounds, i.e. general self-management and clinical practice experiences and needs, and their ideas about sharing PGD through a dedicated system we were able to generate a better understanding of what they believe can and cannot be addressed, let alone solved, with sharing data from mHealth devices. While the primary aim was to gather input about the design and functionalities a system should have,

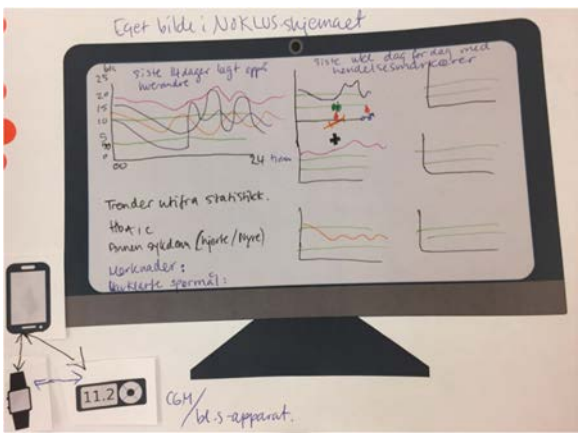

Fig. 3 Specialist 2's paper-prototype for an ideal data-sharing system display

participants provided additional information about issues surrounding the use of the system. Especially those with T2D expressed that they often did not know why their blood glucose values were changing so drastically. This was an example of a solvable issue because their ideal solution was that a data-sharing system could not only identify a patient's challenge areas but correlate the concerning blood glucose values, for example, with their food and medication. Issues that needed to be addressed before such a system could even be realistically implemented were mHealth technology training and support for healthcare providers. Both specialists and GPs expressed their limited knowledge and frustration with not having the resources they need to become aware of or optimize use of mHealth and PGD during clinical practice. For example, specialists repeatedly emphasized their concern about resource management, when technologies required nurses to provide more time and support for a small group of CGM users, and technology training in general, because there are too many different types of technologies to familiarize themselves with.

Proposed data-sharing system vs. state-of-the-art

We aimed to address what it would take to make the collaboration between patients and healthcare providers using PGD possible and useful for all users. Some of the unique design ideas and purposes for the system that resulted from these discussions were the overwhelming agreement that the system should generate discussions, and more importantly, shared decision-making. The system should be flexible and present an overview of patient-relevant data, and give the patient-provider team the option of further exploring certain data at their discretion. These options and intentions differ from many commercial options or other tested interventions available at the time. Typically, the responsibility and ability to interpret the data and make decisions is one-sided - either skewed toward patient self-management, such as apps found on app stores, or clinical monitoring and oversight of only one parameter such as CGMs [34]. For example, an individual with T1D can use an app to track how each type of food affected their BG levels to meet their goals, whereas an HCP may prefer to see summaries of data such as medication use and response, which can then be compared to lab results. However, participants of these workshops agreed that the potential benefit of using a data-sharing system that would allow both parties to explore the data together, would be to foster mutual understanding and discussion of the data, which could lead to feasible recommendations. The presented users' feedback support the notion that patients and providers working separately, e.g. with separate agendas for the consultation and poor communication, is not as

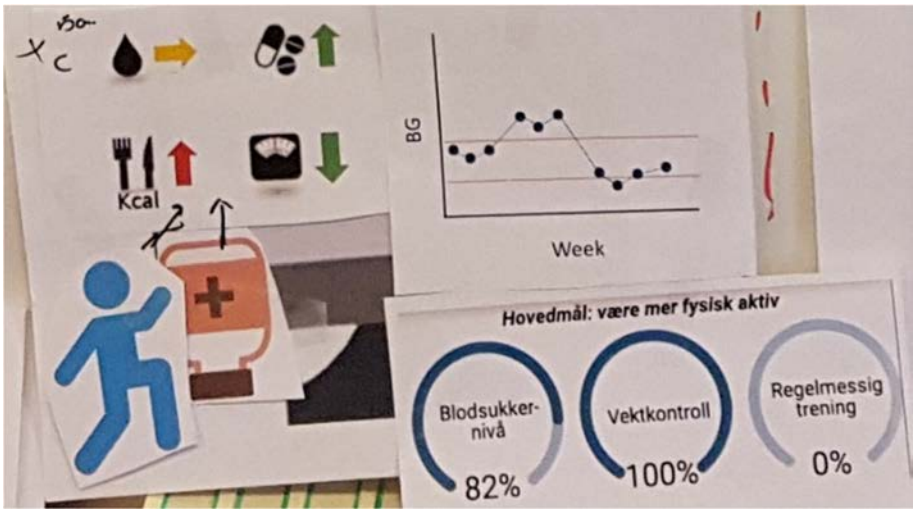

Fig. 4 T2D Patient2's paper-prototype for an ideal data-sharing system display

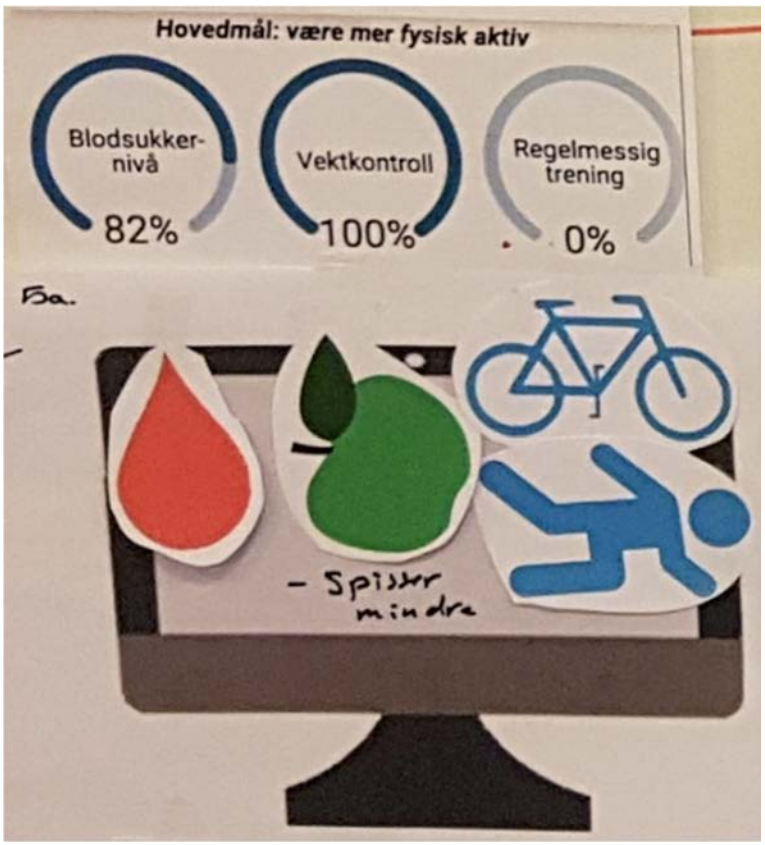

Fig. 5 GP1's paper-prototype for an ideal data-sharing system display

Table 9 Summary of responses to perceptions of mHealth and patient-gathered data being integrated into healthcare providers' electronic health record (EHR) systems

Groups	Codes	Summary	Example quotations
Specialists	Preferences	• Automatic data transfer • Visual summary of specific data types within patient-gathered data	*"Automatically getting the continuous glucose values for the last week, into my electronic diabetes journal system... and the use of insulin or automated data easily, visually presented" (Specialist1)*
	Risks	• Data-overload • Capacity of personnel and resources • Personal liability of not identifying indicators of dangerous habits and symptoms	*"The other thing that comes to my mind when you say [integrating technology] is "Please stop it!" because I if you are the patient and I get your data continuously for your whole life on my screen, then I am responsible because if something happens to you, if you go into your car and have a traffic accident with hypoglycaemia it's my responsibility because I should have seen that last week you had several hypoglycaemias … but we do not have the resources for this" (Specialist1).*
GPs	Preferences	• While prefer no integration, alternatives could include automatic and simple data-transfer that do not require the provider to perform additional tasks • Rely on entering own notes into EHRs about a patient's status	*"We don't need to load [PGD] into the EHRs, because there are many problems and overload of information. And, why should we keep it?" (GP3).* *"If we would to have it on our computers, partly* via *a journal. Not extra software! Then [the patient] can have [their] phone, plug in USB, and I have it, okay, we could do that … a compromise - But not one manually!" (GP3).* *"Instead, I prefer] to type [notes about PGD] myself … write it short. Reminder [to focus on this] for next time" (GP3).*
	Risks	• Data-overload • Overloading the provider with additional tasks	*"It's always a chance of overload … a whole lot of data. We can't relate to it" (GP1)*

effective as identifying common needs of both parties and designing systems to support those.

Reflections on the research method

With respect to the research method itself, it is important to note that these presented results highlighted a significant difference, and challenge, of mHealth research compared to traditional research. Traditional research on medical tools and services follows a thorough, focused and lengthy process. Spending much time on these interventions options is expected and healthcare providers, thanks to the validated and trusted methods of inquiry, accept the results. However, research on mHealth tools and services requires a more user-involved, comprehensive and rapid approach. It calls for not only validation of the technology – which still lacks a standard process, but at the same time, the validation of feasible options for integration into medical system workflows. Therefore, we as researchers must re-evaluate how best to perform research that answers traditional questions, e.g. hard health outcomes, as well as those that are unique to mHealth and personal health alternatives, e.g. ways of gathering and displaying data that both healthcare providers and patient, as experts in their own health, can understand. This includes taking advantage of new resources, e.g. expert patients in mHealth and social media, and more actively collaborating with healthcare authorities and organizations to determine feasible health service options to support mHealth integration for both patients and practitioners. Many co-design workshops do involve patients and HCPs. However, they do so most commonly in separate sessions [35]. In research practice, the interpretation of the resulting participant feedback, often would have to be inferred rather than explicitly stated. In other words, there is usually limited or no possibility for participants in different groups to correct one another's assumptions. We hope that by demonstrating how patients and HCPs can discuss solutions together, we can encourage others to use the EBCD method more in the mHealth and personal health field.

Lessons learned

With regard to the methods and approaches used to conduct these co-design workshops, we have generated a list of "lessons learned" (Table 11). Planning of the workshop sessions and activities were generated iteratively over months to ensure that all participants felt prepared and safe to share their perspectives and that we as a research team would receive the feedback necessary to design an end-user-based system for sharing data. We experienced the need for a research team to be flexible, inclusive and have an open agenda when inviting end-users to participate in directing the research.

Study limitations

Geographical region

Limitations of these workshops resulted largely from the convenience sampling from a specific geographical location – Northern Norway. The relevance of this is that

Table 10 Summary of responses to perceptions of mHealth and patient-gathered data being integrated into healthcare providers' electronic health record (EHR) systems

Groups	Codes	Summary	Example quotations
Participants with T1D	Concerns	• Data overload • That healthcare providers still would not be able to use data to generate personalized recommendations	*"Giving up all of my blood sugar measurements is very much information" (T1D_P4)* *"[I shared] a lot of data … I got little use out of meeting the diabetes nurse...Last time she said it wasn't much she could help me with" (T1D_P3)*
Specialists	Concerns	• Priorities of healthcare providers would be hindered • Healthcare providers' capacity, i.e. time required to use and knowledge about how to use technology	*"The CGM technology is very good, but our nurses – it means that 80% of their time is working with the functional learning patients and [complaints about] "it doesn't work", "how can it do it and change". So instead of actually talking to the patients about "how are you" – we are dealing with problems about "I can't fit it" (Specialist1)* *"10% [of patients] use the CGM. Then those patients get much more consultations with the nurses because they need to be taught the CGM and they need follow-ups. So this small group … maybe they use 80% of the nurses' time" (Specialist2). Also, continuous data transfer potentially meant the need "to have a diabetes nurse continuously, 24 h-a-day, checking on continuous glucose monitors (CGMs), like we do with hospital patients. We don't have resources for this" (Specialist1).* *"There is a lot of different technology now. It is Freestyle and it is CGM and it is 640 G and Freestyle Libre. Of course patients are oriented about this because they talk to other patients, search on internet and so on. But the doctors have very little possibilities … so, we have little time to learn these new systems and to understand how to optimally use them" (Specialist2).* *"During this 30mins where I am also supposed to have nice communication with the patients and also do blood pressure and check their feet and check if they have been to the eye doctors, checking and requiring lab measurements and prescribing insulin– I need to get these data in. That's a problem of time. The other thing is the problem of methodology of how to get the data presented in a way so that it is not time consuming for me" (Specialist1).*
	Alternatives	• PGD could complement and be used together with EHR systems, if it were to be integrated automatically	*"I work in an [electronic health record system] so there we have a lot established already. And what I want is a new screenshot showing blood glucose...and the insulin. It has to happen automatically, either with pen or pump. And then something about physical activity. And then something [about] food, and short [remarks] about stress and questions for the doctor … And then we look at it on the screen together. Then it is easier to see and explain, and with things already in [the electronic health record]" (Specialist1).*

the typical culture of the medical system is less hierarchical. This can sometimes extend to the relationship between patients and their healthcare providers. The consequence is that the use of a joint session in the co-design workshops and gathered feedback therein may not be representative of the type of feedback, e.g. the unabashed correction of assumptions, that could be gathered in other cultures or geographical regions.

Gender balance

Another limitation was the lack of gender balance amongst our participants. The relevance of this is that, in general, there are differences between genders with and without the use of technologies. These differences stem from their daily responsibilities and cultural roles that research should be addressing and that impact the outcomes and application of scientific findings in healthcare practice [34]. While we aimed to recruit equal numbers of each gender, few female or non-gender-binary participants expressed interest in participating, e.g. during the T2D patient session in which there were only men. The consequences of this are that there was an overrepresentation of suggestions about how technology should function that suit men, e.g. the ability to collect and share types of data that may be more or less important to other genders. To ensure more balanced participation in future studies, we could allow for a longer response time during the recruitment process, and/or advertise the study in different media.

Participants' level of technology experience

The convenience sampling also relied on recruiting patients who used the in-house developed Diabetes Diary app and were therefore already engaged in mHealth for diabetes. The relevance of convenience sampling for mHealth studies is to recruit those who have experience and therefore experience-based suggestions for how to address the call for mHealth integration into clinical

Table 11 Lessons learned about conducting a co-design workshop between individuals and their healthcare providers

Aim	Lessons learned	Recommendations
1. Address topics relevant to the design of a data-sharing system.	Participants have their own agendas when participating in a workshop, e.g. specialists spent more time explaining the situation in their clinics and their views of what patients need in general, than expected and often did not respond directly to the question asked.	Plan for participants to take time to explain their situation. This provides more context for their perceptions and expectations of the situation, allows the research team to better understand their needs, and may provide additional and unexpected relevant information.
2. Explain intentions, e.g. explain how to use participants' feedback	Know your audience - What you see as important to the core purpose of the project may not be relevant for the participants.	Do not overwhelm participants with information, especially at the beginning when their priority is to get settled in and comfortable. Test out your explanation on someone completely unrelated to the project, e.g. a family member or friend, and ask that they point out the confusing or unnecessary details.
3. Encourage participants to produce as much input about their needs and ideas as possible.	Engaging and creative activities were planned based off of research and online "toolkits" available from several difference organizations. Despites attempts to make instructions as straightforward and clear as possible, participants felt the need to clarify several times because the instructions were either too detailed and complicated or not understandable.	• Use other researchers or staff in other fields, e.g. product development, as resources for activity ideas • Participants may have a different interpretation of the instructions or may miss instructions, in which case it is best to adjust yourself as a researcher to their interpretation instead of trying to correct them as this may be discouraging
4. Create a comfortable and inclusive atmosphere to bring forward honest feedback	We posted signs and reiterated verbally that there are no small or silly comments; all insights and feedback would be welcome. Disagreements were of course welcome but we encouraged respect in the verbal discussions.	Before the workshop, reinforce within your team that this is about the participants' experiences, not about your own assumptions or preconceived notions of what is happening or, especially, what should happen. Do not take sides if there is a disagreement but encourage participants to explain - ask "why do you feel that way?" or "why do you believe that".
5. During the joint sessions, ensure that both patient and healthcare provider participants feel comfortable and safe to share their opinions, despite the difference in perceived "authority level".	We expected to need to reiterate that everyone's opinion is their own and should be respected. However, possibly due to the less hierarchical cultural structure in Norway, we did not need to reinforce this concept. Participants were respectful and listened without having to be directed.	• Make sure that none of the participating healthcare providers were the clinicians of participating individuals with diabetes. • During the lunch break between the separate morning and afternoon joint sessions, invite all participants to eat together. • Suggest ice-breaker activities, within and between groups?
6. Creating an engaging and creative atmosphere	We chose large rooms and posted the three situations that we aimed to understand (self-management, clinical practice and consultations) on wall-sized poster boards as visual aids. These included pictures and space for participants to draw, write and tape their ideas to.	Introduce each situation and allow participants to familiarize themselves with the posters before starting the activities. Allow them time to brainstorm and encourage physical interaction with the visual aid materials. If participants know what is planned, they can mentally prepare themselves for the day, e.g. develop ideas throughout and know what is expected of them.
7. Allow for the participants to drive the conversation and tell the research team what they need and ideas for the systems' design	Some participants seemed unfamiliar and uncomfortable with suggesting creative solutions for a future system. Instead they wished for us to present prototypes and then form a discussion based off of existing ideas.	• Expect that different participants have had different history with workshop activities and different expectations going into the workshop • Clarify the expectations of the researchers and participants at the beginning • Participants could also help to plan the workshop and select activities that their believe will allow them to most accurately and completely share their opinions

practices; such a group would be likely to consider sharing their app data with their HCPs and would be more likely to know what they would want from a system designed to do so. However, we do acknowledge that these participants were not representative of all patients with diabetes. As the specialist participants echoed, they only meet a small percentage of patients who use medical devices and mHealth technologies. The consequence of

this is the potential to widen the digital divide by focusing on further development of modern technologies instead of focusing on how existing technologies can be more inclusively developed and supplied. In the future, all interested and eligible (18 years +) parties could be included to ensure that feedback about mHealth represents not only additional and advanced functionalities but also improvements on existing functionalities to lower the barrier-of-use and increase the benefits of personal technologies for diabetes self-management.

Focus of the discussion guides

Further, discussion guide questions focused on data-sharing, use of mHealth and healthcare consultations, not on the demographics of the participants. This led to an incomplete data set, i.e. lack of information about duration of diabetes, exact age, HbA1c, education and other potentially relevant factors. While the primary focus of these workshops was to explore the impact of participants' experiences and preferences on the design and potential use of a data-sharing system, the consequence was a lack of consideration for what younger vs. older individuals would need from such a system or how they would experience sharing their data with healthcare providers. This can be overcome in future studies, without affecting the workshop time, by the simple addition of a demographic survey at the beginning or prior to the workshop start, perhaps as a part of the informed consent process.

Conclusion

Those related to T1D care emphasized the need for a system that identifies instances of health issues from individuals' registered data, facilitates patient-provider discussion, fulfils the information needs of individuals for their self-management and makes it easy and efficient for healthcare providers to view the same data in different ways, e.g. reviewing different time periods or combining different data types. Participants related to T2D care expected that mHealth technologies to motivate patients to track their health and be able to learn more effectively and direct the consultation conversation in a more proactive way. Both those with T2D and GPs hoped that sharing this much more representative data during consultations would provide evidence of trouble areas in the individual's self-management that they could both discuss and find solutions for, together.

To benefit both of these end-user groups, the system should structure the data in a relevant and usable way, and be flexible enough to present different levels of information, i.e. summarized and in-depth, and be understandable for both patients and providers in order to generate collaborative and tailored discussions. This argues that there should be a single flexible systems is influenced by the healthcare providers' preference for fewer additional technology solutions and the fact that some individuals with T2D also visit HCPs in the hospital, not just those with T1D. Specialists and GPs agreed that they would prefer not to install, and have to learn, yet another technological system in their practice.

To address healthcare providers' concerns of their own preparedness and workload capacity, healthcare systems should consider developing support services and resources surrounding mHealth and PGD integration, such as topic-specific education. The verified feedback from these co-design workshops have demonstrated the importance and value of including both patients and healthcare professionals in designing a system for integration of PGD during consultations.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-020-05955-3.

Additional file 1.
Additional file 2.

Abbreviations

mHealth: Mobile health; PGD: Patient-gathered data; T1D: Type 1 Diabetes; T2D: Type 2 Diabetes; EBCD: Experience-based Co-design; HCP: Health Care Provider; GP: General practitioner; EHR: Electronic Health Record; CGM: Continuous glucose monitor

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Authors' contributions

MB, RM and EÅ created the discussion guides. EÅ and MB conducted the recruitment, workshops and follow-up as well as created all material used therein. EÅ served as the moderator of the sessions. MB and AG served as facilitators of activities during the workshop sessions. MB, EÅ and RM discussed the transcripts and main themes for analysis. MB performed thematic analysis of the transcripts and paper-prototypes. AG provided input on the questions asked in the discussion guides and co-moderated one of the workshop sessions. All authors read and approved the final manuscript.

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Availability of data and materials
Due to the small population from which the participants were recruited, we believe that sharing the transcripts would be exposing too much identifiable information. Therefore, we will not be making the data openly available. However, as an alternative, we have added Additional File 2, which provides curated quotations from the transcripts that may be relevant for fellow researchers, but were not reported in the main text or directly related to the design of a data-sharing system.

Ethics approval and consent to participate
The co-design workshops were found to be exempt from the purview of the Norwegian Regional Committee for Medical and Health Research Ethics (REC) committee (ref. no 2017/1759). They were instead acknowledged by the Data Protection Officer (Personvernombud) at the University Hospital of North Norway, September 2017 (ref. no 2017/5235). Written consent to participate was gathered from each participant prior to the start of each workshop, i.e. written signature on a provided consent form.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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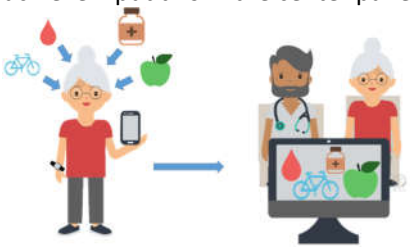
Publisher's Note

Additional File 1. Discussion guide for the Co-design Workshops

The Full Flow research project

Aim (A) and Purpose (P)	Questions/activities	Practicalities/instructions
Patient session (9-12)		
	Welcome & Ice breaker: Year of the Coin	- **Welcome** & return/fill in signed informed consent forms while fill up coffee/tee - **Introductions** of everyone by first name (name tags) ○ Describe research team roles so participants are aware • Discussion moderator (EÅ) • Agenda facilitator (AsGr) • Observers and helpers (MB and AG) - Ice breaker: Year of the quarter (tell what you were doing during that year) ○ 7 coins, one for each patient participant and researcher
A: Common understanding of what we want to achieve from workshop **P: Working within the scope of the project without limiting creativity and input**	Description of project purpose and aim	- **Introduction to the mHealth environment:** ○ We are speaking about patients in general - the average patient may not have so much experience with technology but are interested in using it therefore we must address their needs as well. ○ So, participants can educate us about what is important, what works for them and where they need more assistance/support in managing their diabetes. About the research project: Mention briefly the aims and actors involved, and the main test we aim for. - **Purpose:** ○ Want to know how mHealth and patient-collected data can be used in clinical consultations ○ Help patients and clinicians make better plans for managing their own diabetes ○ All of this will help design a system where you and your clinician, together, can view the health data that you collect yourself. (Visually displaying the ideal situation that we hope to achieve – put this in the center panel of the landscape)  - **Overview of the day and agenda:** ○ So for today, we will get to know how you interact – or wish to interact - with your apps and self-

		collected data and then, in the afternoon together with clinicians, what you would need from a system that helps you to share and discuss your data during consultations

A: Common understanding of how to conduct one's self during the workshop
 	
P: Encouragement and comfort of ALL participants, establish safe environment to share own ideas and receive others' ideas
	Workshop rules	Refer to the large printed: **"YOUR ROLE, YOUR NEEDS"**
		- Everyone's opinions are valid
		- We ask that you only focus on YOUR ROLE and YOUR NEEDS as a patient/clinician – try not to assume what the other patient/clinician believes or is trying to do, this is why we invited both
		- Everyone should feel comfortable and not judged:
		  - everyone wears different hats, experiences situations differently and we need to respect their opinions but feel free to ask clarifying questions or respectfully disagree
		- Enthusiasm is great but gentle reminders will be given if we get off track
		- Sessions will be tape recorded but it can be turned off upon request
		- Everything in the room will be confidential – no names please
		- No identifiable information will be recorded
		- Honest feedback is best to improve research and the system – no need to "save face"
		- No treatment advice will be discussed during this session
		  - If questions of medical issues arise, please note them and discuss later with your own clinician

A: Increase engagement/participation
 	
P: Reassure that all ideas have value and no idea is stupid, breaking the tension and making the atmosphere more casual
	Warm up activity: Worst Possible Idea exercise	***Practical notes:*** *White pieces of paper to draw on or write ideas on (enough for all 7 participants, researchers included)*
		
		- **Purpose** is to reinforce that no such thing as a bad idea because everything leads to something useful: umbrella
		- **Rules:**
		  - Both research team and patients will participate
		  - Everyone should get a chance to talk, but okay if there are no ideas
		- **"Worst Possible Idea" exercise**[i]
		  - Think of the worst design for an umbrella
		  - Write down as many ideas as you can on separate white sheet in 2 minutes
		  - Pass them to the person next to you and elaborate on their bad idea – go through as many separate ideas as possible for 2 minutes X 2 rounds
		  - Then read out loud and place them on a board visible to all
		  - Now propose the best design – no limits (gravity, legal issues, reality etc.)
		  - Plan B: MB comes up with an example in Norwegian

Break (9:40-9:50)		
	Introduce main workshop activity	- Start audio recording of the session - **Explanation:** we will brainstorm and write down some things on our own and then discuss together for most of today – this way, in case we are not able to cover everything, you are still able to provide your input! - **Introduce the landscape**: Explain what the landscape is and how we will use it during the day o Fargelegg Landskapet: Egen behandling, Møte, klinisk diabetespraktis (MB put up graphics to illustrate this) After each question you will be given a few minutes to brainstorm - This is just brainstorming, you can keep writing down ideas as we go so don't think that 2mins for brainstorming - Feel free to post it yourself or hold it up and we will come get it from you

A: Which parameters patients gather, their baseline motivation level and measure of activation on a non-standardized level
 	
P: Understanding what patients prioritize in their self-management, which will primarily inform the functionalities of the system and secondarily enable clinicians to be aware of patients' perspectives
	Discussion: Do you feel like you self-manage your diabetes? Why do you self-manage the way that you do?	***Practical notes:*** *Audio only + cotton balls to initiate conversation and set precedent for equal participation*
		- **Cotton ball method:** each person gets 3 and "uses one up" each time they speak.
		- **Follow-up & examples to use if the conversation stalls**
		  o why do you choose to spend more time on one thing than another
		  o Impacts of the disease?
		  o Realizations, habit changes?
		  o Confidence and self-efficacy/knowledge of disease?
		  o Challenges?
		  o Motivations?
		  o Overall perceptions of how well they self-manage?

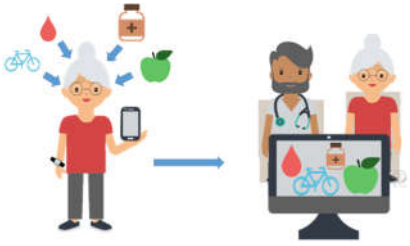
	1. What do you focus on? Do you have a **goal** for any of these or do you just track to find trends or patterns?
	
	2. What data are you saving/collecting?
		Practical notes: *Yellow post-its to write or draw on in response to each question (1-2minutes per question)-* ***1 verb and 1 noun***
		- **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun for each feedback**
		- **Follow-up questions & examples to use if conversation stalls**
		  o Are you gathering: BG, physical activity, diet, medication?
		  o Routines, following a schedule, preparations?
		- Place responses on white board or wall under heading **"Egen behandling"**

A: What tools and support patients use to aid their self-management **P: Depicts possible areas besides health measures**	3. Do you use any mHealth apps or medical tools and which kind? And what is good and/or bad about them?	***Practical notes:*** *Yellow post-its to write or draw on in response to each question (1-2minutes per question)* - **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun** - **Follow-up questions & inspirational ideas**

that the system can/should address	(else it will just be a survey)	○ Smartphone app, smartwatches, BG meters - Place responses on white board or wall under heading **<u>"Egen behandling"</u>**
	Participants place post-its on board in area drawn	MB reads out loud to begin discussion and allow people to comment on the ideas "hva synes du om dette forslag…"".. "
	<u>Discussion:</u> How do you use **these tools** to help you?	***<u>Practical notes:</u>*** *Audio recorded only, no additional supplies or preparation needed* - **<u>Follow-up questions</u>** ○ why are they effective or why not? ○ how could they be more effective…"its good but"
	4. What challenges do you have with self-management? 5. How do you (or could you) overcome that? **<u>Discussion question:</u>** ask them to comment on these suggestions – lets focus on the solutions or any other ideas given other tools etc. that could help solve the challenges?	***<u>Practical notes:</u>*** *Yellow post-its to write or draw on in response to each question (1-2minutes per question)-* ***1 verb and 1 noun*** - **<u>Instructions:</u>** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun.** Post suggestions for 4 and 5 next to each other - Place responses on white board or wall under heading under **"Egen behandling"**
<u>A:</u> Determine how patient participants interpret their responses. **<u>P:</u> To engage participants throughout the activities. Allow them to take ownership of what is produced.**	Creating topic headings together	***<u>Practical notes:</u>*** *MB at board to organize* - **<u>Instructions:</u>** now that we have some ideas on the board, we should organize them so that it will be easier to reference these in the coming activities (because we will be using your suggestions in the future) - **<u>Follow-up questions & examples to use if conversation stalls</u>** ○ Habits? Tools? Technology? Data? Goals?
Break (10:40-10:50)	**Break (10:40-10:50)**	
<u>A:</u> Which data displays are easiest for patients to relate to. Baseline understanding and engagement in diabetes data and disease knowledge. **<u>P:</u> Understanding how patients interact with their registered data,**	6. How do you use your data to self-manage	***<u>Practical notes:</u>*** *Audio only* - **<u>Instructions</u>**: looking at what we wrote for questions 1&2, let us discuss this. - **<u>Plan B: Give example situation to respond to</u>** - **<u>Follow-up questions & examples to use if conversation stalls</u>**

thereby setting a basic or baseline way of displaying data in the system		○ How would you use your data to make a change or decision in self-management?
A: Which data do patients want to share and what answers do they need from their clinicians to understand their data and act on it in self-management **P: The expected scope of the systems functionalities that will facilitate discussion, initiated by patients**	7. What are clinicians helping with? 8. What could they help with? 9. What should they help with? **Discussion:** Have you presented your own data or app data to your clinician? When did you or think that you should present your data? What worked/was successful or easy and what didn't work or you both had trouble discussing?	***Practical notes:*** *Yellow post-its to write or draw on in response to each question (1-2minutes per question)-* ***1 verb and 1 noun*** - **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun.** - Place responses on white board or wall under heading **"Egen behandling"**
A: Generate ideas to facilitate joint discussion **P: Prepare participants for joint session – thereby saving time and establishing concrete topics to discuss**	**Prepare for lunch break:** Given this new situation where you gather data yourself… 10. How do you think this changes yours and your clinician's roles during the consultation? 11. Does it change what you bring to the consultation or how you prepare to talk to your clinician?	***Practical notes:*** *Brainstorm-write down or draw (if they want) ideas on post-its (can take them during lunch)* - **Instructions:** because there is no such thing as a free lunch, we would like you to think through these questions and jot some things down because we plan to come back and discuss consultation during the joint session. Place responses on white board on line between **"Egen behandling"** and **"Møte" -** when you return from lunch

(Stop audio recorders) Patient Lunch (12:00-13:00)		
	patient participants to lunch in cantina at 12:00	- *Preparation tasks for research team* ○ *Workshop rules Bring lunch in the room for the clinicians and 3 researchers - eat when we prep them and MB and AG can help describe the purpose and project etc.*
(Start audio recorders) Clinician Session (12-12:55)		
	Introductions of participants	- **Welcome and introduction:** First Names and Experience with diabetes patients
A: Common understanding of what we want to achieve from workshop **P: Working within the scope of the project without limiting creativity and input**	Description of project purpose and aim Overview of what was done in the patient session	- Current situation of mHealth and EHR data ○ Purpose of the day and project – making the most out of this situation ○ Introduce the Co-design concept (do this also for patients)

		○ Make clear what the patients have done before they arrive and what kind of input we want in this workshop ○ Make clear what will help a safe environment – no judgement and no assumptions of how patients perceive and think about their diabetes ○ Generally about the FullFlow and actors by EÅ - **Ask if they are comfortable with MB and AG introduce Full Flow project in English:** ○ **MB and AG**, 2-3 sentences about purpose of Full Flow and the fact (no details) that we are PhD students, and what they want feedback on. ○ Visually present the ideal situation that we hope to achieve  - **<u>(Refund formalities – if not already done by AsGr)</u>** - **<u>Opportunities for future involvement</u>** ○ This is a large project and we hope to include you in the future if you are interested – what would we need in order to recruit? And approximate interest from these participants? - **<u>Purpose of this workshop</u>** is to generate concrete suggestions using post-its AND fruitful and concrete suggestions and feedback during discussions that we can use to design this ideal situation *(above)* - **<u>Explain the landscape poster:</u>** This is what was produced during the patient session, i.e the yellow post-its on the boards. We will be doing the same thing in this session. Please keep in mind that our aim is to cover this whole landscape today together
<u>A:</u> Common understanding of how to conduct one's self during the workshop **<u>P:</u> Establishing a safe and comfortable environment for <u>ALL</u> participants to share own ideas and receive others' ideas**	Basic workshop rules plus clinician session-specific rules	Refer to poster on wall that says **"YOUR ROLE, YOUR NEEDS"** - Everyone's opinions are valid - We ask that you only focus on YOUR ROLE and YOUR NEEDS as a patient/clinician – try not to assume what the other patient/clinician believes or is trying to do, this is why we invited both - Everyone should feel comfortable and not judged: - everyone wears different hats, experiences situations differently and we need to respect their opinions but feel free to ask clarifying questions or respectfully disagree - Enthusiasm is great but gentle reminders will be given if we get off track - Sessions will be tape recorded but it can be turned off upon request - Everything in the room will be confidential – no names please - No identifiable information will be recorded

		- Honest feedback is best to improve research and the system – no need to "save face" - No treatment advice will be discussed during this session **Clinician session specific rules** - During this session, feel free to speak about your perceptions of patients, but during discussions with patients, we ask that you only focus on YOUR ROLE and YOUR NEEDS ○ E.g. of acceptable phrasing: "ideally it would be good to get X amount of information from the patient"- objective and general in comments - Suggest functionalities that might be used in a good way – do not focus on barriers, focus on what you need and how you would do it regardless of how much time it takes because the technology is intended to help this
A: Baseline of how clinicians conduct their consultations and interact with patients **P: Same as previous**	1. How do you start the consultation? (as separate Post-it sessions?) 2. What do you cover in a typical consultation? **Discussion:** What information (either from memory, written or apps) that a patient presents does and does not have an impact on decision-making? Examples please. **Discussion:** How can patients' use of mHealth and patient-gathered data be beneficial in the consultation?	***Practical notes:*** *Green post-its to write or draw on in response to each question (1-2minutes per question)-* ***1 verb and 1 noun*** - **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun.** - **Place responses** on white board or wall under heading **"Klinisk praksis"**
A: When clinicians believe shared decision making is appropriate. **P: Brainstorm situations in which the Full Flow might be more useful for GPs and T2Ds**	3. **When** would data-sharing be useful or appropriate, i.e. in which situations? **Discussion:** Have your patients ever brought you data on or from an mHealth app? Do you trust it, what are Benefits? Challenges? Opportunities? *(don't want written for patients to see)*	***Practical notes:*** *Green post-its to write or draw on in response to each question (1-2minutes per question)-* ***1 verb and 1 noun*** - **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun.** Your responses can be theoretical or reality that they have experienced. - **Place responses** on white board or wall under heading **"Clinisk praktis"** - **Follow-up questions & examples to use if conversation stalls** ○ If patients have questions, if you gave them a specific task?

(Stop audio recorders) Break (12:55-13:00)		

(start audio recorder) Joint Session (13:00-15:00)		
<u>A:</u> Common understanding of how to conduct one's self during the workshop **<u>P:</u> Establishing a safe and comfortable environment for <u>ALL</u> participants, establishing that all input is equal and valued**	Ice breaker activity: Year of the Coin	Different coins with different years than the morning session - Something that happened in your life during this year
	Reiterate workshop rules	Refer to poster on wall that says **"YOUR ROLE, YOUR NEEDS"** - Everyone's opinions are valid - We ask that you only focus on YOUR ROLE and YOUR NEEDS as a patient/clinician – try not to assume what the other patient/clinician believes or is trying to do, this is why we invited both - Everyone should feel comfortable and not judged: - everyone wears different hats, experiences situations differently and we need to respect their opinions but feel free to ask clarifying questions or respectfully disagree - Enthusiasm is great but gentle reminders will be given if we get off track - Sessions will be tape recorded but it can be turned off upon request - Everything in the room will be confidential – no names please - No identifiable information will be recorded - Honest feedback is best to improve research and the system – no need to "save face" - No treatment advice will be discussed during this session

<u>A:</u> Presentation and common understanding of the "resources", i.e. common tools and ideas, that we can use or refer to during the discussion.
 	
<u>P:</u> Ensure that ALL participants are aware of what we have to work with and each other's ideas. Activity will limit group think and allowing all to contribute even if they are not comfortable being vocal.
	Present where we are in the landscape:	- **<u>Introductions to the joint session:</u>** This is what we have produced together so far today and we can use these during the discussion if they are useful
		  ○ - The morning session produced these – briefly review
		  ○ - the lunch session produced these- briefly review
		- **<u>The overall goal is:</u>** to discuss together, how to meet both of your needs that you have brainstormed during your separate sessions, to be used during the consultation. We want to produce concrete suggestions on post-its AND fruitful and concrete suggestions and feedback during discussions
		- Allow time to ask questions and discuss or clarify these before beginning the activity

	Participant review of the landscape themselves	- **<u>Instructions:</u>** now we should take a few minutes to all of us go up and physically look at what we have produced together – both your own and the other part. Please tell us what you agree with (endorse the idea) by placing a *check mark* (or red page marker) on the post-its that you truly agree with and you think should be highlighted in the coming discussion Each get 3 pieces to place out.
	Break (14:00-14:10)	

	Describe activity and then Present the Data Sharing Story Board	- **Instructions:** Our intention is to colour in this landscape by filling in the important components/aspects of the situation whereby we can all discuss and agree on what is important for data-sharing. Once each person has described "why or why not" during the post-it phase, then we can open up and ask "who had similar suggestions, any comments? Arguments?"
	Describe how the activity will be conducted	- Everyone should write down on post-its their ideas before presenting them out loud/discussing so that everyone has a chance to contribute and discuss. After discussion, the post-its are placed into the landscape - **Cotton Ball method:** each person gets 3 and "uses one up" each time they speak.
A: When/how/what mHealth data should be shared? **P: To establish a foundation for the discussion which will direct how and when the Full Flow system should be used, which will inform which functions are appropriate for each use case.**	1. **When** would it be appropriate to share self-gathered information and data during consultations between patients and clinicians? **(more than today)**	***Practical notes:*** *Respective post-its to write or draw on in response to each question (3minutes per question)-* ***1 verb and 1 noun*** - **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun.** Each person will be allowed to read theirs out loud and explain their perception. **Please** be prepared to say why or why not they wrote that on the post-it during the discussion - **Discussion & Cotton ball exercise:** o the point of this exercise is to allow everyone a chance to speak and then we can open it up once all cotton balls are used up or everyone speaks that wants to. o is anyone willing to say why or why not there is an appropriate time to share self-gathered info/data? o Does anyone have any additions or comments to this? - **Follow-up: (**Once cotton balls are all used) o E.g. to use if silence: When the patient has specific questions? o When there is sufficient data? o During the planning phase during diagnosis and then agreed upon thereafter for specific changes in self-management? o Why is the suggestion effective? - **Place responses** on white board or wall under heading **"When" under "Møte"**, once the discussion has come to an end or we have reached the time limit then everyone should place their post-its.
	2. **What** self-gathered information and data would be useful to share during consultations? *(refer to examples that both brainstormed in separate sessions: suggestions for self-management were XYZ and suggestions for what clinicians*	***Practical notes:*** *Respective post-its to write or draw on in response to each question (3minutes per question)-* ***1 verb and 1 noun*** - **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun.** Each person will be allowed to read theirs out loud and explain their perception. **Please** be prepared to say why or why not they wrote that on the post-it during the discussion - **Discussion:** is anyone willing to say why or why not these data should be shared during the consultation?

	need to know for their clinical practice were ABC- MB can present some of these)	○ Does anyone have any additions or comments to this? - **Follow-up:** How much information should be shared? Very details or overview? → What should not be shared or it is not necessary to share during consultations?
	3. **How** can each of you use this information to a) either make a joint decision about self-management or treatment or b) make own decisions about how you will use this information in self-management or your clinical practice?	***Practical notes:*** *Respective post-its to write or draw on in response to each question (3minutes per question)-* ***1 verb and 1 noun*** - **Instructions:** mark each post-it as # to reference the question we are on and try to use only **1 verb and 1 noun.** Each person will be allowed to read theirs out loud and explain their perception. **Please** be prepared to say why or why not they wrote that on the post-it during the discussion - **Discussion:** is anyone willing to say why or why not these data should be shared during the consultation? b. Does anyone have any additions or comments to this? **Follow-up:**
	Refer back to main idea of the project: data sharing system Then ask participants: do you have any good ideas about how to visualize your data? - Draw on a blank paper	c. Now we have gone through what you need and what questions and purpose you have for the consultation. With these ideas in mind, we want to now figure out HOW a system should work and what pictures or graphs or information the system should have that visual triggers the discussion of what you need to know d. Present the wireframes of graphs and plots that they can draw on if they want AND graphics for inspiration e. One white sheet and one with some wire frames on it i. *MB and AG: print out several copies pictures and descriptions of these that they can draw on or pull out to refer to* Allow for some time to ask questions and clarify or give initial thoughts - **Prompt them to draw ideas:** Before we present our sketches and ideas, we want to give opportunity to brainstorm how to go about sharing data and how it should look ○ *Reinforce that it is okay if no one has any ideas, this is what the next activity is for*
	Briefly present the concept of the data sharing system in a bit more detail than previous sessions: *explain* Introduce research team's ideas for core components of the system and rough sketch: - Use all ideas provided to suggest	***Practical notes:*** *MB to put three scenarios, one for each situation on the landscape in the middle area (MB to print the scenarios – computer screens with headings)* - **Introduction of researcher ideas:** To be more concrete, here are some things that we have played with and discussed amongst ourselves (MB to put up wire frames and graphics etc. - **Explain the purpose of the system in more detail:** the stepwise treatment approach/the fact that the system should progress or evolve with the patient and disease, e.g. no data and just goals to graphs and calculations)

	good views/presentations.	f. **Present wireframe components ALONG WITH:** pictures AND their own graphs that they can now place in the scenarios.: o Wire frames o Goal setting and progress tracking o Presenting only the data that patient gathers and decides to share o Options for what data types are possible to collect during the study o Ability to ID trends and possible problem areas - **Three situations:** Imagine that this is implemented already- how should it look like when…. o Shortly after diagnosis o Learning to self-manage and understand disease o Today Describe that these are example scenarios to illustrate the progress of the system in different situations
A: How should: **1) the system look (i.e. level of detail and functionalities) at each individual stage of the disease and patient's self-management** **2) data be displayed** **3) the system facilitate follow-up from one consultation to the next (facilitate continued care)** **P: How the system can display information in a mutually understandable way that also facilitates continued and collaborative care**	i. 5.a. Consultation in the beginning of treatment/ shortly after diagnosis ii. 5.b. Consultation during your "learning period" – months or years into self-managing the disease	- **Instructions:** Now we will present the scenario from the two perspectives and give you some time to brainstorm, just as before, some notes and ideas about how this should look. Please write down or draw your ideas and then we will post them on the board and discuss together. - **Scenario 1 & 2 Consultation shortly after diagnosis and in the middle of disease management:** you first hear that you have diabetes and clinicians, you have given them information to review on their own. Imagine that you both have had previous meetings that go over some basic information and. Now, you are both back to continue planning treatment and discussing the future. - **Follow-up questions to patients:** Thinking back to the first months or years of your diagnosis. Knowing what you know now about self-managing, what works for you and support you need – o What should the system display as options for the consultation discussion – meaning you have gathered some data, how do you want to show it so that it makes sense for you? o what kinds of images and what should they include that could be helpful to you? o What other information should the system provide to help plan your treatment? E.g. goals for how to start self-management or data gathering options so that you can select where to start? - Allow participants to write down additional thoughts on post its, wireframes (either drawn on or not) before proceeding – *5 minutes to brainstorm* - **Follow-up questions to clinicians:** o what do you look for in the small/large amount of data that you have instructed your patients to gather? o What helps you determine the progress that your patients are making?

		○ What problems or indicators of challenges might you look for? - Allow participants to write down additional thoughts on post its, wireframes (either drawn on or not) before proceeding – *5 minutes to brainstorm* - Referring to the story board, have participants place the post-its on the board in the appropriate location – *3 minutes* - Ask if anyone would like to describe their placement of the ideas - Researcher can say aloud what seems to be important for the system from patients' and clinicians' via the post-it notes - Allow participants to discuss what is shown before moving to next situation – *15mins*
	Break (as needed)	
	iii. 5.c. Today's consultation	- **<u>Scenario 2 Today's consultation:</u>** Think of the last consultation that you had as an individual – you have been working with your diabetes for some time and have learned more about yourself and what helps you manage your health and how to interpret your data. And clinicians: you are now meeting with a patient who has had the disease for a while and has been collecting data. - **<u>Follow-up questions to patients:</u>** ○ what data did you bring? What questions did you have for your doctor? ○ If the system were there to display your data, what kinds of graphs or progress or activities would it show? What should the graphs indicate (e.g. highs and lows of BG, each individual registration or summaries of your data, calculations of X? (E.g. Single events, daily and weekly trends) ○ Describe how you would show this to your clinician? Where do you start? Does anything need to change? - **<u>Follow-up questions to clinicians:</u>** ○ If you were to use this system, ideally, how much data do you need to understand your patient's situation and suggest improvements or explanations? ○ What should the graphs or figures show – how much detail do you need and what kind of detail, e.g. averages, calculations, medication adherence, indicators of change in their habits/goals or health progress?) - Allow participants to write down additional thoughts on post its, wireframes (either drawn on or not) before proceeding – *5 minutes to brainstorm* - Referring to the story board, have participants place the post-its on the board in the appropriate location – *3 minutes* - Ask if anyone would like to describe their placement of the ideas

		- Researcher can say aloud what seems to be important for the system from patients' and clinicians' via the post-it notes Allow participants to discuss what is shown before moving to next situation – *15mins*
Summing up and closing remarks (15:00-15:15)		
A: Common understanding of what was covered, how research team will incorporate these ideas into the next stages and future steps of the project **P: Inform participants that their input was valued. Also that there are future opportunities to participate.**	Sum-up what we have all done together and our plans for future activities etc.	- Reiterate the purpose of the project and why this research is important - Researchers emphasize their thanks to all participants - Have a description ready for exactly how this will inform the study and how we will test it out during the Run-In period - Tell them that we will send out additional information for future study opportunities WITH summary and follow up questionnaire about their experience with the co-design and any other ideas they may have (2-3 weeks after) - Provide research team's contact information (visit cards)

[i] https://www.interaction-design.org/literature/article/learn-how-to-use-the-best-ideation-methods-worst-possible-idea

Additional File 2. Additional information and quotations extracted from the co-design workshop transcripts

We believe that context is of equal importance to design features when understanding how mHealth can impact end-users. The following additional information provides a foundation of understanding of priorities, experiences, challenges and wishes individuals with diabetes have for themselves and from their healthcare providers about diabetes care. In doing so, this information contextualizes and provides background for the input gathered about experiences, expectations, preferences and concerns about using patient-gathered data during diabetes consultations. This feedback helps us – as researchers, healthcare providers and health authorities – understand if and how mHealth technologies and sharing patient-gathered data can address these factors and facilitate a beneficial change for both end-users, i.e. patients and healthcare providers. The following additional quotations and description of the discussion (i.e. summary) are separated into the identified themes and sub-themes presented in the main manuscript. The codes provided are those that were identified in the original qualitative analysis.

Theme 1: Patients' and providers' need for more specific and detailed information in diabetes care

Table 1. Additional quotations, grouped by codes assigned during qualitative analysis, from participants with T2D about their diabetes self-management

Code	Summary	Quotation
Self-management aim	• Welling • Accept responsibility	*"Wholeness and well-being is the focus. The goal is well-being" (T2D_P2)* *"Pretty much it is ourselves that need to find out about things" (T2D_P1)*
Self-management habits	• Focus on diet, exercise • Diabetes-specific info sources	*"Diet and physical training or exercise – at least at my age exercise is the most important in addition to diet. The goal is to stay as low [blood glucose] as possible, maybe satisfy the doctor's wish" (T2D_P3)* *"I use internet and read about diabetes. Every time I eat something new, I can search it up. See how the specific food is built and contains, and if there are any objections about it" (T2D_P3)*
Motivation	• Symptoms as external motivators • Peer support	*"Abnormal warm and sweating and thirsty, then I measure blood glucose extra, to see my value. If I am tired, I also measure, and normally have low blood glucose. Have to add sugar of some sort, juice is the best. The excuse being you can eat chocolate if you want. I use my feelings, then measure, then take action" (T2D_P3)* *"I am in a work out group circle, once a week….If not for that I would give up the diabetes battle, considering I feel like go to the doctor every week and get feedback about blood sugar. It always varies. So basically you rely more on physiology than on your own ability to control it" (T2D_P3)*
Challenges	Diabetes-specific info sources	*"I try to read online magazines, but there are so many articles contradicting each other" (T2D_P4)*

Table 2. Additional quotations, grouped by codes assigned during qualitative analysis, from participants with T1D or T2D about their experiences with diabetes healthcare providers

Group	Code	Summary	Quotation
Participants with T1D	Frustrations with healthcare services	• Experienced less support than had hoped for • Unsure about whether to contact HCP or not	*"I suppose I can call my diabetes nurse but she has never called the healthcare service in the 30 years I have had diabetes to solve a situation today. I have called the diabetes line a few times but they are too far away the specific situation, so they tell me to go further to someone else and then you get answer after a day or two, but that is not when I am in the situation. So being able to solve the situation that you are in… I don't want to disturb doctors and nurses with my small problems. But they are maybe not so small if we… acknowledge what they really are" (T1D_P3)*
Participants with T2D	Positive experience with healthcare services	• Rely on healthcare providers to tell them the status of their health • Experience discussion with GP about patient-gathered data	*"I go to yearly controls and take many blood tests. If I don't hear anything, I assume everything is fine" (T2D_P2)* *"My GP helps with control and coping and looks through the Diabetes Diary [app] on my phone…and then we start discussing" (T2D_P1)*
	Frustrations with healthcare services	• Experienced lack of training/ support/ knowledge • Experienced little use of healthcare services • Limited contact with HCPs	*"The experience I have with the doctor's office is that GP usually is not there, so always a substitute, which it has been the last three years….I feel like my general practitioner doctor that they really lack the knowledge in which we diabetics struggle with. Patients are just a case, do not have enough education to cope with that part of public health" (T2D_P2)* *"After I was diagnosed with diabetes, I haven't gotten any advice… I got an appointment at a nurse. I got a note on how to react on insulin and increase doses eventually. [I was trained] to use the syringe. And three months after to check, and then he was satisfied with HbA1c. After that, I haven't talked to anyone about diabetes at all, regarding healthcare professionals" (T2D_P2)*
	Wishes for healthcare services	Desire more guidance	*"I have little contact with healthcare professionals in relation to diabetes. I was diagnosed three years ago. Was two-three times at my GP. After that, I have felt like I had enough control myself for it not being a necessity. But now I feel like I can use some more contact and input. So a question being if an app which gave more feedback rather than just the average numbers, would be a possibility" (T2D_P3)*
	Understanding of healthcare services	Understand HCP's needs and limitations	*"I don't think GPs have the time it requires to get familiar with it…. It's not so easy you know; the GP have 1000-2000 patients" (T2D_P3)*

Table 3. Additional quotations, grouped by codes assigned during qualitative analysis, from healthcare providers' experiences with patients with diabetes

Group	Code	Summary	Quotations
Specialists	mHealth (positive)	• Positive toward mHealth • mHealth can be easy to relate to • Experience mostly with medical devices (CGMs) • Use of mHealth with EHR systems	*"We are very positive about [mHealth and diabetes care], because we have been in the field for a long time. And we see that it's a revolution. It's fantastic. The fall of late complications in enormous" (Specialist1)* *"Some of it is very easy - in using the DIPS journal system or NOKLUS [the national diabetes registry]. Ideally when a patient comes to me, I can automatically - by Bluetooth or something - get the continuous*

			glucose values for the last week into my electronic diabetes journal system, with insulin taken and glucose measured, so I could have it on the screen and then I could have a look at it" (Specialist1)
	mHealth (negative)	• mHealth is a challenge to clinical practice capacity • HCPs do not have time to learn the new technologies	*"In our business where we are only measured after how many patients we see every day. So if we go to meetings and learning things to learn to use technology it's on the minus side because we do not see patients" (Specialist1)*
	mHealth (neutral)	• Learning about mHealth: literature • Experience with mHealth as learning strategy • Prefer learning by experience than by industry "sales pitches"	*"When we are talking about new technology, it's mainly based on CGM. Because that's the new technology the past 10 years" (Specialist 1)* *"[Instead], we generally read scientific literature…and experience from all of my diabetes nurses and sort of accumulating clinical experience from the use of these devices… which means we see the problems much better than getting the industry coming into the door and telling about "look at the new device" (Specialist1)*
	Priorities of clinical practice	• Coordinate resources • Achieve the greatest good for the most people • Provide support for those who need it	*"CGM is very costly, not only to buy it for... but also costly because it uses all of the time resources for our diabetes nurses" (Specialist1)* *"As to resources and as to budget costs, it is much more helpful or much more saving money and saving pain for people to bring these people here with HbA1c of 10% down to HbA1c of 8%. That is really an advantage for everybody" (Specialist2)*
	Perception of patients	• Perception of patients' concerns and motivations • Patients' locus of control in diabetes • Some do not communicate all symptoms to avoid being hospitalized	*"Of course we want that to be more around 7% but many patients don't want to go that low because they fear hypoglycaemia and they think it would cost too much work and they don't understand why they should be lower, because they think the late complications are far away" (Specialist2)* *"I think the main responsibility is what [Specialist 2] says, is to make them communicate with us because that's a big problem. That patients don't want to come and communicate with us and they find it bothersome so they go to their general practitioner and get an insulin prescription once a year [to avoid hospital admissions]" (Specialist1)* *"This is in general about health and psychology like locus of control -. Is the locus of control of my health within in myself or am I just behaving healthy because you and you and you tell me to – that's a general problem that is exaggerated in diabetes" (Specialist1)*
GPs	Experience during diabetes consultations	Typical consultation experience with someone with T2D	*"Many diabetes controlled are mixed with a lot of other things and I feel that can be confusing because high blood pressure, maybe overweight, maybe low back pain, maybe a lot of other things. I measure the blood pressure, I listen to the heart and lungs, we talk, if they have any problems with the medic since diabetes medicines often has side effects, so we discuss that" (GP3)*
	mHealth (positive)	mHealth technologies as motivation	*"When I think of some of my patients, [I see that] they are so fed up with diabetes" (GP3) [and mHealth could help with motivation]*

Theme 2: mHealth technologies' impacts on patients and providers

Subtheme 2A: Purposes of, and challenges related to, mHealth and patient-gathered data

Table 4. Additional quotations, grouped by code, from participants' experience with mHealth and/or patient-gathered data

Group	Code	Summary	Quotations
Participants with T1D	Experience with mHealth data	• Use of mHealth helps with/ motivates self-management • Use of multiple devices • Reliance on app for self-management • Apps allow one to reflect on previous self-management experiences	*"Data collection gives you experience…if you track the data" (T1D_P3)'* *"When I have it on my phone it is easier to plot insulin and have data on a specific time, amount insulin, blood glucose, and maybe food, if I bothered to" (T1D_P4)* *"I registered them in Diabetes Diary app, but there I also note the physical activity. I tried registering in the new version my medicine, but I gave up because I had to keep up 13 different tables every day. …also I use, and another app [step counter] from Samsung where it was nagging that I am not physical active enough in day time…. If you try to be independent of your mobile phone, you won't be able to follow anything. (T2D_P3).* *"[I collect] a lot of blood glucose measures…too much…I only measure in the morning to see the value [which] affects how I respond", he reflected on longer-term effects like "the results for stress level, drinks and such" (T2D_P1).*
	Desires for mHealth	• Change: additional interoperability • Future use: collecting data to present to HCP	*"To start, I would want that my measurements and phone should talk together….if I don't bother [to collect data consistently] it would be nice for a period – a week- before I have a consultation. Blood glucose for several months is available but food and insulin I take for a set period can be gathered. I don't picture me register all of insulin and all food I eat, but for a period would be nice." (T1D_P4)*
Specialists	Perceptions of mHealth	• Patients do not want data-overload • Automatic data-gathering is necessary	*"So you need to automate things because patients cant bother or are not happy about using all of these data" (Specialist1)*
	Perceptions of patients and mHealth	• Who uses mHealth • CGMs perceived as mHealth • Patients gather a lot of data but do not always reflect on it	*"I think some of them are younger or older, the people in the middle don't have time for all of this. Because they are early in their careers and they make a family and they have children so they have got time for all of this and then if they the CGM people –they can come with all sorts of data because its automatic but they haven't made a diary or sort of explained why was it like this, why did I get a hypoglycemia" (Specialist1)*
Participants with T2D	Use of mHealth in consultations	• How mHealth could change diabetes consultations • Expectations of GPs related to mHealth	*"It ends up with the doctor often being a conversationalist. Of course they want to help you but I experience that they don't have time" (T2D_P2).* When asked by the researcher facilitating the discussion if they thought sharing their patient-gathered data would change this, the participant responded, *"I don't know, could have compared data, and told me what I should do. As you say, maybe not the GP should be the one, but a different healthcare professional. Maybe expect too much from the GP" (T2D_P2)*

GPs	Experience with patient-gathered data in clinical practice	• Reliance on data from patients for information • Observation of which data-types patients collect/bring • Reliability is important	*"If they bring their books, and they're clever sometimes they just test three days before and then stop testing for half a year, and then come back with three lost test days. Some are testing every day, four times a day…Some have blood pressure machine at home, then they show me…. I rely on my patients [for information]" (GP3)* *"Glucose meter yes. Usually bring it yes. And the books, usually blood sugar values, some people bring blood pressure tests" (GP1)* *"If they have some information that we can rely on, a book, writing their values, few of them is quite clear to remember. If they have reliable information, we use that more than medical history because things happen on the way" (GP1)*

Theme 3: Data-sharing system

Subtheme 3A: Expectations of sharing and receiving PGD during consultations

Table 5. Additional quotations, grouped by code, from participants' about their experiences and expectations about sharing and receiving patient-gathered data during diabetes consultations

Group	Code	Summary	Quotations
Participants with T1D	Experience using mHealth with HCPs	• HCPs understand patients' situation • Positive experience discussing mHealth data with HCP	*"I have good help in my diabetes nurse because I can talk with him [about own-gathered data]… because it's no one else I can talk to who understands" (T1D_P4)*
	Expectations for sharing patient-gathered data	• More support • Wish for HCP to see data during consultations	*"I wish that [HCPs] could see it when I'm at checkups….maybe [HCPs] can help me more if they see that there's a reoccurring problem…if I'm high during the evening...we can try to talk more specifically" (T1D_P4)*
Specialists	Negative consequences of mHealth	Consequences if patient is not prepared to explain own-gathered data	*"[The doctor] is going to be the person who is solving all the patient's problems" (Specialist2)* *If the patient has not reviewed or attempted to understand their own-gathered data before sharing it with the doctor, "then it's useless" (Specialsit2)*
	Recommending medical devices	• Technology not appropriate for everyone • Support technology use for specific groups of patients	*"For some individuals, I put a [continuous glucose monitor] on them and say "you are supposed to use it" while others, I keep it away from them" (Specialist2)* *"We also have a lot of compliant patients who try their best. So those in the group below or around 7% are compliant and they meet for consultations and want the new insulins and they want the new technologies – so that is no problem" (Specialsit2)*
Participants with T2D	Expectations for sharing patient-gathered data	Better communication	*"Better communication about your situation if you have your data and can evaluate from it…. As I see the GP, you go to them when you have a specific problem. If you have control with diabetes, it is not a specific problem" (T2D_P2)*

GPs	Expectations of receiving patient-gathered data	• GPs should not have to use new technology if patient comes prepared	*"If you need the GP to go to seminars to learn about it they will do it- they may not necessarily download it….If the patient comes with [PGD] and it is easy to understand" (GP2)*
	Expectations of discussing patient-gathered data	• Patient-gathered data could help streamline discussion • Patient-gathered data could provide more specifics and evidence of patients' self-management	*"The discussion with the patient could at least be more to the point. Now we ask "Have you been exercising lately?", and they say "Yes, I have been every day", and then "Okay". Instead – "I see you have not been exercising every day or at all last week". So we could discuss it, and more specific" (HCP_GP2)*

Subtheme 3B: What data to share and how to display it, and when

Table 5. Additional quotations stated while participants presented their own paper prototypes, grouped by code, about what data to share, how to share it and when to share it

Group	Code	Summary	Quotations
Participants with T1D	How to share data	• Wish for HCPs to have access to patient-gathered data • Possibility of remote data-sharing • Preference to remotely conduct consultations when symptoms/ challenges happen	*"This is what I want and what I want my doctor to get access to, or nurse…. At least that my doctor to have easy access to my blood glucose. And I want him to get HbA1c and possible to see activity. Insulin at night if I bothered to" (T1D_P4)* *"If I could say that now I'm struggling with something, and question if you [the HCP] could connect up and see the data…easier than booking an appointment" (T1D_P2)*
	When to share data	• Prefer remote transfer of data • Prefer to be able to share data when it is needed, outside of consultations • Remote transfer of data outside of a consultation could allow HCPs to review it when they have time	*"Or I upload my data in my program and share with my nurse and then I get the question "Can you note this week what you put of insulin in the given period and then I get the data from you." And then I don't really have to meet up on this…and [I still] get specific answers on it, because then I feel I save a lot of time [for both myself and the nurse]. She can do it when she has the time for it…That is my dream situation" (T1D_P3)*
Specialists	What data to present	• Specific information patients should provide: insulin doses • Data should be accurate • Clinical changes depend on accurate data	*"They should know how much insulin they have taken per day, the last week at least or the last month and not give only an approximation because in case we are going to give them any advice on how they will change their medication we need to know what they actually have been taking" (Specialist2)*
	Patients' responsibilities	• Patient must collect data • Patient must be proactive/ prepare to present data • Sharing data can lead to better communication • Patient engagement can lead to better communication	*"You have the patient already before the consultation – trusting in her responsibility and her interest in doing better. Kind of her personal responsibility for it. As opposed to if a patient comes and has not gathered any data at all and the HbA1c was measured three months ago, and you don't know how much insulin the patient uses and so on. So it will be a proactive attitude from the patient wants to better the communication and make the whole situation better. Both for patient and doctor" (Specialist1)*

	Concern: lack of communication	• Patients afraid to communicate – fear losing "privileges" • Communication is needed if provider is to offer guidance	*"In Denmark, there is this one study that has shown that after these rules [about how many instances of hypoglycaemias means a person is unfit to drive] were implemented then the patients with diabetes type 1 do not report their actual hypoglycaemias because they are afraid to lose their driving licence…it's a problem of communication and openness and frankness between the patient and the doctor… I [would] not be able to give him any advice" (Specialist2)*
Participants with T2D	When to share data	• Preference to send data to GP prior to consultation • Pre-sharing data could be more efficient	"Data already be shown for the doctor before a consultation, so we have a baseline….To not waste time" (T2D_P1)
	How to use a data-sharing system	• Use of the system changes based on diabetes duration • Assume HCPs do not want to store patient-gathered data • Information also about what data to present and how to present it	"I have set up these symbols, because you got to have something. When you get diagnosed with diabetes, [have to know] what you have to be aware of, and so [that information] is there about what you can do. Eventually get graphs and register schemas in and things. We have talked about the possibility of getting a compressed report that we could take to the doctor, since they don't want any files" (T2D_P3)
Exchange between participant with T2D and GP	What to share	Participants clarifying assumptions about one another	Participant with T2D: *"Everything regarding medicines should be in doctor journal, so don't think it's important, it is self-measurements and blood glucose and physical activity and diet and what affects the blood glucose" (T2D_P1)* GP: *"About medicine, we see in journal what we think you are taking, but we won't know it is correct." (GP1)*
GPs	Integrating data-sharing system into clinical practice	• Thought process about how to relate to data-sharing system • Present data and discussion according to patient's duration of diabetes (time since diagnosis) • Alternative information sources when first diagnosed • Must consider time restrictions when discussing patient-gathered data	*"I drew it as if the paper prototype] was my computer at my office, because I think I would like this to be pretty easy in the start. Explain the high blood glucose, where are the limits, health consequences. The day you get diagnosed I think you blank out, and you don't really know anything. So I would [present the data] very simply, and I would give them the website to Diabetes Association, where there is a lot information. And if [a patient] came to me and I have 20 minutes, [we would] look at blood glucose. I don't have time to inform about [patients] about everything, so they have to look into it themselves. [We could] talk about physical activity, a bit on diet, what is good and not good. But don't start with the apps or something at once – [do it] step by step. I would try to make it simple. [I would schedule] a new appointment pretty soon again – about 3 weeks. Then [we could] get into it a bit more and give it more thought" (GP1)*
	Design of data-sharing system	• Needs to be simple • Synchronising data-exchange would be helpful • Ability to use data-sharing system on patients' own computer	*"[I drew a] simple front page. [Maybe have] a synchronization with an app to phone and patient's own computer. Same possibility for both. Simple front page, maybe a bit more thorough here. For example have an exercise diary with possibility to save data" (GP3)*
	What data to share	Wellbeing	*"Wellbeing factor – yes useful…you get a greater understanding of the changes [of the other data types]" (GP2)*
	How to share data	Patient must be present to share data	*"Without the patients, it is not useful. The patients should be there to use it for discussion and planning…knowing what's going on" (GP2)*

	When to share data	Do not want patients to share data prior to consultation	*"I DO NOT want [PGD] in advance [of the consultation]" (GP3)*

Paper 2

Review

Methods and Measures Used to Evaluate Patient-Operated Mobile Health Interventions: Scoping Literature Review

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Abstract

Background: Despite the prevalence of mobile health (mHealth) technologies and observations of their impacts on patients' health, there is still no consensus on how best to evaluate these tools for patient self-management of chronic conditions. Researchers currently do not have guidelines on which qualitative or quantitative factors to measure or how to gather these reliable data.

Objective: This study aimed to document the methods and both qualitative and quantitative measures used to assess mHealth apps and systems intended for use by patients for the self-management of chronic noncommunicable diseases.

Methods: A scoping review was performed, and PubMed, MEDLINE, Google Scholar, and ProQuest Research Library were searched for literature published in English between January 1, 2015, and January 18, 2019. Search terms included combinations of the description of the intention of the intervention (eg, self-efficacy and self-management) and description of the intervention platform (eg, mobile app and sensor). Article selection was based on whether the intervention described a patient with a chronic noncommunicable disease as the primary user of a tool or system that would always be available for self-management. The extracted data included study design, health conditions, participants, intervention type (app or system), methods used, and measured qualitative and quantitative data.

Results: A total of 31 studies met the eligibility criteria. Studies were classified as either those that evaluated mHealth apps (ie, single devices; n=15) or mHealth systems (ie, more than one tool; n=17), and one study evaluated both apps and systems. App interventions mainly targeted mental health conditions (including Post-Traumatic Stress Disorder), followed by diabetes and cardiovascular and heart diseases; among the 17 studies that described mHealth systems, most involved patients diagnosed with cardiovascular and heart disease, followed by diabetes, respiratory disease, mental health conditions, cancer, and multiple illnesses. The most common evaluation method was collection of usage logs (n=21), followed by standardized questionnaires (n=18) and ad-hoc questionnaires (n=13). The most common measure was app interaction (n=19), followed by usability/feasibility (n=17) and patient-reported health data via the app (n=15).

Conclusions: This review demonstrates that health intervention studies are taking advantage of the additional resources that mHealth technologies provide. As mHealth technologies become more prevalent, the call for evidence includes the impacts on patients' self-efficacy and engagement, in addition to traditional measures. However, considering the unstructured data forms, diverse use, and various platforms of mHealth, it can be challenging to select the right methods and measures to evaluate mHealth

technologies. The inclusion of app usage logs, patient-involved methods, and other approaches to determine the impact of mHealth is an important step forward in health intervention research. We hope that this overview will become a catalogue of the possible ways in which mHealth has been and can be integrated into research practice.

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KEYWORDS

mobile health; apps; self-management; chronic disease; noncommunicable diseases; interventions; patient-centered approach; patient-operated intervention

Introduction

Need for Mobile Health Evaluation

Health research is yet to agree upon a framework for evaluating mobile health (mHealth) interventions. This is especially true for tools, such as apps and wearables, that are intended primarily to aid patients in health self-management. Traditionally, the evaluation of mobile medical devices has been based on clinical evidence, and it can take years to bring these devices to the market. The continuous glucose monitor first came onto the market in 1999, but it was not until 2006 that the next version was available [1]. Similarly, the pulse oximeter struggled for decades to become a standard mobile tool for measuring blood oxygenation [2]. Because there are increasingly easy-to-use patient-operated mHealth technologies available on the market, patients are no longer willing to wait for a lengthy evaluation process. Instead, patients often use apps without assurance of quality or guidance from their health care providers [3].

Always-Available Self-Management Technologies

Individuals are more empowered to take greater responsibility for their health, and currently, they enthusiastically seek out mHealth apps and other devices for self-management. For chronic conditions in particular, health challenges occur continuously, not just when it is convenient or at a doctor's office. Technologies for self-management must allow individuals to register and review the measurements that they input into the app or system at any time. Connectivity to devices, such as medical or commercial sensors and wearables, adds to the utility of an app. A report by Research2Guidance [4], an organization that provides market research on digital health, emphasized the central role of patient-operated mHealth apps in the "connectivity landscape" of electronic health technologies [5]. However, their diverse functionalities and intended uses pose great challenges to researchers.

Challenges of mHealth Evaluation: Single Apps Versus Multiplatform Interventions

The amount of assessment and testing that is necessary for health technology is directly related to its potential risks and benefits [6,7]. For example, medications based on patient-gathered health data are associated with higher health risks than those in patients with type 2 diabetes who seek motivation from an activity tracker for weight management. Although multiplatform (ie, system) interventions serve to increase the benefits (eg, automatic and less burdensome operations), they increase the risks related to data safety, integrity, and reliability [8,9]. Researchers must adapt their approaches, methods, and measures for patient self-management interventions involving single mHealth apps and those involving multiplatform systems.

Evaluation Framework: Coverage

There are two main categories of mobile medical or mHealth devices associated with the amount of oversight health authorities will show; those that are "actively regulated" and those that fall under "enforcement discretion." These categories are described in the 2015 Guidance for Industry and Food and Drug Administration Staff [10] and are echoed in the updated 2019 Guidance [11] and included in the terms of The European Economic Area Certification (CE) Mark [12]. Devices that are actively regulated are required to undergo an evaluation and meet security and effectiveness standards for use in health care. On the other hand, many patient-operated technologies fall under "enforcement discretion," and they pose less risk to patient safety and health. For individuals aiming to assess the usefulness or safety of these technologies, there are no evaluation frameworks or guidelines to follow. The year 2015 marked a relevant change in the mHealth arena, which we are still exploring today (connectivity between different device types, development on different platforms, and marked focus on mHealth integration into clinical practice) [13].

Although there have been many strategies [14-17] for the evaluation of this subset of mHealth (eg, National Institute for Health and Care Excellence [18]), there is no agreement about which qualitative or quantitative measures should be addressed or how they should be evaluated [19]. Evaluation frameworks, such as the World Health Organization (WHO) mHealth evidence reporting and assessment (mERA) checklist [20], suggest that traditional health research measures and methods are not sufficient. For assessing the comprehensive impacts of such patient-operated mHealth approaches, research needs to look into additional factors. This can be achieved by producing evidence that is relevant for both patients and clinicians.

Additional Factors for mHealth Evaluation

Although clinical evidence is essential for the evaluation of any health aid, the two major concepts of time and human behavior must also be addressed in mHealth evaluation. As "always available" technologies are being used continuously and uniquely by patients, it is uncertain how much time is needed to produce an effect and what changes in self-management behavior will occur. Traditionally, medical devices rely on established biological knowledge, have fewer alternatives in the market, and do not offer frequent updates. However, patient-operated mHealth approaches require the consideration of patients' motivation, health beliefs, and resources for self-management. They must also compete with hundreds of

other mHealth apps and devices that are continuously developed and updated. In recent years, clinical research has attempted to keep pace with mHealth by employing methods that aim to expedite the research process and produce more tailored knowledge for the field of mHealth [21].

Stakeholders associated with chronic health and care (researchers, individuals, health care providers, and health care authorities) have been calling for evidence related to the personal use of mHealth technologies for many years [22-24]. Regardless of the beneficial or harmful outcomes, we need to know their potential. Without such evidence, people in the health care field will not be able to effectively support and guide individuals in the use of these technologies for health self-management. This evidence must be obtained with appropriate questions and methods.

Recent scoping reviews of mHealth technologies for chronic conditions focused on evidence as it relates to a specific age group [25], the development process [26], or clinical outcomes [27] and not on how the research was performed or which resources were used in the evaluation. The purpose of this scoping review was to identify which methods were used and which qualitative and quantitative data were measured to assess patient-operated mHealth devices for the self-management of chronic noncommunicable diseases (NCDs). As evidence for health authorities and health care providers, quantitative clinical outcomes have historically been considered the primary target for evaluation [28]; however, given the growing trend of mHealth, we included qualitative measures of participants' use of and experiences with the technology.

Research Questions

The research questions were as follows: (1) What methods are used to evaluate patient-operated mHealth apps and systems for self-management of chronic NCDs? (2) Which qualitative and quantitative measures are used to evaluate the impact of patient-operated mHealth apps and systems for self-management of chronic NCDs?

Methods

Scoping Review Objective

We performed a scoping review to document how researchers have evaluated mHealth interventions for self-management of chronic NCDs. Munn et al [29] stated that scoping reviews are favored over other review types in cases in which researchers are using an evolving set of methods owing to the novelty of the field or where the purpose of the review is to inform future questions about the field. We intended to provide an overview of what methods researchers use and which qualitative and quantitative measures were adopted to evaluate mHealth self-management interventions. This review reports information according to the Preferred Reporting Items for Systematic review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist (Multimedia Appendix 1).

Search Strategy and Databases

The scope of the search and definitions of mHealth were discussed among the coauthors (MB, EG, EÅ, and MJ). The databases searched for scientific literature were PubMed, MEDLINE, Google Scholar, and ProQuest Research Library. PubMed and MEDLINE were both included because PubMed includes citations that are not yet indexed in MEDLINE [30]. We searched for articles published in English between January 1, 2015, and January 18, 2019, which were related to the evaluation of patient-operated mHealth interventions for self-management of chronic NCDs. The search string included key terms describing the intervention's intended use (ie, self-efficacy, self-assessment, self-management, or self-monitoring) and the intervention's platform (ie, mobile phones, wearables, sensors, or apps). The full search string was used for titles and abstracts, and the format was adapted to the database being searched (Multimedia Appendix 2).

Medical Subject Headings (MeSH) terms were not considered because our search included articles published recently, which may contain terminology that has not yet been indexed within the MeSH database. The identified abstracts and titles were collected in EndNote [31] and then uploaded into Rayyan [32], an online "library systematic review service" that allows researchers to collaborate on the organization, inclusion, and exclusion of articles for literature review.

Eligibility Criteria

We aimed to include research efforts that may have addressed new guidelines for mobile medical devices. Within our broad search criteria for low-risk mHealth apps and systems, articles were eligible for inclusion if they described low-risk technologies consistent with the FDA and CE Markings' description of mobile medical devices under "enforcement discretion" [10-12]. Multimedia Appendix 3 describes the specificities of this subcategory.

A preliminary search was performed, and a random selection of 10 articles was reviewed for inclusion or exclusion by two authors (MB and EG). Refinements were made to the review criteria.

For this review, we included studies that evaluated interventions involving (1) mHealth technologies for chronic NCDs, including the primary NCDs listed by the WHO [33] (ie, diabetes, cancer, cardiovascular diseases, chronic respiratory diseases, and chronic mental health conditions); (2) mHealth technologies for self-management (tasks which a person must perform in order to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic condition, and efficacious self-management was considered to encompass the ability to monitor one's condition and to affect the cognitive, behavioral, and emotional responses necessary to maintain a satisfactory quality of life) [34]; and (3) mHealth technologies that allow the patient to choose which measures to register and review.

The details of the inclusion and exclusion criteria are described in Multimedia Appendix 4, and they were used during the main review search.

Data Extraction and Synthesis

After removing duplicate articles, reviews, and protocol articles without evaluation results, two authors (MB and PJ)

independently screened the titles and abstracts for eligibility according to the inclusion and exclusion criteria. In case of disagreement regarding eligibility, another author (EG) was called to join the discussion until an agreement was reached. Author MB reviewed the full-text articles and performed data extraction.

The identified studies were classified as either those that evaluated mHealth apps or mHealth systems. Interventions that included a single app were grouped as mHealth apps, whereas those that included services or devices connected to a central app were grouped as mHealth systems. In this way, we could more clearly assess the different approaches taken by researchers when addressing the various impacts of these two mHealth intervention types.

Abilities of Studies to Produce Results

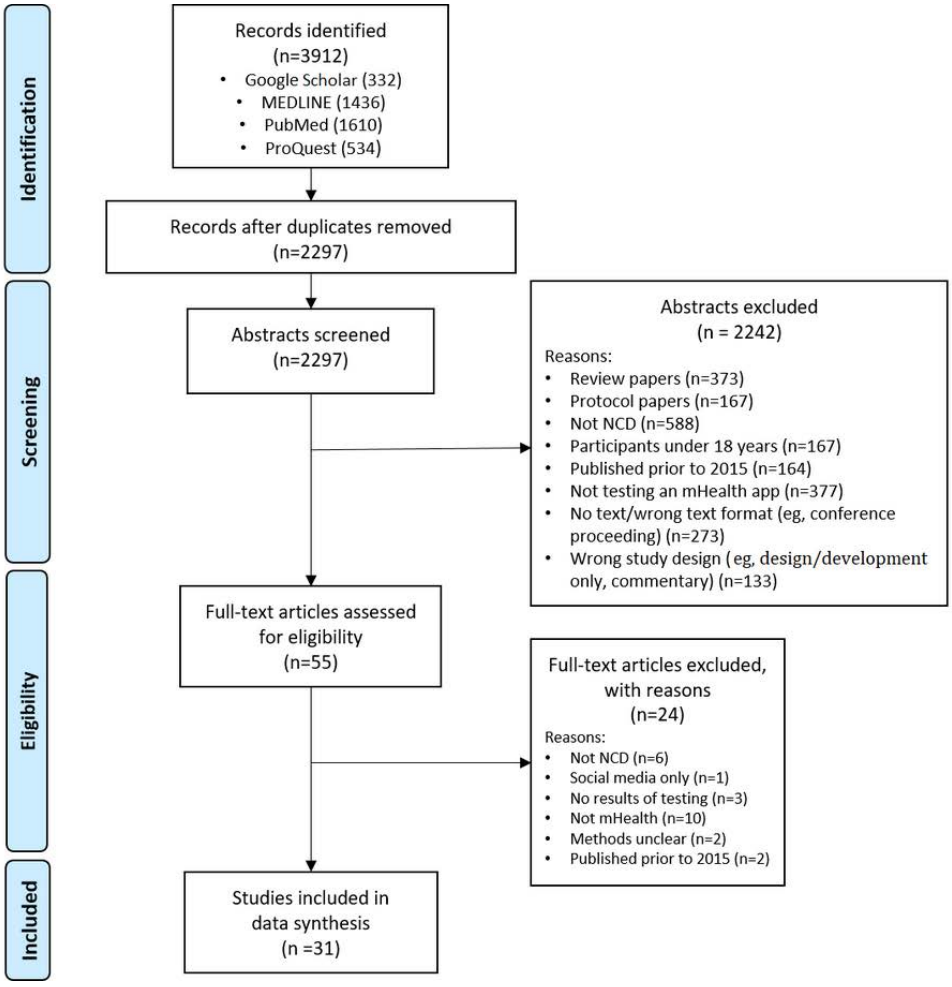
For both groups, one author (MB) assessed whether a study was able to produce the evidence that it aimed to obtain, using the selected methods. This was performed by comparing the objectives as stated by the authors of the identified articles to the methods and reported results. The studies were judged according to their ability to produce the information, and the findings were reported as yes, yes and more than expected, no, and cannot tell. The results of these comparisons are detailed in Multimedia Appendix 5.

Results

Overview

Among 3912 records identified by the search criteria, we reviewed 55 full-text articles and included 31 studies for data extraction and synthesis. Figure 1 illustrates the process of identifying the relevant articles for inclusion in data extraction.

Figure 1. Flow diagram illustrating the selection of studies for inclusion in data synthesis. NCD: noncommunicable disease.



Summary of Studies: Apps Versus Systems

Among the 31 studies chosen for data extraction, 15 were categorized as those that evaluated mHealth apps and 17 were categorized as those that evaluated mHealth systems. One study evaluated both apps and systems [35] and was therefore included in both categories. General information about the selected studies that evaluated mHealth apps are summarized in Table 1 [35-49] and those that evaluated mHealth systems are summarized in Table 2 [35,50-65].

Table 1. Information about the studies that evaluated mHealth apps.

Reference	App name	Year	Country	Study design	Duration	Health condition	Patient participants	Health care provider and caregiver participants	Intended secondary users
[36]	Diet and Activity Tracker (iDAT)	2015	Singapore	Prospective study	8 weeks	Type 2 diabetes	Patients (n=84)	N/A[a]	N/A
[37]	Diabetes Notepad	2015	Korea	Cross-sectional study	Single evaluation	Diabetes	Patients (n=90)	N/A	N/A
[38]	Personal Life-chart app	2015	Germany	Prospective study	72 weeks	Bipolar disorder	Patients (n=54)	N/A	N/A
[39]	HeartKeeper	2015	USA	Cross-sectional study	Single evaluation	Heart diseases	Patients (n=24) and researchers	N/A	N/A
[40]	HeartKeeper	2016	Spain	Retrospective study	36 weeks	Heart diseases	Patients (n=32)	N/A	N/A
[41]	PTSD Coach	2015	USA	Retrospective study	Duration of availability of the app on app stores	Post-traumatic stress disorder	Current users (n=156)	N/A	N/A
[42]	PTSD Coach	2015	USA	RCT[b]	16 weeks	Post-traumatic stress disorder	Patients (n=10)	Health care providers (n=3)	Health care providers
[43]	PTSD Coach	2016	USA	RCT	4 weeks	Post-traumatic stress disorder	Patients (n=49)	N/A	N/A
[44]	PTSD Coach	2017	USA	RCT	24 weeks	Post-traumatic stress disorder	Patients (n=120)	N/A	N/A
[45]	Hypertension management app (HMA)	2016	Korea	—[c]	Single event evaluation	Hypertension	Patients (n=38)	Nurses (n=3) and experts (n=5)	N/A
[35][d]	Multiple commercial apps for heart failure	2016	USA	Cross-sectional study	Single evaluation	Heart failure	Apps (n=34)	N/A	Family, friends, and health care providers (not all apps)
[46]	Multiple commercial apps (n=11)	2016	USA	Cross-sectional study	Single evaluation	Multiple	Patients (n=20)	Caregivers (n=9)	N/A
[47]	I-IMR intervention	2017	USA	Cross-sectional study	Single evaluation	Serious mental health conditions[e]	Patients (n=10)	N/A	N/A
[48]	Serenita	2017	Israel	Prospective study	16 weeks	Type 2 diabetes	Patients (n=7)	Health care providers	N/A
[49]	Sinasprite database	2018	USA	Retrospective study	6 weeks	Depression and anxiety	Patients (n=34)	N/A	N/A

[a]N/A: not applicable.

[b]RCT: randomized controlled trial.

[c]Not available.

[d]Study evaluated both apps and systems and therefore will appear in both categories.

[e]Combination of cardiovascular disease, obesity, diabetes, high blood pressure, high cholesterol, osteoporosis, gastroesophageal reflux disease, osteoarthritis, chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, and bipolar disorder, major depressive disorder, schizophrenia, or schizoaffective disorder [47].

Table 2. Information about the studies that evaluated mHealth systems.

Reference	Intervention name	Year	Country	Study design	Duration	Health condition	Participants	Intended secondary users	Others involved in the intervention	Medical device included (Y/N)	Other devices included
[50]	SUPPORT-HF Study	2015	UK	Cross-sectional study	45 weeks	Heart failure	Patients (n=26)	Health care providers	Health care providers and informal care givers	Y	Blood pressure monitor, weight scales, and pulse oximeter
[51]	__[a]	2015	USA	Cross-sectional study	Single evaluation	Diabetes	Patients (n=87) and health care providers (n=5)	Health care providers	Health care providers	Y	Glucose meter
[52]	Multiple commercial technologies for activity tracking	2015	USA	Prospective study	80-100 days (mean 12.5 weeks)	Serious mental health condition[b]	Patients (n=10)	Health care providers and peers (optional)	N/A[c]	N	Wearable activity monitoring devices
[53]	Diabetes Diary app	2015	Norway	Prospective study	2 weeks	Type 1 diabetes	Patients (n=6)	N/A	N/A	Y	Smartwatch app and glucose meter
[54]	Diabetes Diary app	2015	Norway	RCT[d]	23 weeks	Type 1 diabetes	Patients (n=30)	N/A	N/A	Y	Glucose meter
[55]	Diabetes Diary app	2016	Norway	RCT	48 weeks	Type 2 diabetes	Patients (n=151)	Health care providers	N/A	Y	Glucose meter
[56]	SnuCare	2016	Korea	Prospective study	8 weeks	Asthma	Patients (n=44)	N/A	Research team	Y	Peak flow meter
[57]	HealthyCircles Platform	2016	USA	RCT	24 weeks	Hypertension	Patients (n=52)	Health care providers	Health care providers	Y	Withings blood pressure monitor
[58]	Multiple commercial technologies for activity tracking	2016	USA	Prospective study	24 weeks	Serious mental health condition[b]	Patients (n=11)	N/A	N/A	N	Fitbit Zip
[35][e]	Multiple commercial apps for heart failure	2016	USA	Cross-sectional study	Single evaluation	Stroke	Apps (n=34)	Family, friends, and health care providers (not all apps)	N/A	N	Y
[59]	Electronic Patient Reported Outcome tool (ePRO)	2016	Canada	Prospective study	4 weeks	Multiple	Patients (n=8) and health care providers (n=6)	Health care providers	Health care providers	N	N
[60]	STARFISH	2016	UK	Prospective study	6 weeks	Stroke	Patients (n=23)	Peers (automatic)	N/A	N	ActivPAL™ activity monitor

Reference	Intervention name	Year	Country	Study design	Duration	Health condition	Participants	Intended secondary users	Others involved in the intervention	Medical device included (Y/N)	Other devices included
[61]	HeartMapp	2016	USA	Cross-sectional study	Single evaluation	Heart failure	Patients (n=25) and health care providers (n=12)	Health care providers	Health care providers	Y	Zephyr Bioharness or Biopatch
[62]	EDGE digital health system	2017	UK	RCT	48 weeks	Chronic obstructive pulmonary disease	Patients (n=110) and research nurses (n=2)	Health care providers (automatic)	Informal care givers	N	N
[63]	IBGStar Diabetes Manager Application	2017	Germany	Prospective study	12 weeks	Diabetes	Patients (n=51)	N/A	N/A	Y	iBGStar blood glucose meter
[64]	MyHeart	2017	USA	Prospective study	24 weeks	Heart failure	Patients (n=8) and nurses	Nurses (automatic)	Nurses	Y	Weight scale, blood pressure monitor, and glucose meter
[65]	—	2018	UK	Cross-sectional study	4 weeks	Cancer	Patients (n=23)	Peers and health care providers	N/A	N	N

[a]Not available.

[b]Schizophrenia spectrum disorder, bipolar disorder, or major depressive disorder [52,58].

[c]N/A: not applicable.

[d]RCT: randomized controlled trial.

[e]Study evaluated both apps and systems and therefore will appear in both categories.

App interventions mainly targeted mental health conditions (n=7), followed by diabetes (n=3) and cardiovascular and heart diseases (n=4), with one study evaluating multiple apps that were used to self-manage multiple health conditions (Table 1).

Patients were included in all studies, and the studies had between 3 and 156 participants (median 36, IQR 15-87, maximum 156). The exception was one study in which only researchers evaluated patient-operated apps according to Google recommendations and quality standards [35,39]. Although studies tested single apps intended to be used primarily by patients, two studies also explored the impact of patients sharing their collected data with health care providers [35,42].

Six studies utilized single evaluations, either through a cross-sectional design [35,37,39,45-47] or an analytic service to analyze data available through the app store [41]. The remaining studies evaluated the impacts of app use over time, lasting between 4 and 72 weeks, with a mean period of 22.75 weeks (median 16 weeks, IQR 6-36, maximum 72). Of these, four utilized prospective study designs, three were randomized controlled trials (RCTs), and two used a retrospective design.

Among the 17 studies that described mHealth systems, most involved patients diagnosed with cardiovascular and heart disease (n=6), followed by diabetes (n=5), respiratory disease (n=2), mental health conditions (n=2), cancer (n=1), and multiple illnesses (n=1; Table 2).

As with mHealth app studies, all system studies, except one [35], involved patients. The 16 studies had between 6 and 151 patients (median 30, IQR 14.5-51.5, maximum 151), with eight studies involving health care providers. In these cases, health care providers either provided input on the suitability of an app for patient use or reviewed patient-gathered data during consultations.

In 12 studies, patients were required to share data (n=6) [50,51,57,60,62,64] or encouraged to share data (n=6) [35,53,55,59,61,65] with their health care providers or peers as part of the study. Data were also collected and transmitted to the main app by medical devices [50,51,53-57,61,63,64] and commercial wearables [35,52,53,58,60], demonstrating the prevalence of connectivity in modern mHealth systems.

Few studies (n=3) used single evaluations. RCTs (n=4) lasted longer (35.75 weeks on average) than cross-sectional studies (mean 24.5 weeks, n=2) and prospective studies (mean 12.93 weeks, n=7). Overall system evaluations lasted a mean of 20.32 weeks, which is very close to that for app interventions, but with a higher median number of 23 weeks.

Methods and Measures

Most studies included a combination of qualitative and quantitative methods of evaluation. Evaluation of usage logs was the most commonly adopted method (21 studies), followed by standardized questionnaires (17 studies; Table 3). Only two studies adopted quality guidelines to evaluate mHealth interventions; the Mobile Application Rating Scale was used to evaluate multiple apps [35], and compliance with Google standards for Android systems, in addition to other approaches, was used to evaluate the HeartKeeper app [39].

Table 3. Categories of methods used to evaluate mHealth interventions.

Methods (adopted approaches)	Studies that evaluated mHealth apps	Studies that evaluated mHealth systems
Evaluation of usage logs	[36,38,40-42,44,48,49]	[50,52,54,56-59,62-64]
Standardized questionnaires	[35-39,41-45,48,49]	[35,55-57,60,64]
Ad-hoc questionnaires	[36,37,40,42-44,47]	[51,53,55-58,61-63]
Interviews	[40,45,46]	[50,52,58,59,65]
Clinical outcomes	[36,48]	[54-56,63,64]
Open feedback (ie, oral or written)	[35,41,43,45]	[35,53,62]
Collection of additional device data (eg, medical device data)	N/A[a]	[54,56,57,60,62,64]
Field study and observation	[46,47]	[61,65]
Focus groups	N/A	[59,64]
Observational tests (in a lab setting)	[45,47]	N/A
Quality guidelines	[35,39]	[35]
Medical record entries	[42]	[63]
Attendance (intervention assigned activities/meetings)	[42,48]	N/A
Download count	[41]	N/A

[a]N/A: not applicable.

Among the 14 ad-hoc questionnaires used, four were developed according to concepts or questions from standardized questionnaires [47,58,61,62]. Similarly, two studies included interviews, where the interview guides were based on standardized questionnaires [40,45]. Some standardized questionnaires were used in more than one study. Multimedia Appendix 6 lists these questionnaires and illustrates the combination of questionnaires used in each study. Compared with traditional medical device testing, relatively few studies included information gathered from medical record entries (n=2), clinical outcomes (n=9), or observational tests (n=2).

Of note, some studies inferred more information from usage logs than the count and type of app interactions and patient-gathered data. For example, Triantafyllidis et al [50] interpreted information from the evaluation of usage logs on the usability of the device and participants' engagement in the study. The complete set of the types of data that were measured and collected by the mHealth app and system intervention studies are listed in Table 4.

Table 4. Categories of qualitative and quantitative data that were measured to evaluate mHealth interventions.

Types of data measured	Studies that evaluated mHealth apps	Studies that evaluated mHealth systems
Interactions (via app)	[36,37,40-42,44,45,49]	[50,52,53,56-59,62-65]
Usability/feasibility	[35,37,39-42,45,47]	[35,52,53,56,58,59,61,62,65]
Patient-gathered self-management data (via app)	[36-38,41,45,49]	[50,54,55,57,59,62-64]
Efficacy/effectiveness	[35-37,40,42,43,45,48]	[35,50,51,53,56,58,59,64,65]
Physical well-being	[36,40,42,48]	[54-57,60,62-64]
Perceptions, opinions, and suggestions	[35,40,41,45-47]	[35,51-53,58,64,65]
Intervention experiences	[39,41,46,47]	[50,52,58,59,64,65]
Psychological well-being	[38,41,42,44,49]	[55,60,62]
Patient-reported health	[40-44]	[56,63]
Self-efficacy	[36,44,47,49]	[55,57,61]
Engagement/motivation in self-management	[36,41]	[50,52,56,63]
Health care utilization and impact	[42]	[56,59,62-64]
Task performance	[45-47]	[50,61,65]
Study engagement	[35,41,42,48,49]	[35]
Patient-reported app use	[43,44]	[53,58,59]
Patient-reported self-management	[36,37]	[52,57,60]
Quality of life	[48]	[55,56,60,64]
App features and quality	[35,39,41,47]	[35]
Efficiency	N/A[a]	[62,65]
Security	[39]	[51]
Lifestyle	[48]	N/A

[a]N/A: not applicable.

Although a single method can often provide information regarding more than one measure, over one-third of the studies in this review used more than one method to collect information on one type of measure [40,42,45,48,50,55-60]. For example, two studies used both the collection of additional device data and clinical outcomes to report physical well-being [54,64]. Multimedia Appendix 7 includes a description of which measures were produced by each method. Several of the studies collected information on twice as many types of data measured as methods used to collect them (n=9) [35,41,44,49,58-60,65], with two studies collecting three [51,52] and one collecting four [39] times the number of types of data measured as methods used to collect them. Only one study used four methods to evaluate the most unique data types that were measured (n=10) by utilizing information resources that mHealth technologies make available (eg, automatically collected data from current users in the Android app store) [41].

Conversely, measures can be reported using more than one method. For example, usability/feasibility was the most common measure (22 times in 17 studies), followed by efficacy/effectiveness (20 times in 16 studies), interactions (via app; 19 times in 19 studies), physical well-being (18 times in 13 studies), and patient-gathered self-management data (via app; 15 times in 14 studies; Multimedia Appendix 7).

The study by Possemato et al [42] described the only app intervention that measured health care utilization and impact from these methods. Kim et al [56], Alnosayan et al [64], and Sieber et al [63] described system interventions that measured health care utilization or impact (ie, hospitalizations reported by participating health care providers and hospitalizations recorded retroactively). The remaining studies (n=5) collected information regarding physical well-being from clinical outcomes measured by researchers or health care providers during follow-up [36,48,54,55,61].

More comprehensive mapping of methods and measures revealed that the methods that were used to produce the most diverse set of data were, as expected, interviews (n=9), standardized questionnaires (n=16), and study-specific questionnaires (n=13; Multimedia Appendix 7). However, evaluation of usage logs produced nearly as many different types of measures (n=8).

Objectives and Methods Versus Results

A comparison of the study objectives with the results demonstrated that 30 of the 31 studies reported the results that they intended. One study reported all but one of the intended results described in the original objectives (ie, whether the reviewed apps and systems had been previously validated) [35]. Ten studies reported more than they anticipated, some of which

included the assessment of app [42,48] and system [50] usage patterns, as well as comparisons with other outcomes [41,44]. Other unforeseen outcomes included the accuracy of the app's knowledge base, as evaluated by nurses [45]; usability according to patients' performance of predetermined tasks with the app [47]; usability of connected devices in an mHealth system [53]; health care utilization [56]; and patient-reported symptoms [63]. Two studies stated that the objective was to develop mHealth systems; however, their outcomes also included evaluation results [50,51]. None of the studies phrased their goals as research questions and some reported what they intended, but the objective was not explicitly stated or detailed [40,63]. For example, Velardo et al [62] stated their intention to evaluate their intervention at scale. However, it was not clear how they intended to "evaluate" their intervention.

Discussion

Principal Findings

We identified 31 studies that described evaluations of mHealth apps or systems, with one describing evaluation of both intervention types [35]. Our findings show that studies relied mostly upon more continuous measures. Except for the collection of additional device data used by system interventions but not app interventions, there were no significant differences between apps and systems with regard to their ability to produce the intended outcomes, health conditions, or types of methods or measures used within the studies. Overall, medical record entries [42], attendance of meetings or activities assigned by the intervention [63], and download count [41] were the least used methods for gathering information about an intervention's impact on patients and providers. On the other hand, evaluation of usage logs [36,38,40-42,44,48-50,52,54,56-59,62-64] and standardized questionnaires [35-39,41-45,48,49,55-57,60,64] were the most commonly used methods. These two approaches (ie, one traditional and one mHealth) were also commonly used together in the same studies, demonstrating that mHealth is supplementing, not replacing, traditional research approaches.

mHealth Trends Versus Methods and Measures Used

Although clinical integration of mHealth technologies is on the rise, only two studies described app interventions that were meant to be used by secondary users (ie, health care providers and family and friends) [35,42], with three involving health care providers in the evaluation process [42,45,48]. Despite the focus on data safety and security, as well as patient privacy, as described by the new General Data Protection Regulation [66] and established FDA [10,11] and CE marking [12] expectations for health-related technologies, only two studies included measures regarding security [39,51].

Need to Reassess Evaluation Standards

Health evaluation studies are meant to produce evidence and understanding of how various interventions could affect patients and providers in real-world health care settings. Traditionally, studies have been classified within a hierarchy based on their designs, methods, and measures used to evaluate health interventions [67]. Health professionals consider high-level studies to be those that use rigorous and strict study designs, such as RCTs [68]. These studies provide an objective and quantitative understanding of how an intervention would influence patient clinical health measures, cost, or health care resource use [69]. On the other hand, low-level studies are often those that rely upon subjective and flexible study designs (eg, qualitative studies of participants' perception of the intervention or its impact on their lifestyle) [70].

Challenges of Quality Assessment

Health intervention researchers are not given instructions or guidance about how to evaluate these mHealth apps or which additional evidence is needed to determine their comprehensive impacts on patients and providers. The recent addition of connected technologies, such as wearables and sensors, has introduced even more factors to the evaluation context. Interventions now vary from recording exercise, to decision support for patient self-management, to providing evidence of a patients' actions for health care providers, to review from a variety of data sources. Because of these new information sources, we cannot always anticipate all of the impacts of these diverse networks of mHealth self-management technologies. For example, 10 studies did not intend to obtain results related to certain factors, such as usage logs and patient-reported outcomes [41,42,44,50,53,63].

The assessment of a study's success, validity, or quality presents another challenge to traditional research practice. mHealth resources consist of factors that make standard quality assessments inconclusive for intervention studies. For example, identifying patterns of patient self-management habits and progress describes the impact of an mHealth intervention on a patient's behavior. However, the analysis of usage logs, as a measure of intervention effectiveness, patient engagement, or self-management practices, has been minimally investigated as an appropriate method. As demonstrated by some of the reviewed articles, usage logs, download counts, and online ratings of apps were interpreted as indications of patient engagement, self-management behavior, intervention reach [41], effectiveness, and intervention utility [40] or feasibility.

Comparing Objectives and Results to Determine Successful Use of Methods

As opposed to completing a formal quality assessment, we chose to determine whether a study was able to produce the evidence that it aimed to provide, using selected methods. Some studies that performed usage log analysis were able to produce more information than they anticipated. Possemato et al [42] stated their intention to assess the fidelity of the PTSD Coach intervention by comparing health care utilization and health outcomes between those who used the app with and without clinical support. They were able to provide evidence for the effectiveness and fidelity of the intervention among health care providers, symptoms, and clinical health parameters from questionnaires. Moreover, they provided evidence for participants' patterns of intervention use from usage logs. Thereby, they were able to discuss the relationship between health care provider involvement and reinforced use of the app, as patients may have felt more accountable for using the app to self-manage their post-traumatic stress disorder.

Among the 31 studies identified, one did not obtain all of the intended information (missing one of the intended outcomes) [35] and one was found to be inconclusive [53]. We found that it was challenging to determine the specific objective of a study when objectives were not stated as such or when they were vague. This made it difficult to determine if a study was successful in the use of its selected methods and study design to reach its goals. For example, Velardo et al [62] stated that they intended to evaluate the EDGE digital health system intervention at scale; however, they did not state how they intended to do so or provide a research question that they intended to answer. Sieber et al [63] did not state the objective of their study. Instead, they stated simply what was done (ie, investigated the effects of usage profiles on hemoglobin A1c). Without a stated objective, we are unable to judge the reliability of intervention studies, whether it be through standard traditional means or an alternative approach. Clear objectives must be included in order to validate mHealth resources as trustworthy and relevant measures for evaluating mHealth interventions.

Relevance

mHealth must work for health care providers as well as patients. Patients are more engaged in their health, and they incorporate mHealth into their self-management. Thus, patients are aware of and can even influence how an mHealth intervention should or could be used to influence the kind of impact that is relevant for them. Understanding the potential risks and benefits of patient-operated mHealth requires more continuous evidence of not only technical and clinical outcomes but also personal and psychological impacts. This review demonstrates, through the use of such measures as mHealth interactions and patient-gathered data via an app, that we as researchers have the resources at our disposal and are beginning to use them.

A 2016 study by Pham et al [71] called for alternative or additional methods and measures for mHealth clinical trials that address the additional needs of mHealth. As most mHealth technologies for chronic health self-management are intended to be always available and continuously used by the patient, research questions, approaches, and designs need to reflect the real-world situations in which patients use these apps and systems.

Several studies within the presented scoping review demonstrated an attempt to meet this call by including more flexibility in their intervention design. For example, the EDGE digital health system [62], PTSD Coach app [42,43], and HeartKeeper app [40] made the patient the "decision maker" by allowing the patient to choose which data are relevant for them to gather and share with their health care providers. Further, two studies focused on reporting that patient engagement improved as a result of using mHealth apps [36,52]. User engagement is a necessity for the success of any intervention. It is paramount to consider patients' intentions when using these apps outside of the clinic; we should deem an app's ability to engage patients with their health as necessary as clinical evidence. There are individuals who do not choose to manage their chronic illnesses at all, for example, those deemed "hard to reach," who may benefit from merely acknowledging their health challenge by using an app primarily for education, without the expectation of performing complicated and time-consuming self-management. Therefore, when judging the success, usefulness, or potential benefit of an evaluated mHealth intervention, there should be less of a hierarchical gap between clinical health change or improvement and patients' experiences and change in self-efficacy.

Limitations

We believe our review covers most of the articles that were published during the established period and dealt with mHealth interventions for chronic conditions. This review reported on patient-operated mHealth self-management and did not include other potentially relevant interventions, such as SMS-based interventions.

We chose to focus on self-management of chronic NCDs, as defined by the WHO, in addition to severe mental health conditions, according to the demand for solutions from two fields (the medical system and public app development market) [4,13,33,72]. As such, these health cases represented the most potential for including state-of-the-art technology studies, with chronically ill people consistently being the leading market. However, exclusion of preventive treatments and other chronic health challenges (eg, musculoskeletal diseases) may have excluded a large proportion of cases that both involve the use of self-management options and represent a relevant portion of the chronic disease burden for individuals and health care systems worldwide [73]. As such, this noninclusion may have omitted conditions that could have provided relevant insights into methods and measures used to assess motivational, educational, and empowering mHealth technologies for self-management.

Because we did not collect data on reported results for this scoping review and did not perform a systematic methodological quality assessment, we cannot comment on the usefulness or effectiveness of the mHealth app and system interventions presented in these studies.

Conclusion

Researchers are now using several mHealth resources to evaluate mHealth interventions for patient self-management of select NCDs. This is evident as studies relied mostly on more continuous measures, including usage logs [36,38,40-42,44,48-50,52,54,56-59,62-64] and patient-collected data from medical devices [54,56,57,60,62,64], in addition to pre-post measures, such as clinical health measures [36,40,48,54-56,63,64] and standardized questionnaires [35-39,41-45,48,49,55-57,60,64]. In doing so, they evaluated the health status, engagement, and feasibility of mHealth apps and systems. In this review, which focused on mHealth, we found that only 20% of the included studies relied solely on traditional study designs (eg, RCTs) and methods that measure only pre- and postintervention health changes. The findings illustrate that the tradition of focusing on "clinical effectiveness, cost-effectiveness, and safety" [74] or health-related quality of life and the use of health care resources [75] is not being replaced, but is instead being expanded by taking advantage of additional resources that mHealth provides to evaluate interventions.

There is still no clear standard for the evaluation of mHealth interventions for patient self-management of chronic conditions. However, because mHealth presents additional challenges, needs, and resources to the field of health intervention research, we have the opportunity to expand and maintain our relevance to patients, providers, and health authorities. mHealth provides new types of information that we can and should gather to determine the impact of the interventions.

The presented results demonstrate that health studies have started to take advantage of additional mHealth resources, such as app usage logs and other patient-involved research methods, to determine the comprehensive impacts of mHealth on patients and other stakeholders. We are able to not only answer questions, such as which tasks patients choose to perform during interventions that may affect their clinical outcomes, but also say more about the relevance of mHealth for various types of users. This is essential in health intervention research, as the call for evidence on mHealth continues to push for not only traditional clinical health measures but also impacts on patients' self-efficacy and engagement. We believe that to achieve a compromise between the rigidity of traditional quality standards and the push for more patient-relevant outcomes, the definition of quality or meaningful impact, as well as available and appropriate evidence should be reassessed.

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Authors' Contributions

MB, EG, and EÅ developed the search and inclusion criteria. MB and PJ performed the literature search, article screening, and data collection. EG served as a third reviewer when disputes surrounding the inclusion of an article arose. MB performed data synthesis and drafting of the manuscript. PZ contributed to the planning and editing of the manuscript. EG and EÅ additionally contributed to the editing of the text. MJ and RJ provided quality assurance of the manuscript and the necessary details within the description of the literature search and article selection. LPH guided article content. All authors have read and approved the final version of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA-ScR checklist.
[PDF File (Adobe PDF File), 2500 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Search strategy.
[DOCX File , 127 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Scope of included technologies.
[DOCX File , 81 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Inclusion and exclusion criteria by category.
[DOCX File , 15 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Comparison of study objectives to reported results.
[DOCX File , 26 KB-Multimedia Appendix 5]

Multimedia Appendix 6

List of questionnaires and scales used in mHealth intervention studies.
[DOCX File , 18 KB-Multimedia Appendix 6]

Multimedia Appendix 7

Mapping of measures to methods.
[DOCX File , 15 KB-Multimedia Appendix 7]

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Abbreviations

MeSH: Medical Subject Headings
mHealth: mobile health
NCD: noncommunicable disease
RCT: randomized controlled trial
WHO: World Health Organization

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Paper 3

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RESEARCH ARTICLE

Analysing mHealth usage logs in RCTs: Explaining participants' interactions with type 2 diabetes self-management tools

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Abstract

Background

The Introduction of mobile health (mHealth) devices to health intervention studies challenges us as researchers to adapt how we analyse the impact of these technologies. For interventions involving chronic illness self-management, we must consider changes in behaviour in addition to changes in health. Fortunately, these mHealth technologies can record participants' interactions via usage-logs during research interventions.

Objective

The objective of this paper is to demonstrate the potential of analysing mHealth usage-logs by presenting an in-depth analysis as a preliminary study for using behavioural theories to contextualize the user-recorded results of mHealth intervention studies. We use the logs collected by persons with type 2 diabetes during a randomized controlled trial (RCT) as a use-case.

Methods

The Few Touch Application was tested in a year-long intervention, which allowed participants to register and review their blood glucose, diet and physical activity, goals, and access general disease information. Usage-logs, i.e. logged interactions with the mHealth devices, were collected from participants (n = 101) in the intervention groups. HbA1c was collected (baseline, 4- and 12-months). Usage logs were categorized into registrations or navigations.

Results

There were n = 29 non-mHealth users, n = 11 short-term users and n = 61 long-term users. Non-mHealth users increased (+0.33%) while Long-term users reduced their HbA1c

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(-0.86%), which was significantly different ($P = .021$). Long-term users significantly decreased their usage over the year ($P < .001$). K-means clustering revealed two clusters: one dominated by diet/exercise interactions (n = 16), and one dominated by BG interactions and navigations in general (n = 40). The only significant difference between these two clusters was that the first cluster spent more time on the goals functionalities than the second ($P < .001$).

Conclusion

By comparing participants based upon their usage-logs, we were able to discern differences in HbA1c as well as usage patterns. This approach demonstrates the potential of analysing usage-logs to better understand how participants engage during mHealth intervention studies.

Introduction

Standard approaches for evaluating research activities do not sufficiently address all aspects of mobile health (mHealth) interventions. This is in part due to a reliance on hard clinical endpoints, and part because study designs often follow the ªBlack Box evaluationº method [1], the aim of which is to answer «what» has changed, in retrospect, by comparing end- and baseline measures. In doing so, these studies traditionally produce evidence of, for example, how a new medication will predictably affect individuals with a certain diagnosis in real-world medical practice. For pharmacology, this is acceptable. The usefulness of these results is clear; either the drug is safe and efficient to use, or not. However, intervention studies for chronic illnesses that utilized modern technologies often conclude that their results require further testing [2±4]. This is, in part, due to the complicated nature of chronic illness self-management, requiring individuals' to make daily health decisions in response to biological changes, such as their blood glucose in the case of diabetes. Humans, their decisions and behaviours require greater understanding than biology alone. Therefore, clinical research must adapt to look at how participants choose to behave during the intervention in order to understand why an intervention is±or is not±producing any effects. In other words, tracking and understanding participants' behavior can allow us to understand what is going on inside ªThe Black Boxº during intervention studies.

Today, many who live with diabetes rely on such mHealth devices as smartphones and wearable trackers to aid them in their self-management. These tools can reduce the burden of performing self-management by allowing individuals to more easily record and review their self-management measures, i.e. blood glucose, physical activity, diet and medication at their fingertips. Fortunately for clinical research, these technologies can also provide date-stamped records of a user's self-management decisions through their interactions with the mHealth devices, i.e. usage-logs, and registered health measures, lifestyle habits, and notes [5, 6]. However, due to the novelty of these technologies for health care, there is no standard for how to assess these newly available data. Recent studies have, to a certain degree, incorporated analysis of usage log patterns during clinical trials. Some have even included values of registered health data [7]. However, most of these have only analysed cumulative measures such as total keystrokes or hours interacting with a device [8, 9], and many are inconclusive and fail to contextualize the data.

Therefore, mHealth research calls for a toolbox of sorts±in addition to traditional measures, a collection of concepts adapted to inform new possibilities for explaining the impact of mHealth interventions. Approaches such as theory-driven evaluation [1], program theory evaluation using logic models [10], and logic analysis [11] have been proposed as alternatives to [a]Black Box evaluation[o]. Traditionally, these approaches are used to evaluate e.g. an educational program intervention. These programs consist of complex interactions between inputs and outputs. Theory-driven evaluation is used to explain either part or the whole of these contexts [12]. These approaches can inform the assessment of mHealth interventions because they aim to explain the context of an intervention, such as participants' behaviour and decisions, rather than to predict cause-and-effect, such as the effect of a drug.

For the case of mHealth interventions for diabetes, we must consider the context. Individuals are expected to continuously self-manage their diabetes through a cycle of trial and error. The cycle is characterized by tracking, reflecting upon, reacting and repeating certain health actions, which personifies the behavioural theories of Experiential Learning [13] and Health Habit Change [14±19]. Therefore, the registered data and usage logs that track these actions, available on the mHealth devices, can be interpreted as reflections of an individuals' engagement in their health. This provides a much more detailed picture of how patients are relating to mHealth over the course of an intervention.

In this paper, we present a preliminary study for applying human behaviour theories [13, 18±20] to structure and analyse usage logs. We used the use-case of the logs collected by the mHealth intervention used in the REgioNs of Europe WorkINg toGether for HEALTH (RENEWING HEALTH) Norwegian randomized control trial (RCT).

Objectives and aims

The overall aim is to provide evidence for how applying behavioural theories to usage logs can be used to provide a better understanding of the context of mHealth interventions. In doing so, we aim to inform the appropriate and effective design and administration of future mHealth studies.

Methods

Use case: The RENEWING HEALTH RCT

To demonstrate the potential benefits of analysing usage-logs to explain the impact of mHealth, we use the case of the European Commission funded RENEWING HEALTH project's Norwegian RCT. The study was registered with Clinical Trials, with reference number NCT01315756, and was approved by the Regional Committee for Medical and Health Research Ethics in South-Eastern Norway (REK sør-øst).

This 3-armed study was conducted between 2011 and 2013 to test the impact of a mHealth self-management intervention called the Few Touch Application (FTA) [21], including use of a smartphone application (app) and glucose meter. The FTA intervention tracked when participants registered and reviewed their blood glucose, diet and physical activity, goals as well as accessed general disease information stored within the application. The app was Bluetooth-paired with the OneTouch Ultra Easy blood glucose meter from LifeScan through a Bluetooth adapter from Polymap Wireless, enabling fully automated transfer of BG measurements to the app. Originally, n = 151 participants were recruited and randomized into two intervention groups: n = 51 used the mHealth intervention (referred to as FTA); n = 50 used the mHealth intervention together with health counselling (referred to as FTA+HC); and a control group (n = 50) (Fig 1). The FTA+HC group was followed up by the diabetes nurse five times, remotely by phone, within the first 4 months. The diabetes nurse provided health counselling with principles from motivational interviewing and supported patients' use of the FTA.

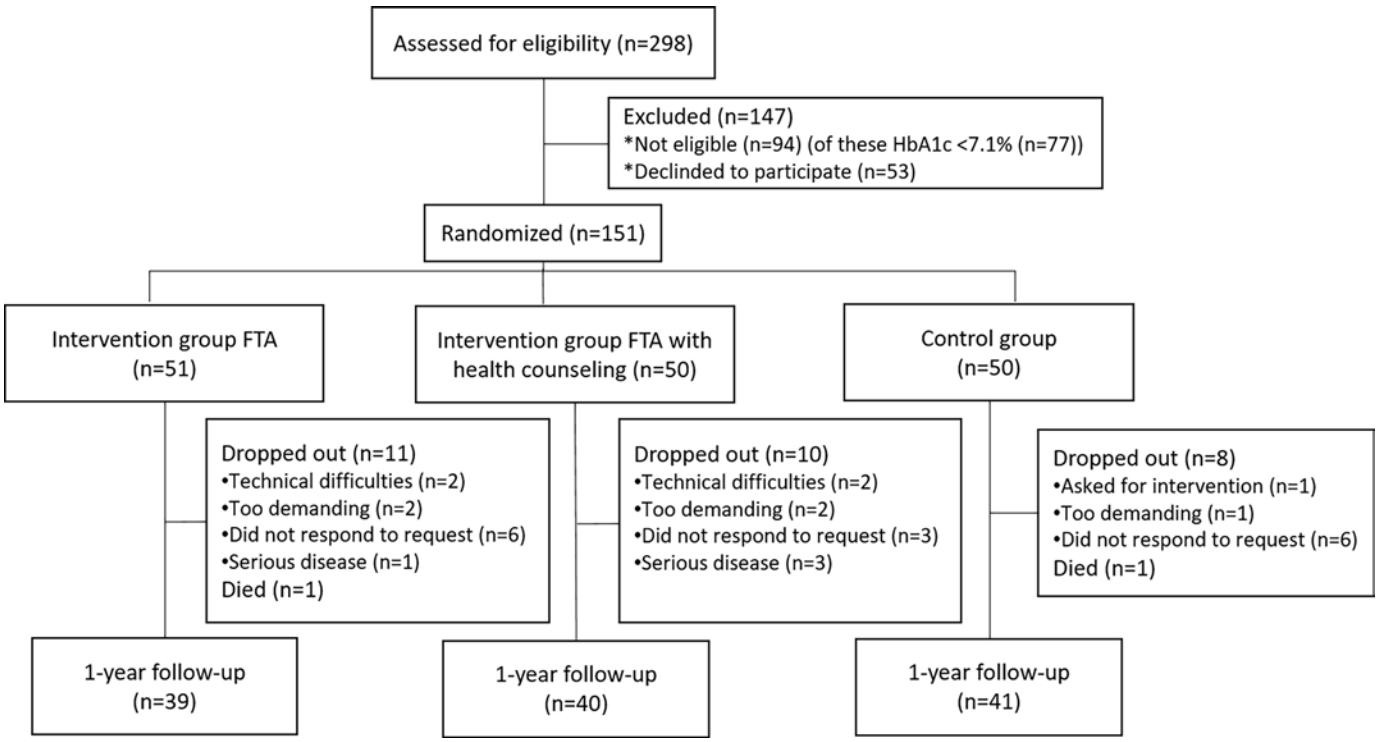

Fig 1. CONSORT flow diagram of the RCT.

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Patients' own registered app data and app usage were continuously gathered and stored. More detailed descriptions of the study design can be found in the protocol paper published elsewhere [22] (S1 and S2 Files).

Training. Both intervention groups were trained on how to use the mHealth intervention at the start of the study. Participants were provided both a paper and an electronic version (USB memory stick) of the user-guide. Included were explanations and screen shots of all app functionalities and step-by-step instructions for registering data using the provided mHealth system, both manually and using the system for automatic data transfer when using the blood glucose meter. The participants also had access to a technical support-service during work hours (9 AM-3 PM), by phone, in the study period.

Previous analysis and results. The primary analysis results for this study have been reported elsewhere [22±25]. These focused on comparing changes in HbA1c and questionnaire responses, with a coarse look at usage patterns. Of the 101 who received the mHealth intervention, with and without health counselling, 79 completed the study. It is important to note that the previous analysis was based upon the participants' completion of the primary outcome (HbA1c level), and did not distinguish between their mHealth usage.

Previous results yielded only a significant increase in self-management related to [a]skill and technique acquisition[o] in the FTA with health counselling group compared to the control group. There was no significant difference in HbA1c or total usage of the mHealth devices at 4- and 12-months between those who received the mHealth intervention and the control group [23, 26]. Recently, a follow-up analysis for this study, found that half of the persons were in pre-action phase according to the stage of behaviour change, reflected in the physical activity and dietary-related usage patterns [25]. This demonstrates the potential of applying theories, related to the context of self-management, to the analysis of mHealth usage logs.

An in-depth analysis of log-data

The mHealth usage logs from the RENEWING HEALTH study contained data and time stamps related to use of blood glucose- (BG), physical activity-, diet- functionalities and access to other disease information within the FTA smartphone app. In addition, the app automatically recorded when and what users registered as well as when they reviewed their past registrations or any other interaction with the app. By interacting with the app in these two ways, the user personifies the cycle of experiential learning by performing active engagement and self-reflection related to their self-management.

Population: Comparison of users vs. Non-users. As mentioned in the original protocol, we focus on those who participated in the intervention [22]. Therefore, in this descriptive analysis of the usage logs, we focus on those who used the mHealth devices. Because there were no statistical differences between the two FTA intervention groups, we consider all the 101 intervention participants as one cohort. We were then able to a) identify those who actually used the mHealth tools at any point in time during the study and b) explore and differentiate mHealth usage patterns in this presented in-depth analysis (S3 File).

Participants were included based upon whether or not, and for how long, they used the mHealth tools. To be considered as a user of the mHealth intervention, as opposed to one who casually explored the functionalities but chose not to continue using the tools, participants must have logged at least 60 interactions with the tool at any time in the 12 months, i.e. a minimum of 5 interactions per month. To be defined as Long-term users, participants must have used the FTA app for three or more continuous months, with at least 5 interactions per month. Because participants used the separate LifeScan BG meter with the adapter for automatic transfer of BG measurements, only functionalities that required user-interaction with the FTA smartphone app were included when categorizing the participants into the three groups: those who did not use the mHealth tools once (ªNon-mHealth usersº), those who used them for less than 3-continuous months (ªShort-term usersº) and those who used them for three or more continuous months (ªLong-term usersº).

Of the 101 participants who received the mHealth intervention, 29 participants fell in the ªNon-Usersº group, while 72 participants interacted with the mHealth devices at least once, and 61 of those participants used the devices for a minimum of three continuous months during the intervention period.

Measures: mHealth-usage logs. To describe how the theory of experiential learning was used to structure and interpret the usage logs, we grouped usage logs into two basic types: ªRegistrationsº, which are an individual's active interaction with their health through entry of self-management recordings into the app, and ªNavigationsº, which are any non-registration, or reflective, interactions with the app.

Due to an error in the logging routine, we were unable to distinguish ªGoal registrationsº from navigations. However, the number of minutes spent watching the app's various screens were collected by the system. The logs were therefore grouped as follows:

- Diet/Exercise registrations (D/E Regs): indicating when a user manually registers information related to diet or physical activity.
- Diet/Exercise navigations (D/E Navs): when a user accesses previously registered data related to diet or physical activity, thereby demonstrating actions relevant for self-reflection.
- Blood glucose registrations (BG Regs): when a user measures blood glucose levels via the BG meter.
- Blood glucose navigations (BG Navs): when a user reviews previously measured blood glucose values, thereby demonstrating actions relevant for self-reflection upon past BG levels.

Table 1. Differentiation of the 6 Usage groups based on two most used FTA functions.

	Diet/Exercise registrations	Diet/Exercise navigations	Blood Glucose registrations	Blood Glucose navigations	Goals registrations and navigations	Disease information navigations
Registrations usage group	X		X			
Navigations usage group		X		X		X
Diet/Exercise management usage group	X	X				
Blood Glucose management usage group			X	X		
Goals usage group					X	
Inconsistent usage group	Any combination of functionalities not otherwise described					

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· Disease Informational navigations (Info Navs): when a user accesses disease information, thereby demonstrating actions relevant for active learning behaviour.

In addition, minutes spent per screen were calculated for the following screens: Home Screen, Data Navigations, and Goals (S1 Text).

Identifying emergent user subgroups. We used the FTA usage logs from the first three months, i.e. the first quarter, to identify usage patterns. Of the six main functionalities the FTA provided, a range of different usage patterns are possible (Table 1). We based the usage groups on the two most frequently used FTA functions. Conceptually, a patient may use the FTA mainly for registering self-management habits or also for reflections / navigating through previously registered health information. The FTA may also be used mainly for diet / exercise management, or blood glucose management. A range of other combinations is also possible. To investigate this in our sample, we employed k-means clustering (S2 Text).

Statistical analysis

In the first part of our analysis, we compared app-users to Non-app users. In the second part we focused the analysis on those who used the app for three or more consecutive months, i.e. Long-term users. The details of extracting and analysing of the log data can be found in the supplementary material (S1 Text).

To determine differences between participants based on overall duration of mHealth use, demographics, baseline HbA1c as well as interactions and logged time spent with the interventions' mHealth tools' usage were compared between Non-users (n = 29), Short-term users (n = 11) and Long-term users (n = 61) (Table 2).

The remaining tests of these in-depth analyses focused upon investigating relationships between patterns of app usage, and health outcomes from the Long-Term users (n = 61) (Fig

Table 2. Descriptives for the three FTA usage groups.

M (SD)	Non mHealth users (N = 29)	Short-term users (N = 11)	Long-term users (N = 61)	F-value	*P*	η^2
Gender	17 female	5 female	37 female			
Age	57.45 (12.97)	55.18 (12.86)	58.84 (11.26)	.49	.62	.01
Duration (years)	9.69 (7.87)	11.27 (7.14)	9.25 (8.3)	.30	.74	.01
Education (years)	3.72 (1.19)	3.91 (1.38)	3.61 (1.48)	.25	.78	.01
SMBG* (per week)	7.17 (7.315)	5.5 (5.11)	9.43 (10.46)	1.18	.31	.02
HbA1c at baseline	8.41 (1.11)	7.99 (.062)	8.08 (1.17)	1.01	.37	.02

*: SMBG is self-monitoring of blood glucose

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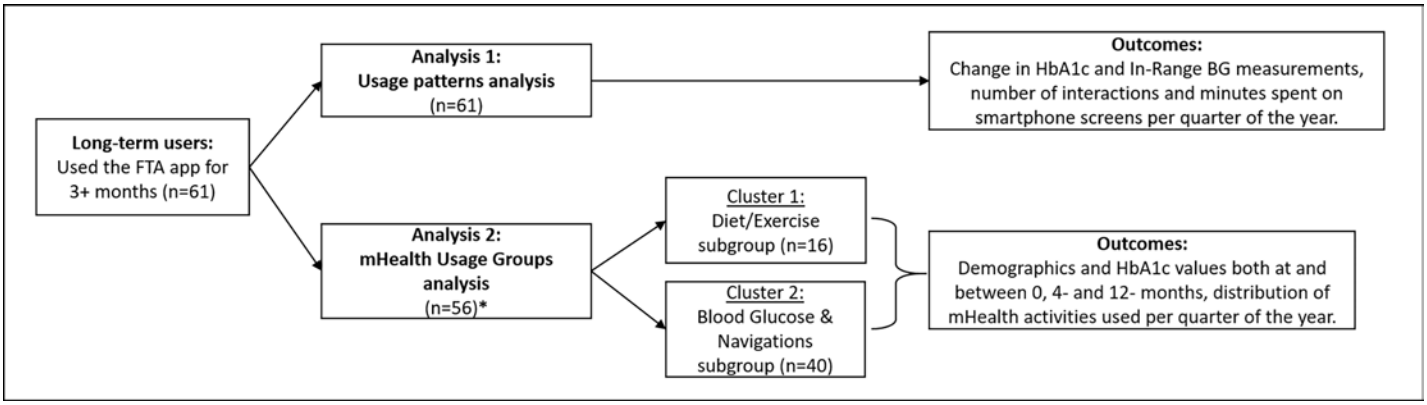

Fig 2. Diagram showing two approaches for analysing the usage logs. *Five participants were grouped in two very small clusters and not considered for Analysis 2.

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2). In addition to comparing usage patterns based on emergent groups, we also explored the smartphone app's recorded blood glucose levels. Because the goal of blood glucose self-management (SMBG) is to keep BG levels within a certain range (4-10mmol/L), we chose to compare the number of In-Range BG values both within and between quarters.

Pearson Correlation and Repeated Measures ANOVA were used to compare change in HbA1c and app-usage activities (total as well as individual Diet/Exercise and BG Registrations and Navigations and Disease information Navigations) within and between groups, over the 12-months pooled into 3-month intervals (quarters of the year). Pearson Correlation analysis and Linear regression were used to analyse relationships between interactions with app-activities and minutes used on each app-screen over the four quarters. We have chosen the pooling into quarters as it reduced the number of missing values compared to a monthly or bi-monthly analysis. The statistical package for social sciences (SPSS) version 19 software, and JASP version 0.8.5 [27] were used to run the statistical tests.

Ethics

This study was approved by the Regional Committee for Medical and Health Research Ethics in South-Eastern Norway (reference number 2010/3386). All patients provided signed informed consent documents before participation in the intervention. If patients revoked their consent, their data was removed from the database and not included in analysis.

Results

As seen in Table 2, there was no selection bias between those who did and did not use the mHealth intervention tools for self-management.

According to a repeated-measure ANOVA among the 101 participants, time, i.e. the 12 months, did not affect HbA1c , $F(2, 148) = .541$, $P = .583$, $\eta^2 = .007$. However, the Non-users, Short-term and Long-term users differed in change in HbA1c, $F(2, 74) = 3.794$, $P = .027$, $\eta^2 = .093$. Among the Non-mHealth users and Short-term users were drop-outs, reducing the N in this analysis to n = 9 for non mHealth users, n = 7 for Short-term users, and n = 61 for Long-term users. The data does not change if one uses only the 0 and 4 months where there are slightly fewer dropouts. To compare specifically which groups differed from one another, a pair-wise comparison, or post-hoc test, was run. This showed that the only difference between groups was between the Non-mHealth users, who increased their HbA1c by 0.33%, and the Long-term users, who reduced their HbA1c by -0.86%, $P = .021$, Cohen's d = .311. Short-term

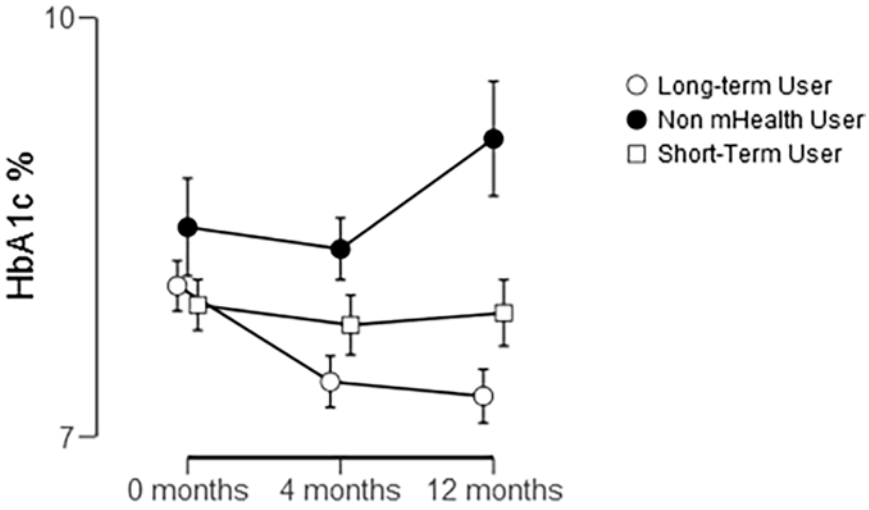

Fig 3. Comparison of HbA1c between users grouped by duration of FTA use. Error bars denote standard error of the mean.

https://doi.org/10.1371/journal.pone.0203202.g003

users did not differ from either of the other two groups. The interaction between time and group did not significantly impact change in HbA1c, $F(4,148) = 1.26$. $P = .288$, $\eta^2 = .033$ (Fig 3). Note that the participants, in general, did not achieve the target (Norwegian) of achieving an HbA1c below 7mmol/L during the mHealth intervention.

Exploration of Long-term users' mHealth data and logs

We explored and compared the usage logs and data of the 61 participants who engaged in the intervention for three or more continuous months.

Baseline self-reported SMBG did correlate positively with the number of BG registrations (Pearson's r = .579, $P < .001$, CI [.383; .725]), BG navigations (Pearson's r = .436, $P < .001$ CI [.207; .62]), D/E registrations (r = .339, $P = .008$, CI [.095; .544]), and Goals (r = .409, $P = .001$, CI [.176; .599]), but not with D/E navigations (r = .229, $P = .076$, CI [-.024; .455]), made during the study. In contrast, change in HbA1c did not correlate with number of interactions spent on mHealth device functionalities, (all $P > .15$).

Use of the FTA differed significantly both within and between individual functionalities over time. Fig 4 illustrates the results of a repeated measures ANOVA (Greenhouse-Geisser correction for sphericity violation), which revealed that total use significantly decreased over the four quarters: $F(1.642, 98.528) = 45.02$, $P < .001$, $\eta^2 = .429$. Participants used the FTA mostly for diet / exercise (D/E) registration and navigations. Post-hoc tests revealed that the steepest decline is from first to second quarter with a decrease in 64.91 interactions on average (t = 9.234, $P < .001$), and for navigations in general. Use overall plateaued after this first quarter, with differences of fewer than 25 interactions between successive quarters (all $P < .001$). However, BG registrations were more consistent over the 1-year intervention, with the greatest difference was 21.51 BG registrations (t = 3.202, $P < .05$, effect size = .410) between the first and second quarter, whereas for example, participants decreased their use of D/E registrations significantly moreÐby 63.44 (t = 3.344, $P < .01$, effect size = .428)Ðover the same time. The use of each of the six functionalities differed significantly from one another in total ($F(1.62, 97.2)$, $P < .001$, $\eta^2 = .202$), as well as from one quarter to another: $F(3.213, 192.795) = 13.26$, $P < .001$, $\eta^2 = .181$.The only functionalities that did not significantly differ were D/E Regs and D/E Navs, and BG Navs compared to D/E Regs and D/E Navs.

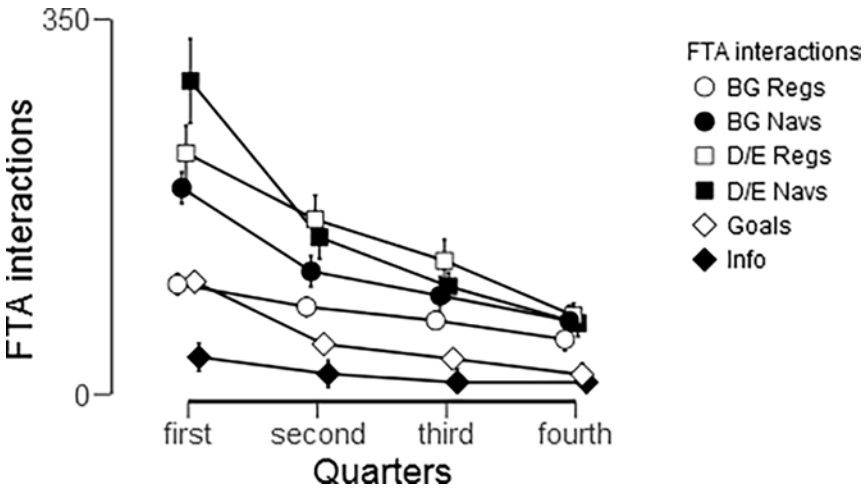

Fig 4. Used functionalities of the FTA per quarter. Error bars denote standard error of the mean (SEM).

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Next, we looked more closely at the first 3 months to identify where the reduction in FTA usage occurred the most (Fig 5). Overall, the same trends were found in use of the FTA between months as between quarters. In other words, use of the FTA differed significantly between these first three months ($F(1.386, 83.14) = 23.545$. $P < .001$, $\eta^2 = .282$). Participants used the functionalities the most in the first month (461.2 ± 63) with a significant drop by 212.25 interactions ($t = 5.022$, $P < .001$, effect size = .643) during the second month. This was especially true for D/E navigations, which dropped by 35.374 interactions, on average, after the first month ($t = 8.158$, $P < .001$, $d = 1.044$). The plateau in use of the FTA actually began after the second month, as the second month did not differ from the third ($t(60) = 1.379$, $P = .519$, $d = .177$). However, BG registrations and Disease Information navigations were stable throughout the first 3 months with less than a 15 interaction difference between successive months ($P < .05$, except Disease Information Navigations between the second and third months). In addition, all functionalities differed from each other (all $P < .01$), with the exception of BG Regs and Goals which did not differ significantly.

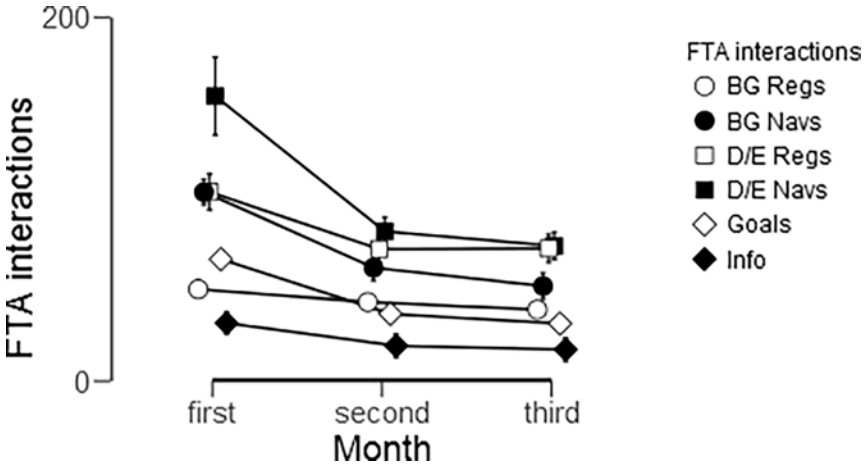

Fig 5. FTA usage over the first three months among the 61 Long-term users. Error bars denote standard error of the mean (SEM).

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We explored the barriers and opportunities for analysis of patients' self-measured blood glucose values by comparing the in- and out-of-range values to number of registrations taken using the LifeScan blood glucose meter. Figure A in S4 Text demonstrates the great variability in frequency of SMBG both within and between participants over quarters of the study. S1 Table displays the significant Pearson Correlations between in-range BG measurements and goals functionality interactions for most quarters as well as in-range BG measurements and HbA1c for three of the four quarters.

Identifying clusters and patterns from mHealth usage

The FTA offered six main functionalities and participants differed in their usage. Among the 61 Long-term users we performed a cluster analysis (k-means with at least N = 5 in a cluster) of the six functionalities: BG registrations, BG navigations, D/E registrations, D/E navigations, goals, and disease information. Cluster analysis yielded two clusters differing in their usage patterns (Fig 5), one dominated by diet/exercise registrations and navigations (n = 16), while the other cluster was dominated by BG registrations and navigations, as well as overall navigations (n = 40). Five participants were grouped in two very small clusters and were not included in further analysis.

Repeated measure ANOVA confirmed that there was a significant difference between the use of the individual functionalities: $F(2.987, 161.325) = 59.79$, $P < .001$, $\eta^2 = .392$, as well as use of each functionality over time between the clusters ($F(2.987, 161.325) = 38.88$, $P < .001$, $\eta^2 = .25$). As can be observed in Fig 6, the only interactions in which these two clusters did not differ were for BG navigations, in total ($P = .302$) and between quarters ($P = .129$), and for Disease Information navigations, in total ($P = .398$) and between quarters ($P = .689$).

Not only did Cluster 1 use the mHealth intervention more than Cluster 2 throughout the study, participants in this group also spent more time on interactions with goals functionalities in total ($F(1,53) = 54.54$, $P < .001$, $\eta^2 = .507$) and between quarters ($F(1.815, 96.211) = 42.47$, $P < .001$, $\eta^2 = .241$) (Fig 7). During the study, participants in Cluster 2 drastically decreased their use of goals, disease information and registration of diet/exercise. However, Cluster 1 was more consistent in their use of all functionalities overall. This can be seen in S5 Table, which details these changes in use over time by comparing percentages of functionalities used per quarter between and within each cluster. Of note is that while Cluster 1 spends most

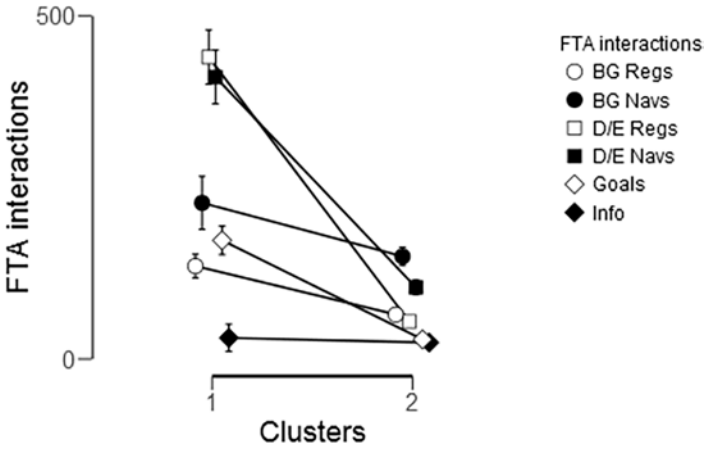

Fig 6. Comparison of the six interaction types between Cluster 1 (diet/exercise functionalities) and Cluster 2 (blood glucose functionalities and overall navigations) for the whole study period.

https://doi.org/10.1371/journal.pone.0203202.g006

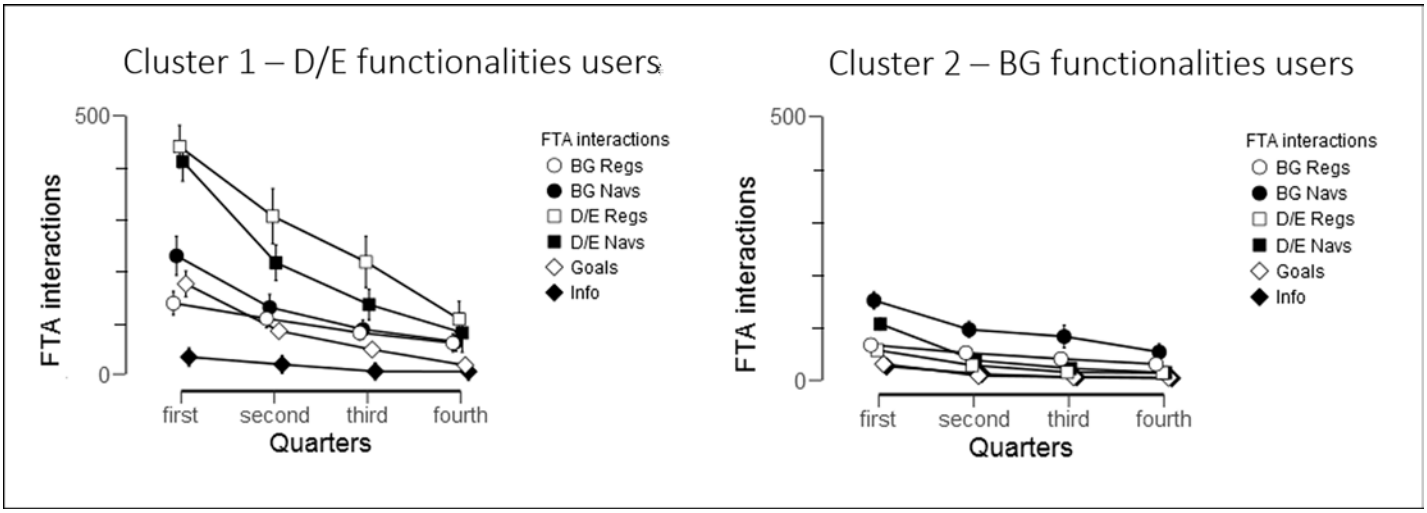

Fig 7. Distributions of functionalities used between Cluster 1 and Cluster 2 over the four quarters of the year. Error bars denote standard error of the mean (SEM).

https://doi.org/10.1371/journal.pone.0203202.g007

interactions on D/E activities, they still maintain their use of BG registrations, ranging from between 10%-16% per quarter, and BG navigations, ranging from between 12%-16% per quarter. On the other hand, while not statistically significant, Cluster 2 seems to increase BG activities while decreasing all other activities over the quarters.

Comparing the two groups, we found a non-significant group difference in HbA1c over the duration of the intervention ($F(1, 55) = 3.642$, $P = .062$, $\eta^2 = .062$) (Fig 8). There was a significant difference between months ($F(2, 110) = 5.043$, $P = .008$, $\eta^2 = .084$) but not between groups over time ($F(2, 110) = .298$, $P = .743$, $\eta^2 = .005$). While not statistically significant, the group using the D/E functionalities of the FTA improved HbA1c over the course of the study, whereas the group using mainly the BG functionalities showed improvement during the first half of the year, but did not further improve in the second half of the year.

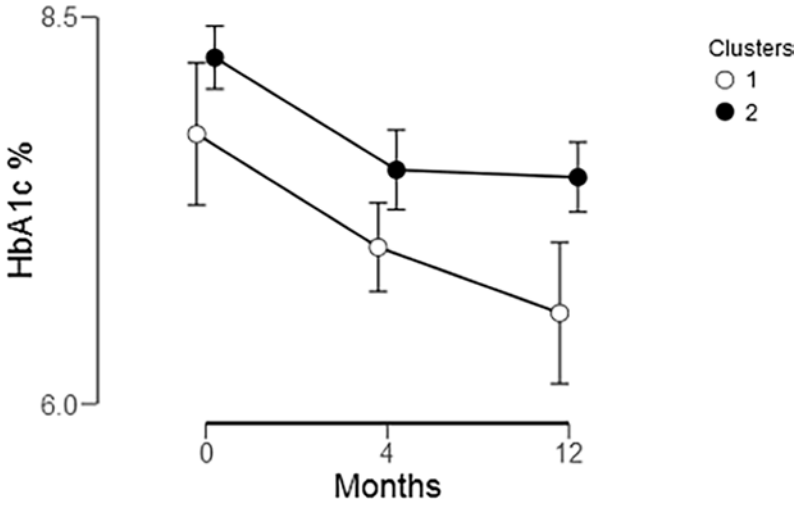

Fig 8. Comparison of change in HbA1c between Cluster 1 (D/E users, empty circles) and Cluster 2 (BG-users, filled circles) over baseline, 4- and 12-months.

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Adverse events

While there were no clinical adverse events reported during the intervention, participants did report some technological issues. Of impact to this analysis were issues with the Bluetooth transfer of BG registered measurements from the BG meter to the Diabetes Diary app. This may have caused frustration and additional psychological stress and time when participants tried to engage in self-management during the intervention. While BG registrations were among the more stable types of interactions, it was postulated by Holmen et. al. that this may have discouraged participants from using that functionality or the FTA as a whole [26]. However, all participants were informed of these possibilities before the study began, including the possibility to get support via phone.

Discussion

Theory-based evaluation is typically used to evaluate program interventions, such as education or, business management programs [12]. In fact, theory-based diabetes program interventions are common, but are characterized by structured instruction, external motivation and collaboration with clinical staff or support groups [28, 29]. However, programs and individuals' diabetes self-management are similar in that they A) involve complex interactions and B) require that intervention evaluators acknowledge and understand these complex interactions. Therefore, we argue that it is appropriate to consider this presented approach as a supplement to hard clinical measures for mHealth studies. However, to the best of our knowledge, this study is the first to approach analysis of mHealth usage-logs by grouping such data based upon behavioural theories.

The insights from using the presented approach on this study are two-fold. The first is related to patients' change in use of the mHealth intervention and the effect on their health. The second is related to what was learned about the proposed methods and approaches for analysing the impacts of the mHealth devices. As described below, additional data is required to properly interpret the impact of mHealth in self-management intervention studies. Therefore, the presented analysis should only be considered as a preliminary study of log data.

Main results

90% of an iceberg's mass is not noticed at first sight±the same can be said for mHealth interventions. First analysis of the data, based upon intervention groups, revealed no significant difference in change in HbA1c [30]. However, this additional analysis of actual and detailed mHealth logs revealed that those who did not use the mHealth tools increased their HbA1c over the course of the study while those who did use these tools significantly decreased their HbA1c. For all FTA users, the observed decrease in HbA1c between baseline and 4 months and the increase between 4- and 12-months suggests that the impact of using the FTA for 3 + months actually occurs during the first 4 months. This is just a coarse preview of the kind of relevant information that we can gain by categorizing users and reassessing outcomes based on actual usage.

Analysis of usage-patterns, for all mHealth users, and the comparison of groups based on functionalities used, revealed much more about how patients chose to engage in the intervention and their health over time than originally thought possible. By splitting up participants into similar groups based upon their own preferred use of the intervention, we were able to better understand the opportunities and limitations of how mHealth logs can reflect realistic and varied self-management habits. Comparison of how the functionalities were used by each cluster confirmed that individuals did in fact use the functionalities differently, which should be accounted or adjusted for in future analysis of mHealth interventions. Over the year, most

patients fell into the blood glucose management cluster, and only 16 out of the 61 (or, when considering all of the users involved in the study, 101) patients also used the FTA's lifestyle functions, i.e. diet and exercise registrations and navigations, significantly. Similarities also provide insights as to common approaches to treatment that may aid in adherence to clinical recommendations. For example, both clusters were similar in their use of goals functionalities in total±the main difference being when they used these functionalities (S2 Table). This information can be used to design improved mHealth interventions that encourage experiential learning by reinforcing the functionalities that patients already use and encouraging the use of un-used functionalities.

Further consideration of temporal relationships between usage of each functionality revealed that the number of interactions, and not time spent, with mHealth tools seem to be more suggestive of sustained mHealth use, as was demonstrated by the analysis of mHealth use related to goals (S3 Text). Those who did use the devices, their use significantly decreased after the first months suggesting that the first month reflects the novelty-effect of a new device. Therefore, the following months may have been more reflective of the realistic day-to-day use of mHealth devices for self-management. However, the assumed more familiar functionalities, such as BG registrations, were more consistent throughout the course of the study.

These logs not only provided insights about patients' self-management habits, but could potentially provide a better understanding of how their health changes through their own-recorded health measures in self-management. For example, self-recorded BG values are informative of a patient's health. However, inconsistency and lack of sufficient data limited our ability to suggest conclusive outcomes related to mHealth use and participants' health (S4 Text). Further, we demonstrate how this approach to analysing usage logs can complement traditional measures. For example, the use of the goals functionalities suggested not only a relationship on both HbA1c and number of In-Range BG values over time, but also future and more sustained use of the mHealth functionalities (Table A in S3 Text).

Experiences and future directions

We don't know what we don't know. Unless we ask the right questions in research, we cannot hope to achieve understanding of any endeavour regarding health interventions. In order to successfully measure the impacts of complex interventions such as mHealth interventions, we must look more deeply into how patients useÐand differ in their useÐof self-management technologies.

Therefore, we endeavoured to explore new concepts related to usage log analysis in this paper. In doing so, we aimed to provide accounts of practical and useful lessons learned and recommendations for future mHealth interventions. In Table 3, we summarize the main implications of the presented analysis for both research efforts and clinical practice.

Strengths and limitations

This presented analysis of the RENEWING HEALTH study is underpowered. However, barriers, limitations and setbacks are only as negative as your reaction to them. In fact, limitations experienced during this study provided greater insight for how to not only improve future mHealth interventions but also how to approach their evaluation. Of those who received the mHealth intervention, 29 participants (30%) did not use it once after the start-up meeting, which rose to 45 participants not using it after the first three months. Furthermore, all participants reduced their usage of the mHealth tools significantly over time. This led us to question where the barriers for sustainable use occurred and how we could address these in the next iteration of mHealth intervention studies. Analysis of the usage-logs, such as those actions

Table 3. Aims, lessons learned and recommendations regarding analysis of usage-logs generated from the presented analysis.

Set	Aim	Lessons learned	Recommendations
1	To suggest and test a way of grouping log-data based on theories of human behaviour, to improve upon the tradition of summative analysis.	By grouping usage logs into "registrations" and "navigations" we were able to more easily and meaningfully identify how patients change their interactions with the mHealth devices.	When combined with traditional measures, established theories from complementary science fields, e.g. psychology, should be used to provide additional insight for mHealth intervention studies.
2	To explore what log-data can tell us about patients' experience or relationship with the intervention technologies.	· The reduction in usage after the first month demonstrated the "novelty effect" of this technology. · Sustainable use, past the novelty effect, are dependent on relevant and easy-to-use functions.	· Analysis should consider and account for the "novelty effect" as a "run in" period, during which patients become more familiar with a technology before the intervention begins. · Automated functionalities, e.g. automatic registration of physical activity via Bluetooth from a wearable sensor, should be incorporated into the intervention when possible.
3	To suggest how researchers can tailor administration of the intervention to patients' preferred use of the mHealth technologies.	The cluster analysis demonstrated that individuals indeed use mHealth tools differently based on the focus, or own priorities, of their self-management.	Reminders or recommendations for continued use and self-management practice can be tailored based on usage patterns of each patient during the first 3-months.
4	To propose a solution to achieve adequate data-collection.	The variability both within and between participants' use was expected, and can be seen as a realistic representation of self-management amongst those with Type 2 diabetes.	Suggest minimum mHealth usage requirements for intervention studies to make data collection more consistent and reliable.
5	To determine how research and analysis can approach patient collected health measures.	Self-collected health data, such as BG values, diet and exercise, can supplement health measures collected at the point-of-care by providing details of health change between consultations. However, consistency and reliability of the data is required.	While lifestyle measures such as diet and exercise can be episodic and without schedule, measures such as SMBG should be done on a consistent schedule to ensure their comparability over time and two other measures during interventions.
6	To determine what more is needed to understand not only what and how, but also why patients choose to self-manage.	Usage logs are a valuable resource for understanding how use of diabetes mHealth tools change during the intervention. However, why changes occurred during the intervention period were not clear.	Related and complementary questionnaires include, e.g. Patient Activation Measure [31], Health Education Impact Questionnaire [32], Patient Health Locus of Control [33], which measure motivation and patients' intention to engage in their health, as well as the Health Care Climate Questionnaire [34], which may provide insights as to the impact of the therapeutic relationship related to not only engagement in self-care and health outcomes but also mHealth use.

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related to the manual entry of diet/exercise data, revealed that time-consuming or burdensome usage-requirements discouraged many from long-term engagement with those functionalities. However, those in Cluster 1, who used the FTA largely for diet/exercise management, also reduced their HbA1c. While this is both encouraging and telling of how usage can be associated with health change, we cannot rely solely on statistical testing of small and diverse samples to conclude on the impact of any mHealth intervention. Another point that is both positive and negative for future studies is that this technology it still changing rapidly. In fact, the mHealth devices used in this study had become almost outdated by the end of the trial, which may have contributed to frustration and a steep decline in use over the year.

These trends raise two common plights of research interventions: 1) the desire or habit to trust statistical output at face value, without scepticism and assessment of the reliability of the data itself compared to real-world scenarios and 2) sustaining use of the intervention so as to collect enough consistent and reliable data to produce conclusive results. In order to both improve participants' experience during interventions and also ease the burdens of self-management instead of creating them, the use of mHealth technologies should be less time-consuming, more relevant and provide greater reinforcement of beneficial habits than standard modalities. In relation, participants were not given long-term reinforcement for when and how to use the devices. The benefit of providing such reinforcement could be two-fold. First, participants may feel more supported and engaged. Second, we as researchers may be able to

reduce variability and inconsistency in device usage, which would facilitate actionable statistical analysis and more insightful interpretation of the intervention results.

Conclusion

Today's mHealth technology can allow researchers and health-care practitioners to not only better understand but also better reinforce patient's self-management behaviorsÐbut we need to adapt research practices to keep up. Analysis of quarterly accounts of usage-logs, differentiated by functionality and purpose, illustrated that clinical research can benefit from studying usage patterns in such a way that provide meaningful and actionable information beyond the typical conclusion of ªfurther studies are neededº. This is evident in the comparison between previously reported results of the Renewing Health project versus the presented study of log data. The previous study used total measures of logs based on originally assigned intervention groups and demonstrated no difference in use of the app or HbA1c's between intervention groups. However, in the present study using log data, by analysing the impact of the app based on how individuals used the apps functionalities, we were able to identify for which users the mHealth intervention yielded a significant improvement in HbA1c. We propose the presented exploratory analysis as a novel supplement to the traditional hard-measures of diabetes health and self-management, and encourage others to use, comment, suggest and discuss this approach. We also aim to apply this approach both retroactively to the now completed Tailoring Type 2 Diabetes Self-Management Study [35] data-set and proactively to the design and testing of the mHealth data-sharing intervention in the Full Flow of Data between Patients and Health Care Systems Project's [36].

Supporting information

S1 File. RENEWING HEALTH study protocol.
(PDF)

S2 File. CONSORT checklist.
(DOC)

S3 File. Analysed data.
(XLSX)

S1 Text. How-to: selection of relevant data from usage logs.
(DOCX)

S2 Text. K-means clustering.
(DOCX)

S3 Text. Minutes vs. interactions with goals functionalities.
(DOCX)

S4 Text. Patients' self-registered blood glucose values.
(DOCX)

S1 Table. Results of Pearson Correlations run between interactions with the Goals functionalities within the app and In-Range BG measurements per quarter of the year (n = 61).
(DOCX)

S2 Table. Percentage distribution of the six FTA interaction types used by clusters 1 (n = 16) and 2 (n = 40) for each quarter.
(DOCX)

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Writing ± review & editing: Meghan Bradway, Gerit Pfuhl, Ragnar Joakimsen, Lis Ribu, Astrid Grøttland, Eirik Årsand.

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Paper 4

Protocol

Measuring the Effects of Sharing Mobile Health Data During Diabetes Consultations: Protocol for a Mixed Method Study

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Abstract

Background: There is rising demand for health care's limited resources. Mobile health (mHealth) could be a solution, especially for those with chronic illnesses such as diabetes. mHealth can increases patients' options to self-manage their health, improving their health knowledge, engagement, and capacity to contribute to their own care decisions. However, there are few solutions for sharing and presenting patients' mHealth data with health care providers (HCPs) in a mutually understandable way, which limits the potential of shared decision making.

Objective: Through a six-month mixed method feasibility study in Norway, we aim to explore the impacts that a system for sharing patient-gathered data from mHealth devices has on patients and HCPs during diabetes consultations.

Methods: Patients with diabetes will be recruited through their HCPs. Participants will use the Diabetes Diary mobile phone app to register and review diabetes self-management data and share these data during diabetes consultations using the FullFlow data-sharing system. The primary outcome is the feasibility of the system, which includes HCP impressions and expectations (prestudy survey), usability (System Usability Scale), functionalities used and data shared during consultations, and study-end focus group meetings. Secondary outcomes include a change in the therapeutic relationship, patient empowerment and wellness, health parameters (HbA_{1c} and blood pressure), and the patients' own app-registered health measures (blood glucose, medication, physical activity, diet, and weight). We will compare measures taken at baseline and at six months, as well as data continuously gathered from the app. Analysis will aim to explain which measures have changed and how and why they have changed during the intervention.

Results: The Full Flow project is funded for 2016 to 2020 by the Research Council of Norway (number 247974/O70). We approached 14 general practitioner clinics (expecting to recruit 1-2 general practitioners per clinic) and two hospitals (expecting to recruit 2-3 nurses per hospital). By recruiting through the HCPs, we expect to recruit 74 patients with type 2 and 33 patients with type 1 diabetes. Between November 2018 and July 2019, we recruited eight patients and 15 HCPs. During 2020, we aim to analyze and publish the results of the collected data from our patient and HCP participants.

Conclusions: We expect to better understand what is needed to be able to share data. This includes potential benefits that sharing patient-gathered data during consultations will have on patients and HCPs, both individually and together. By measuring these impacts, we will be able to present the possibilities and challenges related to a system for sharing mHealth data for future

interventions and practice. Results will also demonstrate what needs to be done to make this collaboration between HCPs and patients successful and subsequently further improve patients' health and engagement in their care.

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KEYWORDS

diabetes; patient-gathered data; mHealth; data sharing; therapeutic relationship

Introduction

How Patient Mobile Health Apps Are Changing Consultations

Mobile health (mHealth) technologies originally were designed for and used by patients to better understand and self-manage their health. For those with diabetes, this means tracking and understanding how many different factors, such as diet, exercise, and medication, affect their blood glucose levels. As a result of collecting and reviewing these data, patients are more empowered and knowledgeable, eager to take control and responsibility of their daily health, and more knowledgeable patients are able to better understand how their actions affect their diabetes health. Some information and subsequent decisions are more evident than others after reviewing their data. In other words, patients can only understand or explain a portion of the data that they collect without the medical expertise of health care providers (HCPs) to contextualize these data with known disease processes. Patients have begun to bring these data from their mHealth technologies to their health care consultations, hoping that the HCPs can provide explanations for the results seen in their gathered data [1].

Mobile Health Data Sharing

The expected benefits of mHealth integration and data sharing are to decrease health care costs, increase patient engagement and aid options, and improve clinical outcomes [2,3]. However, HCPs have traditionally relied on scientifically proven, professionally collected clinical data, such as laboratory test results and biological measures taken at consultations, to understand the patient's health status. There is evidence that by using these data to inform a clinical recommendation, HCPs can be confident that they have provided a relatively accurate diagnosis and that their treatment will produce a known clinical outcome [4]. Ideally, presenting app-collected data to HCPs would provide a greater understanding of the patient's situation. However, the data have not been collected, structured, or validated in relation to disease status like traditional laboratory data. The presentation and structure of the data (ie, dozens or hundreds of data entries), including many different types of data from a variety of different mHealth technologies, is a challenge to relate to from the HCPs' perspective.

Further, HCPs aim to use medical data in a slightly different way than patients use their patient-gathered data. In other words, each wants to know different things. The patient wants to know if their daily decisions are having a positive effect on their disease management, and the HCPs want to know how their clinical recommendations and medications are affecting the disease status. These priorities are complementary; as part of daily self-management, diabetes patients need to observe, understand, and respond to fluctuations in their blood glucose [5], often instantly for those with type 1 diabetes. The focus of HCPs is on the progress or trend to determine if a treatment modality or approach is a practical choice for that patient in the long run [6,7]. Therefore, for mHealth data sharing to be useful for patients and HCPs, the information should be presented in a way that both can understand, discuss, and use together to determine how best to maintain or improve treatment and self-management strategies. This is an example of shared decision making.

The Potential of Shared Decision Making

Shared decision making describes the communication and health care decisions made between patients and their HCPs [8]. When used in such a way, shared decision making is key to successful therapeutic relationships—those between patients and their HCPs—and, ultimately, patients' adherence and achievement of treatment aims [8]. Several studies have demonstrated that patients' improvement in HbA_{1c} (glycated hemoglobin) and perceived diabetes competence are associated with a medical environment where clinicians encourage patients' autonomy [9,10].

Sharing Mobile Health Data Enables Shared Decision Making

With mHealth, individuals have been presented with the opportunity to bring patient-relevant data to the conversation during consultations, as opposed to relying on only patient memory of their self-management and clinical test results. In doing so, true shared decision making between the HCP and patient is not only possible but necessary to effectively support and validate patient decisions in their self-management. For example, a patient may collect diet or exercise data that could explain fluctuations in clinical test results, such as lipid levels or imbalances between insulin and blood glucose levels during those periods. Patient-gathered data could even bring to light challenges that the patient faces in their self-management that are not evident from clinical test results, such as dangerous nightly hypoglycemic events. The result of bringing such information to the consultation is, for example, that the patient could provide concrete evidence of their challenges and self-management activities, with specific questions that would improve their understanding and ability to self-manage. Then the HCP could explain why adverse outcomes are occurring and give patient-tailored guidance about how to better deal with such situations in the future. Therefore, patient-gathered data from these devices could strengthen patient-clinician collaboration in tailored diabetes treatment.

How to Approach Mobile Health Intervention Research

The purpose of health intervention research is to develop and test the ability of such things as a new device, system, or service to improve patient health outcomes or experiences. To develop a solution that facilitates shared decision making using mHealth data, one must consider two main questions: (1) how to effectively present the mHealth-gathered data during consultations between patients and HCPs, and (2) how to promote conversation about the patient-gathered data in a way that leads to shared decision making. The goal of testing such a solution is typically to determine if a system can successfully convert patient-gathered data to a form that is understandable and useful for patients and HCPs and shows that the use of the data can produce positive clinical or experiential outcomes.

The Proposed Solution

To assess how mHealth data sharing comprehensively affects patients, their health outcomes, HCPs, and their therapeutic relationship, we must first have a suitable data-gathering and data-sharing platform that can facilitate and validate this new situation. As the data-gathering platform, we use a mobile phone app, the Diabetes Diary, which has been tested in several studies [11-14]. In the Full Flow of Health Data Between Patients and Health Care Systems project, we aim to design, develop, and test a system for sharing patient-gathered mHealth data with HCPs during diabetes consultations by iteratively involving both patients and providers throughout the research activities [15].

The Diabetes Diary app is a research tool that allows patient participants to register their self-gathered health measurements (eg, blood glucose and physical activity) and review previously registered data either as a summary or list (Figure 1). Patients then have the option to select the data they want to share with their HCPs, which is then displayed via the FullFlow System, a platform for sharing and presenting patient data.

The FullFlow System's Web interface allows both patients and providers to view together selected summaries and preliminary information about the set of shared data. This system also allows users to choose the summary forms to view, which is intended to be guided by the information about the patient's progress on their goals, measurements, and identified areas of possible concern illustrated on the home screen (Figure 2). The development details and initial clinical testing of the data-sharing system are described elsewhere [16,17].

Figure 1. Home screen of the patient-operated Diabetes Diary app (English version).

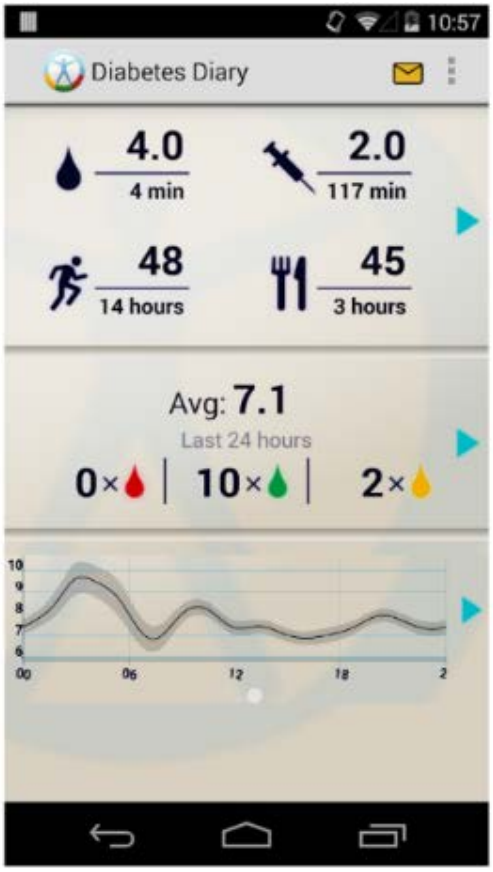
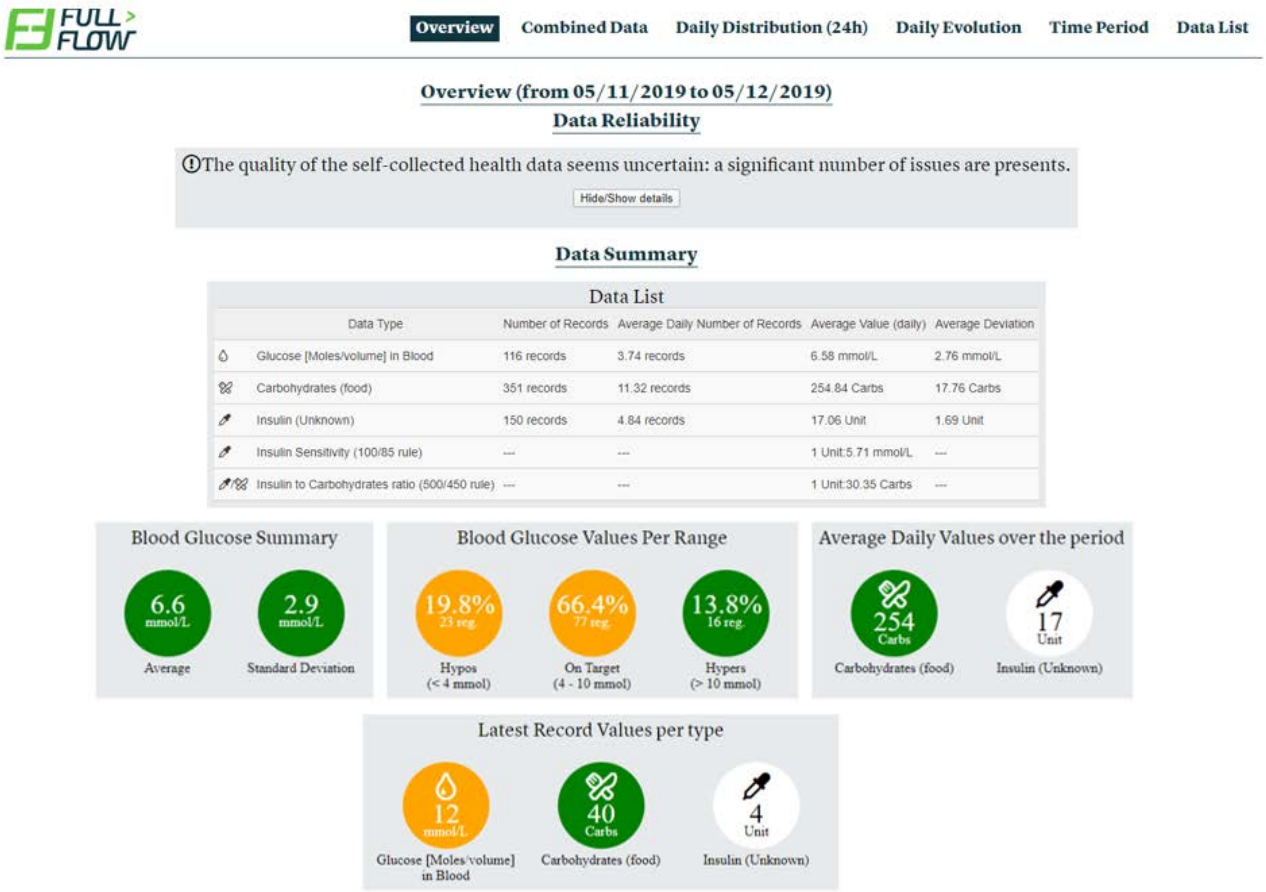


Figure 2. The FullFlow System's Web-based home screen (English version).



Study Aims and Objectives

A working version of the system was developed in 2018 [17-19]. We now aim to comprehensively measure its impacts on patients and providers and its role in encouraging patient-provider collaboration in diabetes care. Further, by using diverse measures (mixed methods) based on different research fields (eg, psychology, medicine, and technology), we can better understand which impacts mHealth can have on health care services.

The overall objective is to understand and test the effects of using a data-sharing system (exemplified by the FullFlow System developed in-house [17,20]) for patient-gathered mHealth data and the Diabetes Diary mobile phone app. We hypothesize that sharing such data, in the form of mutually relevant information, will enable patients and HCPs together to generate more tailored and concrete self-management recommendations for patients. This protocol includes a description and justification behind why the selected measures, evaluation methods, and study implementation methods were chosen.

Methods

Study Design

This protocol describes a six-month mixed method study, which is part of the larger Full Flow project [15], in which the FullFlow data-sharing system is used to enable the sharing of patient-gathered mHealth data during diabetes consultations. The design of both the data-sharing system itself and mixed method study structure (Figure 3) are based on developmental studies and activities within the Full Flow project, described elsewhere [16,18,19,21,22].

Traditionally, health studies report only the pre- and posteffects of interventions, perhaps with some participant-recalled experiences. However, human memory is prone to forgetfulness and mistakes. Using mHealth technology that can provide real-time recording of information about what patients did and how their health responded to their self-management is an invaluable resource for health studies. Therefore, in the described study, we include a comprehensive set of measures that take advantage of the reliability of clinical measures and standardized questionnaires with the record of how patients performed their self-management between consultations (see Table 1). In doing so, we aim to understand not only the pre- and posteffects of using such a system but also how patients performed their self-management between consultations.

Figure 3. Study design flowchart. HCP: health care provider; T1D: type 1 diabetes; T2D: type 2 diabetes.

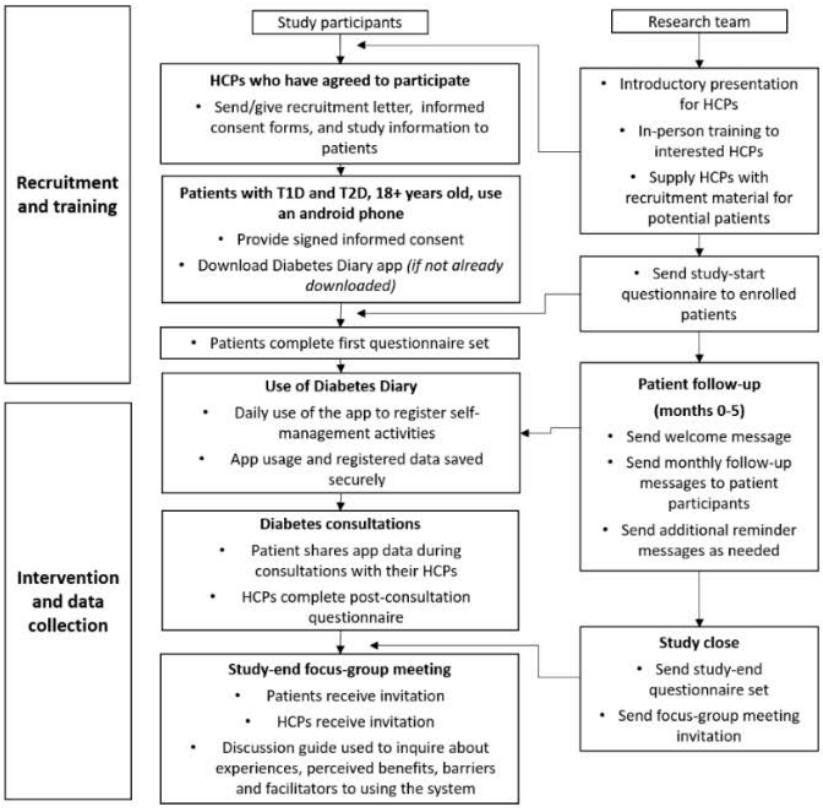


Table 1. List of data types, their sources, and purpose for measurement.

Data collection tools[a]	Purpose: to measure...	When collected
Primary outcomes		
Prestudy survey to HCPs[b]	HCPs' first impressions of the system and their expectations	Before study start
Postconsultation questionnaire	Functions of the system used, HbA_{1c}[c], and blood pressure of patients	After each consultation
Data displayed by the FullFlow System	What patients chose to share during consultations	At each consultation
Study-end focus group meetings[d]	Experiences, perceived benefits, barriers to, and facilitators for using the system	After study end
System Usability Scale [23]	Usability of the system for patients	After study end
Secondary outcomes		
Diabetes Empowerment Scale [24]	Patient engagement (ability)	Before and after the study
WHO-5 wellness [25]	Patient engagement (likelihood)	Before and after the study
Health Care Climate Questionnaire [26]	Therapeutic relationship	Before and after the study
Patient-registered health data (app)	Patients' self-measured health parameters: blood glucose, weight, diet, physical activity, and medication	Continuously throughout the study
App usage logs	Patients' interactions with the Diabetes Diary app	Continuously throughout the study

[a] Norwegian versions of all questionnaires will be used. The five-question World Health Organization Wellness Index (WHO-5) is the only Norwegian version of a questionnaire to be officially validated [27].

[b]HCP: health care provider.

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

[d]Focus group sessions will be held in Norwegian, audio-recorded, transcribed, cleared of all identifiable information, and translated into English for analysis.

Online Study Administration and Management

The online study management platform provides a real-time overview of participants' progress through the study. The platform allows study administrators to deliver recruitment material and collect informed consent electronically. After it is confirmed that the patient has downloaded the app and entered the code, we can collect their data. Each participant is assigned an anonymous user ID, which is not directly linkable to the user's personal information (eg, personal email, sensitive personal information) that is stored elsewhere. Electronic questionnaires and direct follow-up messages can then be sent to these user IDs, directly to the app, and registered personal email. This direct channel with the app also allows the platform to collect both registered measurements and usage log data from the app. Preliminary and summative analysis is accessible via the system as well to identify data gaps, such as possible technology challenges that participants are experiencing that study administrators can efficiently respond with follow-up messages when necessary.

Study Population

We recruited general practitioners (GPs), diabetes nurses, and individuals diagnosed with either type 1, type 2, or other types of diabetes in the Troms and Finnmark region of Norway between October 2018 and July 2019. Inclusion to participate as a health care provider required that they had the ability and willingness to use the FullFlow data-sharing system during their consultation setting, which required an internet connection and a Web browser on their office computer. Persons with diabetes who were older than 18 years were eligible to participate. Inclusion required that they have a mobile phone with an Android operating system through which the Diabetes Diary app could be downloaded and used for data collection. Participants had to be willing to use the app to gather and share data during consultations, and to consider participation in a study-end focus group meeting. No restrictions were placed on applicants' disease duration or HbA_{1c} level. Exclusion criteria included any mental or physical illness that interfered with their ability to fulfill study expectations.

Recruitment and Training

Health Care Personnel

We require sets of patients and their health care professionals to agree to participate together; therefore, we will first approach diabetes nurses and endocrinologists through our research team's current network, including the University Hospital of North Norway and Hammerfest Hospital. A member of our research team will identify potential GP participants and cold-call them directly. Emails will also be used to request in-person recruitment meetings. Two representatives of our research team will give a brief lunch presentation to HCP offices accepting such meetings. For those interested in participating in the study, we will schedule one-hour training sessions to demonstrate the FullFlow data-sharing system in more practical detail on the HCP's own computer. The HCPs will be asked to complete a brief survey about their perceptions of the presented FullFlow System after these in-person training sessions.

As GP offices in Norway do not commonly have agreements or contracts with local or national research projects, we will provide additional compensation for the time taken outside of their regular work schedules for the training sessions for each patient enrolled and for any additional time spent on the study, such as study-end focus group meetings. These will follow standard reimbursement schemes for health care professionals in Norway.

Patients

When needed, we will also assist HCPs in identifying potential participants from their diabetes patient lists. We will provide both electronic and paper copies of the patient recruitment materials. HCPs will provide patients the recruitment letters and study information in-person during consultations, or they will mail the letters to those not scheduled to meet for consultation shortly after. Patients will be instructed to contact us if they are interested in enrolling in the study. Patient recruitment letters will contain a link to the study webpage where interested patients will be able to read and sign the informed consent form electronically (Multimedia Appendix 1). Patients who have not already downloaded the tailored version of the Diabetes Diary app, including an associated website and user guide [28], will be requested to do so to participate. We will also inform patient participants of their right to withdraw their data or participation from the study at any time. Patients will be reimbursed for travel and consultations if the meetings are scheduled in addition to their usual care.

All participants will be encouraged to participate in the study-end workshop. The participants are informed that technical support will be available via email or by visiting our office. Patient recruitment ended on July 1, 2019.

Sample Size

We plan to approach 14 GP clinics, with an estimated one to two interested GPs in each clinic, and two hospitals, with one to three nurses and one endocrinologist in each.

The GPs in the Troms and Finnmark regions of Norway have listed 1000 to 1500 patients [29]. The prevalence of type 2 diabetes is 4.7% [30]; therefore, our recruitment pool is expected to be 1234 patients with type 2. The average expected response rate is 15% (range 10% to 20%), and approximately 40% of these patients are estimated to meet the inclusion criteria. Therefore, we expect to recruit 74 patients with type 2 diabetes.

There are 511 patients with type 1 diabetes registered at University Hospital of Northern Norway (UNN) Tromsø and 62 registered at Hammerfest Hospital in the Norwegian Diabetes Registry for Adults [31]. With the same estimated response rate of 15% and 40% of these meeting the inclusion criteria, we estimate to recruit approximately 30 patients from UNN and three patients from Hammerfest Hospital.

Intervention Description

Diabetes Diary Application—Tailored Version

Our research team previously developed a tailored version of the Diabetes Diary app [32,33], which we will provide to all patient participants. We developed the app over several years

to act as the research platform for many projects [13,34,35]. The app itself allows patients to tailor the app to their diabetes type and self-management foci, including the ability to register and review the following data types: goals, blood glucose, medication, physical activity, nutrition, and weight.

For the study, both registered measurements and usage log data from this app will be continuously encrypted and transferred to the project's secure online study management platform [36], which was used during two previous projects [34,37]. However, for consultations, the patient will be able to control the data they share with their health care team via the tested FullFlow System.

The FullFlow Data-Sharing System

The FullFlow System will summarize and display information based on the data provided. If patients do not share data, patients and HCPs can plan goals together about which data to collect and discuss during future consultations. We have designed the dynamic, Web-based interface of the FullFlow System to facilitate easy navigation of this information. The FullFlow System will register the data that patients choose to share, which we will then qualitatively analyze after the study. A more detailed description of the FullFlow System itself is described elsewhere [17].

Consultations and Self-Management

We will ask that each patient-clinician team schedule at least one consultation by the sixth month of the study related to diabetes treatment. To the best of their ability, HCPs and patient participants should use the FullFlow System during these consultations. HCPs are requested to report the functions that were used, the usefulness of the FullFlow System, and the patients' HbA_{1c} and blood pressure via a postconsultation questionnaire (requiring three to five minutes).

We will send monthly messages to patients using the online study management platform. These messages will appear both in the participants' email and the Diabetes Diary app. We detail the scheduled messages (eg, reminders to schedule appointments and register data throughout the study) in Multimedia Appendix 2.

Data Collection

We will administer questionnaires through LimeSurvey [36,38] and our study management platform. Information about which data was registered in the Diabetes Diary app will be collected continuously through connection to our secure research platform.

We will request patient participants to report the following before study start: age, gender, level of education, disease duration, medication type, and delivery system (eg, pens, pumps, pills). We will also request data, described in the Evaluation Measures section and Table 1, about patients' self-management habits and perceived health status and challenges that they may have with the self-management of diabetes parameters.

Evaluation Measures

We chose to include standardized and validated questionnaires where possible, supplemented by measures specific to impressions of the use of the technologies involved. The combination of questionnaires was chosen to limit the number of questions because we are also asking them to track several other factors as part of the intervention on the mobile phone app. Table 1 introduces an overview of the purpose and selection of our data collection tools.

System Usability

We will assess the usability of the system with three data collection tools: the prestudy survey to HCPs, the System Usability Scale (SUS) [23], and the postconsultation questionnaires. The reason for combining these to measure usability is that responses from each build on one another. In other words, we measure not just overall satisfaction or dissatisfaction with the system, but information about how each pair of patients and providers used the system during each consultation.

The postconsultation questionnaires provide a specific indication of the functions the HCPs and patients chose to use (ie, which characteristics of the system contributed to their use).

Patient Well-Being and Health

Postconsultation questionnaires will also request that the HCP provide the laboratory values for each patient's HbA_{1c} and blood pressure. The participants' own app-registered health data (ie, measured values of blood glucose, administered insulin or other medication, weight, physical activity, diet, and goals) will provide a more continuous illustration of a patient's self-management foci and health. By comparing these recorded values to the other measures mentioned, we aim to explain how patient self-management habits contribute to measures of health, engagement, and communication with their providers.

The World Health Organization Wellness Index (WHO-5) is a five-question measure of an individual's subjective health during the previous two weeks using a six-point Likert scale [39]. We chose this measure based on its simplicity, brevity, and ability to cover a diversity of concepts related to well-being.

Patient Empowerment and Engagement

The Diabetes Empowerment Scale-Short Form (DES-SF) is an eight-item questionnaire that measures an individual's psychosocial self-efficacy [24]. Self-efficacy refers to a person's belief in their own ability to perform the activities necessary to achieve a specific level of performance; in this case, those necessary to maintain or improve their diabetes health. Although this is a measure of a person's belief and not actions, self-efficacy is strongly correlated to an individual's self-care actions in the case of diabetes [40,41].

The participants' own app-registered health data are evidence of their real-world self-management habits. Similarly, the interactions with the app (ie, app usage logs) indicate time spent using the app that includes not only time taken to enter values but also the use of other functionalities (eg, reviewing previously recorded materials).

Therapeutic Relationship

The Health Care Climate Questionnaire (HCCQ) is a six-item measure of patient perception of whether their HCP supports their autonomy [26,42]. In other words, the HCCQ measures

the relationship between patients and HCPs. This questionnaire is based on the concepts of self-determination or one's ability to choose their own actions [43]. The therapeutic relationship supports one's health self-management and has been shown to significantly contribute to an individual's health-related outcomes [44]. These concepts describe a collaboration based on mutual contribution to care decisions rather than a patient-provider relationship based on a hierarchy of knowledge and power. In combination with the other questionnaires listed, we can better understand how, and possibly why, a system that encourages communication, initiated by the patient's choice to share patient-gathered data, affects the patient's motivation, self-care actions, and health, as described previously.

Study-End Focus Group Meetings

We have chosen the presented questionnaires to limit "burnout" from answering too many written questions; however, we still expect there to be missing responses. In addition, as this is the first time these measures have been used together in a study for mHealth—to the best of our knowledge—we expect that we will have follow-up questions and clarifications about the patients' and providers' responses. Therefore, the study-end focus group meetings will focus on elaborating the participants' responses from the measures mentioned previously and encouraging the participants to share their experiences and opinions. We also aim to gather more specific input and explanation of the system's function, use, and suggested improvements.

Data Analysis

Baseline measures will be described using descriptive statistics. We assume that some variables will differ between participants with different types of diabetes due to the limited size of the study population.

Analysis of responses for all standardized tests will follow the scoring guidelines provided with each measurement tool. Postconsultation questionnaires will be assessed quantitatively and qualitatively, depending on the question type. The transcripts from the study-end focus group meetings will be analyzed using inductive thematic analysis to contextualize the quantitative results. Paired *t* tests will be used to compare all quantitative baseline (0 months) and study-end (6 months) measures. Correlation analysis will be used to assess relationships between quantitative and coded qualitative variables, when possible.

Results

Ethical Approval

The protocol, questionnaires, interview guides, recruitment material, and other adjoining study material have been submitted to the Regional Committees for Medical and Health Research Ethics for Northern Norway, who found the study exempt from their purview of approval. Instead, the study was declared and approved by the Personvernombudet (Personal Data Protection Officer) at UNN.

Funding

This study is part of the first author's PhD program and has been funded through a larger project, entitled "The Full Flow of Health Data Between Patients and Health Care Systems (2016-2020)," by the Research Council of Norway (number 247974/O70).

Progress to Date

Recruitment for this six-month study began in October 2018. As of September 2019, we recruited 13 GPs, two diabetes nurses at two hospitals, and eight patients. We expect all results to be collected by March 2020. We will then have results about patient and provider usage of the technologies, collected automatically, as well as their reported experiences. From these, we can identify whether the tested system met their individual needs and potential improvements needed to facilitate collaboration in diabetes care consultations. Results will also include the impact of collaborative use on the patients' clinically measured data from mHealth tools, as well as their measured health and wellness.

Discussion

Collaboration Between Patients and Providers

The described Full Flow mixed method study is the final phase of the Full Flow project. Previous phases of this project engaged individuals with types 1 and 2 diabetes, and a variety of HCPs, in iterative and experience-based activities to design the studied FullFlow data-sharing system. During these initial phases, the concepts of end-user perspective and collaboration between patients and providers, not only in clinical practice but also in research, was emphasized.

Although many studies and commercially available systems involving shared patient-gathered data focus on the provider's interpretation of the information, we believe that it is not only possible but necessary to encourage more collaboration between and contribution from both parties in mHealth interventions and care practice. Through our choice of methods and measures, we aim to exemplify the importance of accounting for the unique additional needs and opportunities of mHealth in research practice.

True Shared Decision Making

Shared decision making is described as patients and their HCPs working together to collaborate on the process of making health decisions [45]. However, most interventions describe this process with HCPs taking on the bulk of the decision making [46]. Instead, the patient is queried about their goals and preferences, acting mostly as an information source for the HCP. This lack of a true, equal partnership between patients and HCPs has been cited as mainly due to time constraints and lack of patient engagement or knowledge of their health situation [47]. This highlights the importance of using a patient's capacity and willingness to contribute to this process.

Today, patients' use of mHealth and the ability of these technologies to enable collecting and sharing of patient-gathered data make true shared decision making possible. Sharing patient-gathered data allows for a more balanced and

patient-initiated process of developing recommendations for self-management (ie, tasks that are performed by the patient on a daily basis).

Other Measures Are Needed

Within research, we must also adapt to the new situation that mHealth creates. A major challenge of understanding the effects of mHealth interventions is determining which traditional measures are applicable and which others are needed. The World Health Organization (WHO) is an example of several attempts to develop a comprehensive set of information that is needed from mHealth intervention studies. In addition to the traditional usability reports for new health technologies, the mERA (mHealth Evaluation, Reporting and Assessment) checklist also calls for evidence of barriers and facilitators to participants' access to the intervention (eg, "factors that may limit the users' ability to use the intervention") as well as its potential to be implemented into clinical care [48]. The dynamic network of interactions that mHealth represents calls for more than pre- and postintervention measurements. In this context, where patients can use several tools and services continuously in their everyday lives, it is no longer sufficient to merely understand what has changed and by how much [49]. This is our opportunity to invite not just patients and their devices but also their HCPs to participate in considering and understanding the interactions within and outside of clinical practice.

Not only has mHealth provided researchers with a more informed patient, it has also provided us with ways of tracking how they use mHealth (eg, by analyzing app and system's usage logs) [50]. These allow us to more effectively observe and record patients' self-management tasks and health measures, their data shared during consultations, and other factors that static questionnaires are not able to collect. One of these factors, which now plays an even more crucial role than before, is the motivation to be more involved in the data collection and sharing process. The relationship—now hopefully, collaboration—between patient and provider is not only something that can change but also something that can play a role in patients' motivation to engage in their health [51,52]. By including standardized psychological questionnaires with the other measures of patients' well-being, health, and self-management activity, we can contribute to a better understanding of this relationship. The planned study-end focus groups will allow us to elaborate on why some of these changes are happening and provide insight from all the participants about the context of their decisions.

Conclusion

In this study, we aim to address and understand the nuances of mHealth. By including measures of what has changed, including how and why, we can begin to more effectively and accurately explore the impacts of mHealth on not only the before and after measures but also events during the intervention itself. In addition to the relevant research communities, the information gained from this study will inform our electronic health record vendor partners and both The Norwegian Directorate of eHealth and overarching Ministry of Health and Care Services [53], which will better prepare Norway, and other countries, when forming future health systems that support mHealth integration.

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Authors' Contributions

Coauthors Bradway, Årsand, Joakimsen, Hartvigsen, and Giordanengo contributed to the application for funding, and many of the authors contributed to the study administration and design. All authors have approved the protocol and the presented manuscript. As part of their individual PhDs, Alain Giordanengo has been the main contributor to the working version of the FullFlow data-sharing system, and Meghan Bradway has been the main contributor to the methods and perspectives necessary for this mHealth intervention. Eirik Årsand serves as the project manager and main supervisor to the PhD candidate, Meghan Bradway, while Gunnar Hartvigsen is the main supervisor of Alain Giordanengo. Anne Helen Hansen played a significant role in the recruitment of the health care professionals, as well as insight into the general practitioners' working environment. Pietro Randine maintained the study administration platform and provided oversight of the data collection and structuring process in preparation for analysis. Astrid Grøttland was the project officer, overseeing practicalities, while Ragnar Joakimsen contributed to valuable insight into the hospital working environment and diabetes services offered to patients today.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Informed consent form.
[DOCX File , 41 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Scheduled follow-up messages to patient participants.
[DOCX File , 17 KB-Multimedia Appendix 2]

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Abbreviations

GP: general practitioner
HbA_{1c}: glycated hemoglobin
HCP: health care provider
UNN: University Hospital of Northern Norway

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Appendix A

A researcher’s toolbox

Appendix A. A researcher's toolbox

1 Established resources, methods and measures of medical research

In this section, I introduce established approaches, resources, methods and measures that we have to choose when planning any health intervention study. I present those that are relevant and commonly used for health interventions involving patients or HCPs for the treatment or self-management of a chronic illness. I will summarize the definitions, pros and cons of these research practices. In doing so, I aim for you, the reader, to understand the process we go through to choose the appropriate study design, methods and measures. In the following section, I will exemplify specific and state-of-the-art research approaches and tools that are being applied to mHealth intervention research, which use traditional approaches, this "toolbox", as a foundation.

1.1 Research approaches and study designs

Research approaches and study designs are dependent on the field of study. These narrow the ways in which to address a research problem including: what questions to ask, whom or what to "ask", how to ask them, in what setting to seek these answers and how to approach data collection and analysis. For example, while Logical Research approaches are more commonly used in mathematics, qualitative approaches focus more on exploring aspects of society, human behaviour, decision-making etc. (1). Jason and Reed, in their paper "The use of mixed methods in studying a chronic illness", they perfectly summarized the benefits of the different approaches to research when they wrote: "quantitative procedures have the most power to appeal to collaborators in funding and policy, while qualitative studies are more likely to empower community members and gain insights about how to identify and work with participants" (2).

Qualitative (constructivist approach): the aim of this approach is to understand or explore human experience or social occurrences, based on the notion that reality is subjective. This involves observing and describing what changes occur for individuals or groups, how these individuals experience the changes and explaining why they may be occurring. The geographical setting, culture, social norms, political structure or even fashion trends in which these individuals exist are often considered in parallel with the observations or feedback, i.e. data that are gathered (3).

Pros: explanatory, e.g. can help explain participants' motivations, and intentions, data can be continuous and/or universal for participants, e.g. beliefs. *Cons:* no way to conclusively and objectively measure the amount something has changed, analysis is largely biased based upon the formal and informal backgrounds of those conducting the study, not considered to be an approach of high enough rigor to influence healthcare policy or practice change.

Quantitative (positivist approach): the aim is to measure the difference between distinct, often numerical, outcomes and interpret them as "X cause", or independent variables, resulted in "Y effect", or dependent

variables. Depending on the study, there can be several X's and Y's measured at once. This often involves organizing a study so that enough variables are controlled and accounted for statistical analyses to be able to conclusively determine to what degree the X variables were associated with the Y variables (4).

Pros: measurable, objective, conclusive, e.g. can say decisively how much something has changed and to what extent it has changed in relation to other measured variables, reproducible based on specific, validated and dictated methods, low bias, considered to be an approach of high enough rigor to influence healthcare practice and/or policy. *Cons:* cannot explain how or why changes occurred, data can only be gathered at distinct points in time.

Mixed-methods: the aim of this approach is to explain a situation more comprehensively than qualitative or quantitative on their own. This involves combining both qualitative and quantitative data based on theoretical frameworks for or assumptions about how these types of data affect one another (4).

Pros: can help to explain not only what has changed but also how and why, combines the benefits of both qualitative and quantitative approaches. *Cons:* difficult to reproduce, analysis of different data types are, to an extent, subjective based upon the theoretical framework or assumptions made, not considered to be an approach of high enough rigor to influence healthcare policy or practice change.

Participatory action research: as the most recent addition to the toolkit of research approaches, participatory research was originally based upon research about what users wanted, performed in public sectors such as commerce, marketing and business (5). This form of research is based on involving the "end-users", i.e. those stakeholders who will be affected by or use the outcome, in the decision-making throughout the design, development and testing phases of whatever the end result aims to be, e.g. a product, service or improvement to existing system (6).

Pros: has a greater chance of the outcome becoming a useful and used product or service because the needs and considerations, of those who will be using it, have been taken into account. *Cons:* difficult to reproduce, there is a great possibility that several influencing variables were/could not be accounted for, not considered to be an approach of high enough rigor to influence healthcare policy or practice change.

1.2 Data and associated analysis

Methods are established protocols for how data can be collected, measured and analysed. While in the medical realm, repeatable, measurable and objective quantitative data is king, as mentioned in the section above, each type of data fills in a different piece of the puzzle that we are trying to understand – each of which must be treated differently. We cannot statistically analyse two sentences, nor can we completely explain why someone's physical activity habits changed by measuring the distance they ran that week. How the data is collected (from whom or what), measured and analysed change how we can and should interpret the outcome of research intervention studies. In other words, no amount of data can be useful without a way to structure and interpret it in context.

Interviews and focus groups: Interviews are conducted between a research team member and a participant in the study. Interviews can be one-on-one or group interviews. Focus groups involve multiple

participants in a study, usually grouped by like participants, e.g. patients vs. HCPs. Data are often collected as research team member observations, audio and/or visual recordings, which are then transferred to text for analysis.

Qualitative analysis can focus on describing the feedback, experiences, ideas and physical/written material through one of five methods: i) content analysis, whereby data are grouped and tabulated, e.g. pros and cons, ii) narrative analysis, whereby participants' stories are described in context with one another, e.g. a set of stories given by the same family describe a year in their life, iii) discourse analysis, whereby the details of a conversation or written text are account for, e.g. speech including every pause or natural language trait, iv) framework analysis, whereby iterative stages of processing the data occur to structure, codify, map and interpret the data, or v) grounded theory, whereby an idea or theory is based upon the set of data that was collected and then compare to similar situations to see if that established theory holds.

Co-design: is a form of participatory research whereby, in the case of healthcare, patients, their family, friends and formal HCPs are gathered to not only say what needs to change in a self-management technology, medical process or treatment, but how to change it and, in some cases, factors that need to be taken into account to correctly measure if that change is successful (5). Data can be gathered as audio and/or visual recordings of meeting(s), participants' drawings or paper-prototypes, pictures, and written notes. Analysis is performed in the same way as described above under Interviews and focus groups.

Questionnaires and surveys: these can be both or either quantitative and/or qualitative data depending on the questionnaire type and the data collected. They can also be standardized, i.e. iteratively tested and validated through several studies, participant groups and settings (7), or designed by the author for use in a specific study. A questionnaire is meant to explore a participants' perspective, and collects open-ended or free-written responses as its data, is an example of an author-designed qualitative questionnaire. If these responses are ordered and assigned numerical values, they can be analysed using statistical methods (8). For standardized questionnaires, it is most common to perform statistical analysis to measure the change in responses as a distinct value. Examples of these standardized ordinal questionnaires include customer satisfaction and diagnostic questionnaires, e.g. Diabetes related distress scale (9). In these cases, even if the response choices are worded as a scale from "agree" to "disagree", these options correspond to ordinal values, i.e. "1-disagree" and "3-agree", whereby a change in response indicates more or less agreement with a given statement. Analysis for standardized questionnaires can be performed by statistically comparing these responses between participants and/or between repeated measurements over time. Statistical models are applied based on the type of data, when the data was collected, what or whom is being compared in the analysis and assumptions about the population from which the data was collected. For qualitative data, analysis can follow the same approaches as those of transcripts from co-design, interviews or focus groups, as described above.

Quantitative measurements: these include anything that can be counted. Within health intervention research, this often involves pre-post or repeated measures of clinical data, e.g. blood pressure, or indications of quantifiable status, e.g. standardized questionnaires to measure behavioural decisions (10). These are often collected via standardized procedures, e.g. blood pressure measured via a medical grade

blood pressure cuff at the clinic by a nurse practitioner in a specific manner, or validated diagnostic questionnaires, e.g. scales for self-efficacy, anxiety, depression etc. Statistical analysis is performed in the same way as that of standardized questionnaires or those that collect numerical data (11). If there are too few participants or responses or too many gaps in the data, alternative methods can be used such as descriptive statistics, whereby the data itself is summarized and/or the magnitude of change is simply described in conjunction with any other gathered data, instead of compared using a statistical model. Descriptive statistics are also generally used to report a summary of all collected data before formal or in-depth analysis is performed.

2 References

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Appendix B

Ethical approval documents for PhD-related studies

1. Exempt from REC approval (Co-design workshops): "2017/1759 Workshop for design av datadelingssystem"
2. PVO approval (Co-design workshops): "GODKJENNING AV BEHANDLING AV PERSONOPPLYSNINGER"
3. Exempt from REC approval (mixed-method study): "2018/719 Studie av datadelingssystem mellom diabetespasienter og helsevesenet"
4. PVO approval (mixed-method study): "ANBEFALING – BEHANDLING AV PERSONOPPLYSNINGER"
5. Finnmark PVO approval to include Finnmark Hospital (mixed-method study): "ANBEFALING – BEHANDLING AV PERSONOPPLYSNINGER"

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord	Veronica Sørensen	77620758	22.09.2017	2017/1759/REK nord
			Deres dato:	Deres referanse:
			15.09.2017	

Vår referanse må oppgis ved alle henvendelser

Eirik Årsand
Postboks 35

2017/1759 Workshop for design av datadelingssystem

Vi viser til innsendt fremleggingsvurderingsskjema datert 15.09.2017.

Prosjektleder: Eirik Årsand

Bakgrunn og formål (original):

Målet med workshoppene:

Målet med disse workshoppene er å samle pasienter/superbrukere med diabetes type 1 og type 2, og helsepersonell – for å diskutere og designe funksjonalitet som et datadelings system, der pasienter kan dele sine egeninnsamlede data under konsultasjonen med helsepersonell (typisk sykepleiere).

Spørsmål vi ønsker besvart:

1. Hvordan en konsultasjon der pasienten har data å vise helsepersonell ideelt bør foregå.

2. Hvordan disse data bør vises slik at både pasient og helsepersonell forstår pasientens helsesituasjonen på en best mulig måte.

3. Hvordan et slikt datadelingssystem kan designes slik at man oppnår en best mulig beslutningsstøtte for diabetesbehandling.

4. Hvordan systemet kan støtte en best mulig oppfølging av pasientens egenbehandling og helsesitasjon.

Spørsmålene vil bli besvart under workshoppene ved å diskutere disse med 3-4 pasienter (første workshop type 2 og andre workshop type 1) første del av dagen, deretter diskuter det med 3-4 helsepersonell separat, og til slutt bringe alle sammen og diskutere disse i en "co-design" sesjon. Det vil bli tatt lydopptak av diskusjonene og analysert i ettertid. I tillegg vil vi be deltakerne å skrive ned forslag til spørsmålene. Forskerne vil også gjøre notater av reaksjonene og engasjement av alle deltakerne under de ulike diskusjonene.

Framleggingsplikt
De prosjektene som skal framlegges for REK er prosjekt som dreier seg om "medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger", jf. helseforskningsloven (h) § 2. "Medisinsk og helsefaglig forskning" er i h § 4 a) definert som "virksomhet som utføres med

vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom". Det er altså formålet med studien som avgjør om et prosjekt skal anses som framleggelsespliktig for REK eller ikke.

I dette prosjektet beskrives formålet som å samle pasienter/superbrukere med diabetes type 1 og type 2, og helsepersonell i workshoper for å diskutere og designe funksjonalitet som et datadelings system, der pasienter kan dele sine egeninnsamlede data under konsultasjonen med helsepersonell (typisk sykepleiere).

REK anser at slik prosjektet fremstår nå , faller det ikke inn under definisjonen av de prosjekt som skal vurderes etter helseforskningsloven.

Godkjenning fra andre instanser
Det påhviler prosjektleder å undersøke hvilke eventuelle godkjenninger som er nødvendige fra eksempelvis personvernombudet ved den aktuelle institusjon eller Norsk senter for forskningsdata (NSD).

Veiledning vedrørende framleggingsplikt
Etter søknaden fremstår prosjektet ikke som et medisinsk og helsefaglig forskningsprosjekt som faller innenfor helseforskningsloven. Prosjektet er ikke framleggingspliktig, jf. hfl § 2.

Prosjektleder skriver at «Siden dette omsøkte workshop aktiviteten er del av et større prosjekt, der formålet er å forbedre kommunikasjonen mellom pasient og helsepersonell, som igjen kan forbedre pasientenes helse, vil vi undersøke om vi skal søke REK eller ikke.»

Dersom det er slik at data som samles inn i dette prosjektet og som defineres som helseopplysninger ,skal benyttes i et senere forskningsprosjekt, vil REK anbefale at dette kommer eksplisitt frem i samtykkeskrivet til deltagerne.

Videre har prosjektleder skrevet at «Vi vil også forsikre oss om at det er grei praksis å kompensere pasientene med tapt arbeidsfortjeneste på 2000». Det uttales i forarbeidene til helseforskingloven at et honorar ikke må vær av en slik art og størrelse at det er eget til utilbørlig påvirkning av deltager. Selv om 2000 kroner isolert sett kan høres mye ut, må prosjektleder vurdere beløpets størrelse opp mot hvor mye innsats og tid som er påkrevet av hver enkelt deltager.

Vi ber om at alle henvendelser sendes inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

May Britt Rossvoll
Sekretariatsleder

Veronica Sørensen
seniorrådgiver

Kopi til:

UNIVERSITETSSYKEHUSET NORD-NORGE
DAVVI-NORGGA UNIVERSITEHTABUOHCCEVIESSU

PERSONVERNOMBUD

Til
Eirik Årsand
Nasjonalt senter for e-helseforskning

Deres ref.:	Vår ref.:	Saksbehandler/dir.tlf.:	Dato:
	2017/5235	Kristin Andersen/77626506	27.9.2017

GODKJENNING AV BEHANDLING AV PERSONOPPLYSNINGER

Det vises til Meldeskjema for forskningsprosjekt, kvalitetsprosjekt og annen aktivitet som medfører behandling av personopplysninger som er melde- eller konsesjonspliktig i henhold til helseregisterloven og personopplysningsloven med forskrifter, mottatt 15.9.2017
Meldingen gjelder prosjektet/registeret:

Nr. 0751

Navn på prosjektet: *Workshop for design av datadelingssystem, del av prosjektet: «Full Flow of Health Data Between Patients and Health Care System»*

Prosjektet er et ***forskningsprosjekt*** hvor Universitetssykehuset Nord-Norge HF er behandlingsansvarlig.

Formål: «*Målet med disse workshoppene er å samle pasienter/superbrukere med diabetes type 1 og type 2, og helsepersonell – for å diskutere og designe funksjonalitet som et datadelings system, der pasienter kan dele sine egeninnsamlede data under konsultasjonen med helsepersonell (typisk sykepleiere, fastleger og spesialister).»*

REK nord sak 2017/1759 har vurdert prosjektet, og finner at behandlingen av personopplysningene ***ikke faller inn under medisinsk- og helsefaglig forskning etter Helseforskningsloven.*** Prosjektet trenger ikke REK godkjenning. Behandlingen vil være regulert av § 7-27 i Personopplysningsforskriften og hjemlet etter Helseregisterloven § 6, jf. Personopplysningsloven § 11. Forskningsprosjekt vil som hovedregel kreve samtykke.

PVOs anbefaling forutsetter at prosjektet gjennomføres i tråd med de opplysningene som er gitt i henhold til Personopplysningsloven og Helseregisterloven med forskrifter.

PVO gjør oppmerksom på at dersom registeret skal brukes til annet formål enn det som er nevnt i meldingen, må dette meldes særskilt.

PVO skal ha melding når registeret er slettet. PVO skal også ha melding dersom registeret ikke er slettet eller ikke ferdig behandlet innen 3 år.

Postadresse: UNN HF 9038 TROMSØ
Avdeling: Kvalitets- og utviklingssenteret
Besøksadr.:
Fakturaadr: UNN HF, c/o Fakturamottak, Postboks 3232, 7439 Trondheim
Telefon: 77 75 58 55
Internett: www.unn.no
E-post: personvernombudet@unn.no

Med hjemmel i Personopplysningsforskriften § 7-12 godkjenner PVO at behandlingen av personopplysningene settes i gang som beskrevet.

Med vennlig hilsen

UNIVERSITETSSYKEHUSET NORD-NORGE HF

Kristin Andersen
Personvernombud forskning

Kopi: Stein Olav Skrøvseth

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord			07.05.2018	2018/719/REK nord
			Deres dato:	Deres referanse:
			20.03.2018	

Vår referanse må oppgis ved alle henvendelser

Eirik Årsand
Postboks 35

2018/719 Studie av datadelingssystem mellom diabetespasienter og helsevesenet

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK nord) i møtet 19.04.2018. Vurderingen er gjort med hjemmel i helseforskningsloven § 10.

Forskningsansvarlig institusjon: Universitetssykehuset Nord-Norge HF
Prosjektleder: Eirik Årsand

Prosjektleders prosjektomtale (original):
Formålet med studien er å gi et teste et system for deling av pasientgenerert data under kliniske konsultasjoner mellom personer med Type 1 og Type 2 diabetes, og helsepersonell, og vurdering av dette. Metoden brukt i studien vil være måling av både systemets funksjonalitet og brukbarhet, og en vurdering av helseeffekt og effekt på pasient-kliniker forhold, gjennom spørreskjema, journalsystem (HbA1c og blodtrykk), intervju og fokusgrupper. Systemet under utprøving er basert på en egenutviklet forskningsapp for innsamling av pasientdata og et egenutviklet sikkert system for visning av informasjon basert på disse data. Studien vil demonstrere mulighetene og effektene ved en ny måte å fasilitere en pasient-sentrert diskusjon omkring egenbehandling basert på egeninnsamlede data. Vi vil også undersøke om dette vil øke pasientenes engasjement i egen helse.

Vurdering

Framleggingsplikt
De prosjektene som skal framlegges for REK er prosjekt som dreier seg om "medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger", jf. helseforskningsloven (h) § 2. "Medisinsk og helsefaglig forskning" er i h § 4 a) definert som "virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom". Det er altså formålet med studien som avgjør om et prosjekt skal anses som framleggelsespliktig for REK eller ikke.

Selv om det skal innhentes helseopplysninger og at et av delmålene angis som «reseraching the effects of the designes solutions on health outcomes» vurderer REK at formålet med prosjektet ikke er å fremskaffe ny kunnskap om helse og sykdom, men uttesting av et datadelingssystem med diabetes som «case». Prosjektet skal således ikke vurderes etter helseforskningsloven.

Godkjenning fra andre instanser
Det påhviler prosjektleder å undersøke hvilke eventuelle godkjenninger som er nødvendige fra eksempelvis personvernombudet ved den aktuelle institusjon eller Norsk senter for forskningsdata (NSD).

Vedtak
Etter søknaden fremstår prosjektet ikke som et medisinsk og helsefaglig forskningsprosjekt som faller innenfor helseforskningsloven. Prosjektet er ikke framleggingspliktig, jf. hfl § 2.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningsloven § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK nord. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Kopi til: Stein.Olav.Skrovseth@ehealthresearch.no

Eirik Årsand
Nasjonalt senter for e-helseforskning

Deres ref.:	Vår ref.:	Saksbehandler/dir.tlf.:	Dato:
	2018/4027	Kristin Andersen/776 26506	9.8.2018

ANBEFALING – BEHANDLING AV PERSONOPPLYSNINGER

Det vises til Meldeskjema for forsknings- og kvalitetsprosjekt og annen aktivitet som medfører behandling av personopplysninger, mottatt 25.5.2018 samt avklaringer i e-post senere

Meldingen gjelder prosjektet/registeret:

Nr. 02080
Navn på prosjektet: *FullFlow - Full Flow of Health Data Between Patients and Health Care Systems*

Prosjektet er et ***forskningsprosjekt*** basert på samtykke, hvor Universitetssykehuset Nord-Norge HF er behandlingsansvarlig.

> ***Formål:*** *Formålet med studien er å gi et teste et system for deling av pasientgenerert data under kliniske konsultasjoner mellom personer med Type 1 og Type 2 diabetes, og helsepersonell, og vurdering av dette. Metoden brukt i studien vil være måling av både systemets funksjonalitet og brukbarhet, og en vurdering av helseeffekt og effekt på pasient-kliniker forhold, gjennom spørreskjema, journalsystem (HbA1c og blodtrykk), intervju og fokusgrupper.*
> *Systemet under utprøving er basert på en egenutviklet forskningsapp for innsamling av pasientdata og et egenutviklet sikkert system for visning av informasjon basert på disse data. Studien vil demonstrere mulighetene og effektene ved en ny måte å fasilitere en pasient-sentrert diskusjon omkring egenbehandling basert på egeninnsamlede data. Vi vil også undersøke om dette vil øke pasientenes engasjement i egen helse.*

REK har vurdert prosjektet, og finner at behandlingen av personopplysningene ***ikke faller inn under medisinsk- og helsefaglig forskning etter Helseforskningsloven.*** Behandlingen vil være hjemlet etter Helseregisterloven § 6, jf. Personopplysningsloven § 10.

PVO har på bakgrunn av tilsendte meldeskjema med vedlegg registrert prosjektet og forutsetter at prosjektet gjennomføres i tråd med de opplysningene som er gitt og i henhold til Personopplysningsloven og Helseregisterloven med forskrifter.

PVO forutsetter at infoskrivet oppdateres med å fjerne henvisning til REK-godkjenning. Når/hvis man tar i bruk PAM-løsning fra USA må dette meldes som endring til PVO og oppdateres i infoskrivet. Oppdatert infoskriv og avtale med Insignia (USA) må vedlegges endringsmeldingen.

PVO gjør oppmerksom på at dersom registeret skal brukes til annet formål enn det som er nevnt i meldingen, må dette meldes særskilt.

PVO skal ha melding når registeret er slettet. PVO skal også ha melding dersom registeret ikke er slettet eller ikke ferdig behandlet innen 3 år.

Med hjemmel i Personopplysningsloven § 10, jf. Personvernforordningens artikkel 39, anbefaler PVO at behandlingen kan iverksettes.

Med vennlig hilsen

UNIVERSITETSSYKEHUSET NORD-NORGE HF

for Personvernombudet

Kristin Andersen

Kopi: Senterleder Stein Olav Skrøvseth

FINNMARKSSYKEHUSET
FINNMÁRKKU BUOHCCIVIESSU

PERSONVERNOMBUD

Eirik Årsand
Nasjonalt senter for e-helseforskning

Deres ref.:	Vår ref.:	Saksbehandler/dir.tlf.:	Dato:
	2018/2558	Eva Henriksen / 95731836	7.11.2018

ANBEFALING – BEHANDLING AV PERSONOPPLYSNINGER

Det vises til Meldeskjema for forsknings- og kvalitetsprosjekt og annen aktivitet som medfører behandling av personopplysninger, mottatt 2.10.2018.

Meldingen gjelder prosjektet/registeret:

> ***Nr. 036***
> ***Navn på prosjektet:*** *FullFlow - Full Flow of Health Data Between Patients and Health Care Systems*

Prosjektet er et ***forskningsprosjekt*** hvor Universitetssykehuset Nord-Norge HF er dataansvarlig og Finnmarkssykehuset HF deltar.

> ***Formål:*** *«Formålet med studien er å et teste et system for deling av pasientgenerert data under kliniske konsultasjoner mellom personer med Type 1 og Type 2 diabetes, og helsepersonell, og vurdering av dette. Metoden brukt i studien vil være måling av både systemets funksjonalitet og brukbarhet, og en vurdering av helseeffekt og effekt på pasient-kliniker forhold, gjennom spørreskjema, journalsystem (HbA1c og blodtrykk), intervju og fokusgrupper.*
> *Systemet under utprøving er basert på en egenutviklet forskningsapp for innsamling av pasientdata og et egenutviklet sikkert system for visning av informasjon basert på disse data. Studien vil demonstrere mulighetene og effektene ved en ny måte å asilitere en pasient-sentrert diskusjon omkring egenbehandling basert på egeninnsamlede data. Vi vil også undersøke om dette vil øke pasientenes engasjement i egen helse.»*

REK har vurdert prosjektet og finner at behandlingen av personopplysningene ***ikke faller inn under medisinsk- og helsefaglig forskning etter Helseforskningsloven.*** Prosjektet trenger ikke REK godkjenning. Behandlingen vil være hjemlet etter Helseregisterloven § 6, jf. Personvernforordningen artikkel 6.1.a) og artikkel 9.2.j).

Personvernombudet (PVO) ved UNN har tidligere tilrådd samme prosjekt hos UNN (prosjekt nr. 02080, ref. 2018/4027). Meldeskjemaet til PVO i Finnmarkssykehuset inneholdt ingen egne vedlegg, men vedleggene sendt til PVO UNN gjelder også i dette tilfelle.

PVO har på bakgrunn av tilsendt meldeskjema, samt vedleggene til meldingen sendt til PVO UNN, registrert prosjektet og forutsetter at prosjektet gjennomføres i tråd med de

opplysningene som er gitt i henhold til Personopplysningsloven og Helseregisterloven med forskrifter.

PVO skal ha melding når prosjektet er slutt. PVO skal ha melding hvert 3. år inntil prosjektet er avsluttet.

Med hjemmel i Personvernforordningens artikkel 39, anbefaler PVO at behandlingen kan iverksettes.

Med vennlig hilsen

FINNMARKSSYKEHUSET HF

For Personvernombudet

Eva Henriksen

Kopi: Kvalitets- og utviklingssjef Anne Grethe Olsen

Appendix C

Results of the 2016 online survey and HCP co-design workshop

"Differentiating Presentation Of Patient-gathered Data Between Type 1 And 2 Diabetes During Consultations"

3-mg NG 15 minutes later (opposite nostril); 4) 2 concurrent 3-mg NG doses (both nostrils).

Results: 32 subjects were enrolled (T1D: 23, T2D: 9). Number of subjects who received Trts 1, 2, 3, 4 were 27, 28, 25 and 29, respectively. Baseline (BL) blood glucose was 40-181 mg/dL. For Trts 1-4, PK parameters of change from BL for glucagon were mean area under the curve 0-3 hrs: 2471, 4097, 4639, and 3611 hr·pg/mL, median T_{max}: 0.17, 0.33, 0.50, and 0.33 hrs; PD parameters of change from BL for glucose were mean area under the effect concentration 0-3 hrs: 157, 168, 190, and 194 hr·mg/dL, median T_{max}: 0.75, 1.00, 1.00, and 1.00 hrs. Repeated NG doses resulted in higher glucagon concentrations, but gave glucose responses comparable to single dose (Figure). The only serious adverse event (AE; cellulitis) was not drug-related. Most drug-related AEs were transient and resolved within 2 hours.

Conclusions: Although repeat dosing resulted in greater systemic glucagon exposure, it did not result in a meaningful increase in observed glucose response. All NG treatments were well-tolerated.

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DIFFERENTIATING PRESENTATION OF PATIENT-GATHERED DATA BETWEEN TYPE 1 AND 2 DIABETES DURING CONSULTATIONS

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Background and Aims: The integration of mobile health (mHealth) technology within medical practice is a discussion riddled with debate and unresolved questions. In addition to privacy and security is the question of how to present patients' mHealth self-gathered data during consultations. For chronic and resource-heavy illnesses, such as diabetes, it is necessary to consider adaptive formatting for the presentation of patients' sensor/app data to medical personnel, with the aim to determine sound strategies and formats for presentation during consultations.

Methods: Both an anonymous online patient survey as well as three workshops involving clinicians involved in diabetes treatment, EHR-vendors, patients and researchers were conducted. Diabetes patients in Norway answered questions related to experienced challenges and desired consultation discussion topics, given more time for discussing self-gathered data.

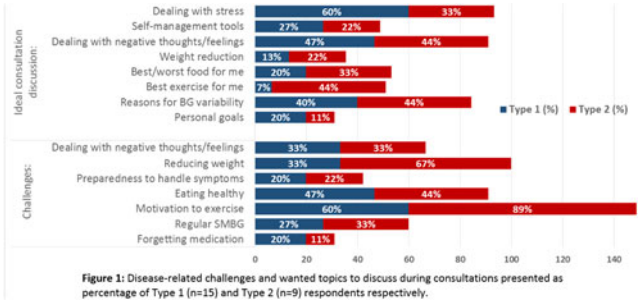

Figure 1: Disease-related challenges and wanted topics to discuss during consultations presented as percentage of Type 1 (n=15) and Type 2 (n=9) respondents respectively.

Table 1. Differences between how Type 1 and Type 2 patient-gathered data should be focused upon and presented during GP and Specialist consultations: main points and common preferences reported in workshops with health professionals.

Main points	Type 1 related consultations (specialist)	Type 2 related consultations (GP)
What data	Context of BG excursions, i.e. physical activity, diet and medication activities before and after excursions.	Long-term trends of health parameters related to patients' challenges, thus supporting discussion of behavior change, i.e. related to diabetes or other health priorities.
When should patients share data	Between 1 day and 1 week before consultation. Can discuss data in detail.	During consultation. Can spend only 1-3 minutes to receive & review data.
How to present data	Processed data, e.g. graphs and trends, from multiple self-management tools	Summaries of data related to patient's general or special health challenges as well as personal goals.
Common preferences for integrating data in primary & secondary practice		
Integration	Novel products/services must operate within existing technological infrastructure and workflows.	
Data preparation	Solutions must avoid sending "data noise", i.e. "unsolicited events" and information overload outside of consultations. Patients should prepare discussion points for the consultation based upon own review of data.	
Data storage & transfer	Data should only be entered into EHRs upon patient permission. Transfer between and within care teams should be on a higher or aggregate level to protect patients' privacy.	

Results: Individuals with Type 1 (n = 15) and Type 2 (n = 9) completed the survey (Figure 1). While ''motivation'' was a common challenge, stress management (Type 1), BG variability, exercise and mood (Type 2) were the most wanted consultation topics. The workshops revealed large differences in preferred ways of data presentation, e.g. GPs preferred quick ways of reviewing data during consultation, while specialist preferred to receive and review more detailed data before consultations (Table 1).

Conclusions: Due to numerous factors associated with diabetes, it is necessary to not only consider a patient's diabetes type and clinicians' specialties but also patients' personal challenges, resources, and capacity when preparing patient-gathered data for consultations. The Full Flow project (2016-19) will study use of dynamic data-formats for presenting patient-gathered data during consultations.

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THE IMPLEMENTATION OF MYSTAR CONNECT® CLINICAL INFORMATION SYSTEM IMPROVES INTERMEDIATE OUTCOMES IN 42498 PEOPLE WITH DIABETES

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Background and Aims: The Diabetes Network of Palermo District links all the public healthcare diabetes resources of Palermo District. Since 2012, DNPD implemented a Chronic Care Model (CCM) mainly based on the full sharing of clinical data between primary care resources and specialized diabetes centers, through a single clinical information system (MyStar Connect®). Aim of the present study is to assess if the implementation of MyStar Connect® was followed by an improvement of the management of people with diabetes.

Methods: Assessment of the trend of the proportion of people with diabetes who yearly (from 2012 until to 2015) achieved some target values of intermediate (primary) outcomes: HbA1C <7.0%; LDL <100 mmHg; systolic blood

Appendix D

Results of the grey literature search

"Frameworks for evaluating mHealth technologies lack patient focus"

Frameworks for evaluating mHealth technologies lack patient focus

Meghan Bradway[1,2], Konstantinos Antypas[1,3], Natalia Wroblewska[4], Jennifer Lee[5,] Eirik Årsand[1,2]

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Introduction

There have been many attempts to create multi-level frameworks for mHealth evaluation. However, due to the complex environment of mHealth technologies, there has been no consensus on a standard. With the aim of providing input for a consensus, we performed a review of different mHealth assessment frameworks.

Methods

Literature searches were performed in Google Scholar, Google and PUBMED for publically available descriptions of mHealth assessment efforts and strategies. Exclusion criteria included descriptions of single method "frameworks", e.g. questionnaires. The data extraction strategy is described in Figure 1.

Data extraction

- Framework name
- Country and/or responsible organization
- What is produced from the framework
- Process suggested by the framework for mHealth assessment
- Target audience/intended users of the framework
- Differentiation of technologies
- Criteria/characteristics of mHealth technology assessed

Figure 1. Descriptions of data extracted

Results

Three main types of frameworks were identified: implementation frameworks (n=20), assessment frameworks (n=28), and service frameworks (n=13). These frameworks are defined/described in Table 1. The most commonly covered areas in the implementation frameworks were security (n=18), privacy (n = 17), usability (n = 16), and user experience (n = 16). Target audiences included developers, policy-makers, researchers, and health professionals (Figure 2).

Table 1. Descriptions of the three main types of identified mHealth frameworks.

mHealth Implementation Frameworks*	mHealth Assessment Frameworks	mHealth Service Frameworks
• Offers detailed suggestions, strategies and criteria to assess an environments' readiness for mHealth implementation	• Offers 2+ methods - for a series of evaluation measures - to assess an individual or group of mHealth technologies	• Describes an organization's own services and products or assessing mHealth technologies
• Often include case studies or examples as well as practical tools, e.g. worksheets for the instruments to track and assess an environment for mHealth implementation	• Intended for use by mainly developers, clinicians, policymakers, and researchers	• Often includes a publicly published "Library", but the detailed processes used by the frameworks themselves are not often publicly available
• Intended for use by mainly policymakers, and medical groups * Mainly include mHealth assessment frameworks		• Intended for use by independent organizations and available for those who apply for/request an organization's services

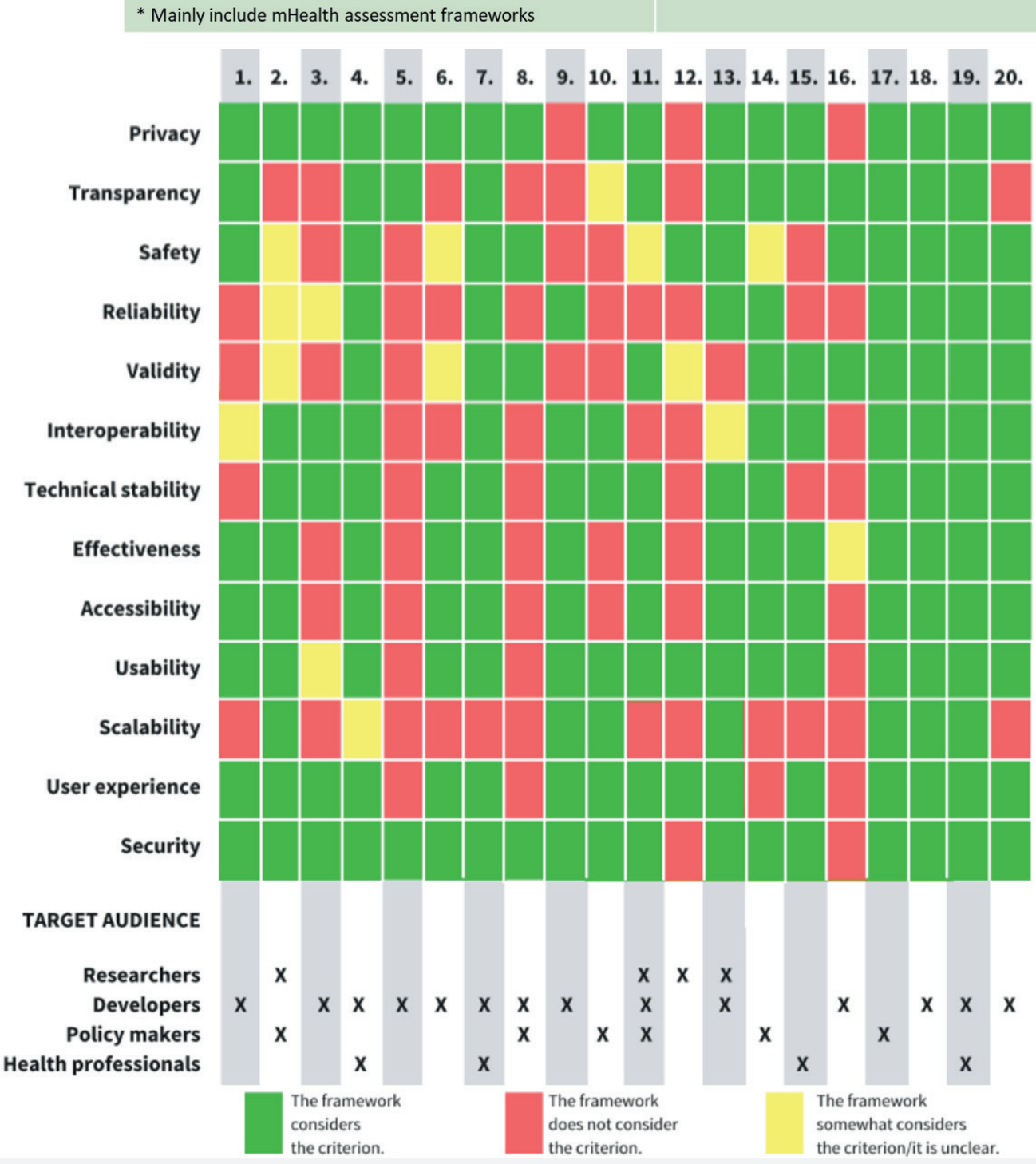

Figure 2. The extent to which domains were covered and which audiences were targeted by implementation frameworks.

Discussion

While user experience was considered a common priority for frameworks, with the most frequent users of mHealth being individual citizens, surprisingly few frameworks had this stakeholder group as its target audience.

Conclusion

Stakeholder-specific frameworks spanning a diversity of target audiences have both advantages and disadvantages, but overall, create a fragmented mHealth assessment landscape. It is clear that any one existing framework cannot be expected to assess all the different aspects of mHealth. In order to develop one comprehensive framework, or interoperable frameworks, coordination of stakeholder expertise is needed. As citizens are the most experienced and prevalent mHealth users, they must be involved in the development and have easy access to the framework(s).

Appendix E

Results of Tailoring project goal setting

"Goal-setting and duration of app use: selected results from the "Tailoring Type 2 Diabetes Self-Management" RCT"

Goal-setting and duration of app use: selected results from the "Tailoring Type 2 Diabetes Self-Management" RCT

Meghan Bradway[1,2], Alain Giordanengo[1,3], Håvard K. Blixgård[1], Silje C. Wangberg[4], Eirik Årsand[1,2]

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Introduction

Setting goals and seeing one's progress is a motivating factor in self-management. Here we present results from a study where participants were able to register and review self-management measures in either a tailored (Intervention group) and/or simple version (Control group) of a diabetes diary app.

Methods

Participants were randomized to the Control group (used the regular Diabetes Diary app for the first 3-months and the tailored version for 3-months) and Intervention group (used the tailored app for the full 6-months) (Figure 1). We compared the number and types of baseline-goals, reported via a questionnaire, and usage-patterns for those who registered in the app.

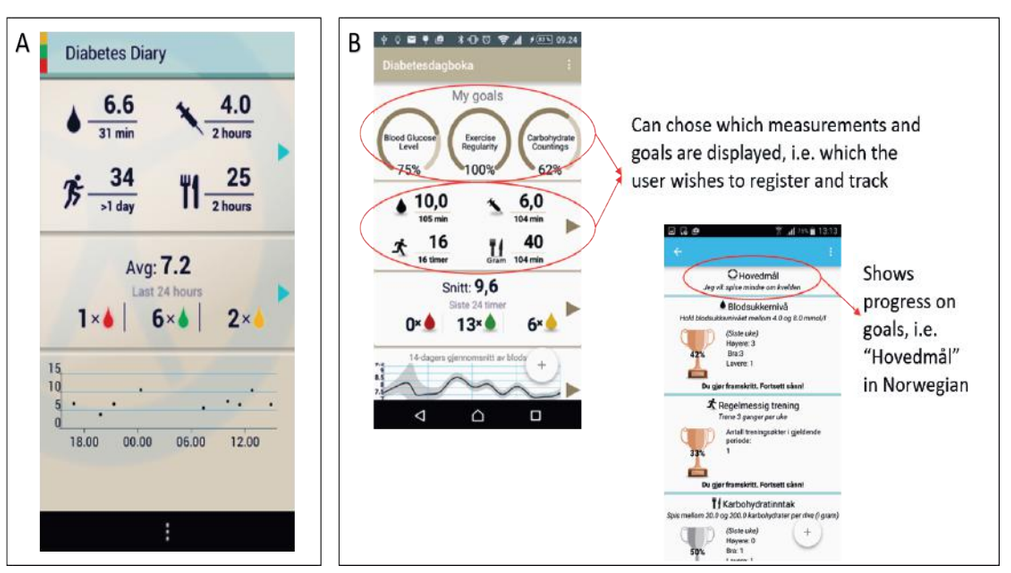

Figure 1.Illustration of the regular Diabetes Diary app (A) and Tailored Diabetes Diary app, including screen displaying progress on goals (B).app, including screen displaying progress on goals (B).

Results

While all participants set at least one goal (n=41), only half (n=20) made registrations in the app. No significant difference was found between groups in terms of number of goals or registrations. Those who made more "Registration types" than baseline "Number of goals" (n=12), used the app for, on average, 4.08-months. Those who made fewer "Registration types" than their baseline goals (n=8) used the app for 3.12-months (Table 1).

Table 1. Goals and registration patterns and duration of usage for those who registered in the app (n=20)

User*	Number of goals	Goals related to	Number of Registration types	Registrations related to…	Duration of use (months)
1	1	BG	2	Exercise, BG	6
2	1	Other (weight)	3	Exercise, food, BG	3
3	1	Food	2	Exercise, BG	6**
4	2	Exercise, BG	2	Food, BG	6
5	2	Exercise, BG	3	Exercise, BG, insulin	4
6	2	Exercise, BG	2	BG, insulin	4
7	2	Food, BG	2	BG, insulin	6**
8	3	Exercise, food, BG	3	Exercise, food, BG	3
9	3	Exercise, food, BG	2	Exercise, BG	6**
10	3	Exercise, food, BG	1	BG	5**
11	3	Exercise, food, BG	1	BG	5
12	3	Exercise, food, BG	2	BG, insulin	1
13	1	Food	2	Food, BG	1
14	1	BG	2	Food, BG	2
15	2	Exercise, BG	2	BG, insulin	2**
16	3	Exercise, food, BG	3	Exercise, food, BG	6
17	3	Exercise, food, insulin	2	Exercise, BG	4
18	3	Exercise, food, other (weight)	2	Exercise, BG	2
19	3	Exercise, food, BG	1	BG	1
20	3	Exercise, food, BG	2	Exercise, BG	1

*Anonymous **Not continuous

Discussion

Setting goals seems to contribute to duration and focus of self-management app-usage. Also, not only patients but researchers and clinicians must make tailored and realistic goals for each patient - evidence for which includes those who were unable to or did not register as many measures as they intended.

Conclusion

This analysis not only suggests that goal setting may imply future app-use, it also demonstrates what more can be explored by focusing analysis on those who chose, themselves, to use apps in addition to comparing assigned intervention groups.

Appendix F

Results of Tailoring project usage-log analysis

"What can be Learned by Analyzing Patient-gathered Data From a Self-Management Diabetes App"

The Official Journal of

ATTD

Advanced Technologies & Treatments for Diabetes CONFERENCE

20-23 FEBRUARY, 2019 I BERLIN, GERMANY

Table 1. Users' feedback on what was perceived as most useful

Group	3 month	6 month
Control (n=16)	n=12 • A curve of your blood glucose levels for different time periods • Ability to get a full overview • Ability to keep track of how food and exercise affect my BG • Curve on measurements and ability to transfer activity • Promotes own discipline	n=6 • The curve of fasting blood sugar, and all other measurements • Integration with physical activity apps • Good overview. • The whole app. • Graph and average calculations • Overview of blood glucose over time, and ability to track weight, exercise and diet.
Intervention (n=25)	n=6 • Goal setting • Curves and BG over time • Average Measurement of Blood Sugar	n=5 • Curve of BG for the last day • Follow-up of exercise, weight control and blood sugar levels. • Graphs

Table 2. Users' suggestions for improving the app

Group	3 month	6 month
Control (n=16)	n=9 • Make it easier to enter food than just grams • Ability to connect with other activity apps • More options for physical activity • Ability to enter comments under each registration • Ability to post other drugs than insulin • More options for calculations • Ability to enter HbA1c once you have measured it	n=7 • More options for those who use insulin • More frequent feedback from the app • Ability to write down meals without weighing the food • Ability to retrieve statistics • Ability to extract data in a spreadsheet • Ability to connect with other activity apps • Make it easier to enter food than just grams* • Ability to enter HbA1c*
Intervention (n=25)	n=7 • More frequent feedback from the app • Make it easier to enter food than calories • Ability to register food by scanning [bar codes] • It is difficult to enter registrations after the fact • Reminders for SMBG • Ability to connect with other activity apps	n=4 • Ability to automatically measure BG • Reminders for SMBG • Simpler interface • Ability to adjust "ranges" for "in-range" etc. on the BG graphs • Ability to register food by scanning [bar codes]

*More frequent comments on this than at 3-months

to the following standardized questionnaires: WHO-5, Summary Of Diabetes Self-Care Activities Assessment (SDSCA), and Perceived Competence Scale (PCS). The app continuously collected patient-gathered self-management data.

Results: Participants in both groups offered written feedback regarding what was useful (Table 1) and what could be improved in the apps (Table 2).

Discussion/conclusion: Written comments are rarely answered by participants. We believe that because these participants were ''self-recruited'', they were more engaged. This is evident in their willingness to provide both constructive criticism and details for future development of mHealth technologies. This also demonstrates what we can expect from - and the value of - involving engaged users of technology aids in diabetes research today.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD19-0309

WHAT CAN BE LEARNED BY ANALYZING PATIENT-GATHERED DATA FROM A SELF-MANAGEMENT DIABETES APP

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[3]*UiT - The Arctic University of Norway, Department of Health and Care Sciences- Faculty of Health Sciences, Narvik, Norway*

Introduction: Self-management interventions for diabetes are still limited in the analysis of patient-gathered data and mHealth usage - focusing mainly on HbA1c. From the ''Tailoring Type 2 Diabetes Self-Management'' RCT, we analysed detailed app-data as a supplement to the traditional measures.

Methods: Participants were randomized to two groups. The Control group used the regular Diabetes Diary app for the first 3-months and the tailored version for 3-months. The Intervention group used the tailored app for the full 6-months (Figure 1). Measures were taken at 0, 3, and 6-months including HbA1c. The app continuously stored user-recorded each blood glucose, insulin dose, diet, and exercise registration.

Results: N = 16 participants were randomized to the Control group and n = 25 to the Intervention group. Total registrations made and HbA1c did not differ significantly between those who made registrations in the in the Control (n = 12) and Intervention groups (n = 8). Therefore, all participants who registered in the app were treated as one cohort in the following analysis (n = 20) (Figure 2). While not significant, participants seemed to reduce HbA1c between zero and three months.

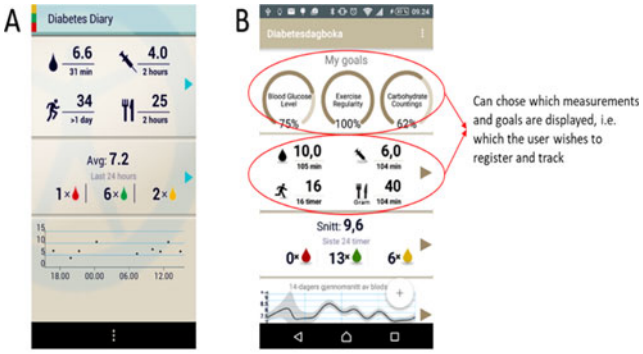

Figure 1. Illustration of the regular Diabetes Diary app (A) and Tailored Diabetes Diary app (B).

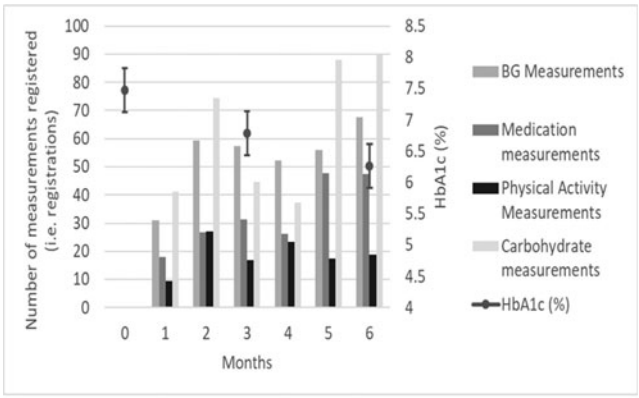

Figure 2. Distribution of types of registrations made in the app over the 6-months with HbA1c (0, 3 and 6-months) overlaid (standard error bars included).

Discussion/conclusion: By looking past assigned groups to additionally include app-usage patterns, we may be able to more effectively address how and why participants do - or do not - engage in mHealth-use over time, and which functionalities are most relevant to them. By incorporating such understanding, we may also be able to address when, and for which functionalities, users need encouragement to self-manage via apps, during both future interventions and daily clinical practice.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD19-0329

HEART RATE VARIABILITY DURING HYPOGLYCEMIA IN PATIENTS WITH TYPE 1 DIABETES AND IMPAIRED AWARENESS OF HYPOGLYCEMIA

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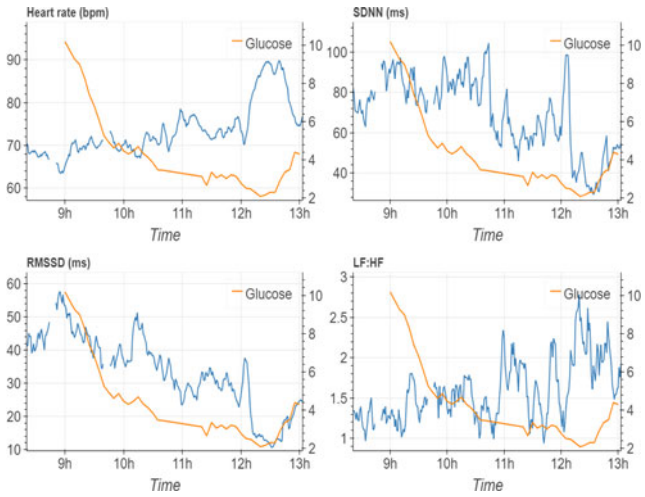
Background: Patients with type 1 diabetes (T1D) and impaired awareness of hypoglycemia (IAH) are at very high risk of severe, potentially hazardous, hypoglycemia and would benefit from an early alert device for the detection of hypoglycemia. Heart rate variability (HRV) may change at the initiation of hypoglycemia due to sympathetic nervous system activity. The aim of this study was to investigate whether these HRV-changes are retained in patients with T1D and IAH, in whom sympathetic nervous system activation during hypoglycemia is reduced.

Methods: Eligible participants underwent a modified hyperinsulinemic hypoglycemic clampwhile HRV was measured simultaneously by a Vital Connect Health Patch on their chest. Parameters of HRV included Square root of the mean standard differences of successive R-R intervals (RMSSD) representing parasympathetic nervous system activity and low and high frequency ratio (LF:HF) representing sympathetic nervous system activity.



Results: We included a total of 10 patients (4 men, age 38.5 ± 4.4 years, diabetes duration 21.7 ± 4.3 years, HbA1c 55.2 ± 1.5 mmol/L, modified Clarke score 3.7 ± 0.3). The glucose nadir during the clamp averaged 2.8 ± 0.1 mmol/L, which elicited minimal symptoms. Preliminary data analysis shows typical HRV patterns at the initiation of hypoglycemia, i.e. a decrease in RMSSD and an increase in LF:HF ratio (figure 1). Group differences also showed decreased RMMSD (36.1 ± 24.5 to 25.7 ± 9.5) and increased LF:HF ratio (1.35 ± 0.35 to 1.52 ± 0.24). Final results are pending.

Conclusion: Hypoglycemia affects HRV patterns in patients with type 1 diabetes and IAH. Considering developments in wearable devices and data analytics,real time HRV seems promising for early detection of hypoglycemia in patients with IAH.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD19-0351

DIABETES APPS USAGE AMONG INDIAN ENDOCRINOLOGISTS

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Aims: To assess the knowledge,attitudes and usage of diabetes smartphone apps among Indian Endocrinologists.

Materials and Methods: An online survey was done with REDCap and was emailed to a list of Indian Endocrinologists. The survey link was also disseminated through a WhatsApp group of Endocrinologists with 256 members. The endocrinologists were encouraged to share the link with their friends and colleagues. One hundred and ninety one(191) people completed the survey. Of these, 179 were endocrinologists. The analysis was limited to Indian Endocrinologists.

Results: 179 endocrinologists from India participated in the sur- vey. Majority of them were from the urban area. The mean experience of the respondents was 9.22 years (SD = 5.25 years). Their patient profiles included questions on litera- cy and specifically English literacy. In the survey, 74.7 % of the respondents felt their patients were literate(SD-19.47%) and 53.8% of patients were felt to be English literate (SD = 22.48%). 59.3% responded that their patients had smartphones. Only 16.5 % had ever prescribed an app. HealthifyMe, MyFitnessPal and GoogleFit were the most commonly prescribed apps.

Conclusion: The usage of diabetes apps is very low among Indian Endocrinologists. The main barriers to usage is awareness of the doctor. Availability of apps in local languages, diabetic education through the app and emergency alert/notification to the physician are the top preferred features in a prospective diabetes app. Incorporating mobile technology in diabetes management should start with improving physician awareness.

Appendix G

Mixed-method study: patient baseline questionnaire

"FF-Q-set-1-before-study-start"

FF-Q-set-1-before-study-start

Dette spørreskjema tar ca 5 minutter å fylle ut. Tusen takk for at du deltar i studien og hjelper oss med denne forskningen!
Det er 14 spørsmål i denne undersøkelsen.

Spørsmål - demografi

[]Fødselsår (år)

*

Kun tall er tillatt i dette feltet.
Svaret ditt må være mellom 1900 og 2017

Vennligst skriv her:

[]Kjønn

Velg kun en av følgende:

- ◯ Kvinne
- ◯ Mann

[]Hvilken er den høyste utdanning du har fullført?

Velg alternativene som passer

Vennligst velg alle som passer:

- ☐ Grunnskole
- ☐ Ett- eller toåring videregående skole
- ☐ Studieforberedende utdanningsprogram, allmennfaglig (studiekompetanse), gymnas, eller Artium
- ☐ Høgskole eller universitet mindre enn fem år
- ☐ Høgskole eller universitet mer enn fem år

[]Hvilket årstall ble din diabetes oppdaget?

Kun tall er tillatt i dette feltet.

Vennligst skriv her:

[]Hvilken type medisin bruker du til din diabetes? (dersom du bruker både insulin og Piller/tabeletter velger du "insulin")

Velg ett av alternativene

Velg kun en av følgende:

- ○ Insulin
- ○ Piller/tabeletter
- ○ Matregulert

[]Bruker du noen av de følgende verktøy:

Velg alternativene som passer

Vennligst velg alle som passer:

- ☐ Insulinpen
- ☐ Insulinpumpe
- ☐ CGM (kontinuerlig blodsukkermåler)
- ☐ Blodsukkermåler
- ☐ Diabetesdagboka appen
- ☐ Andre apper for diabetes (ikke Diabetesdagboka)
- ☐ Smartklokke eller andre bærbare sensorer
- ☐ Papirdagbok
- ☐ Annet: _____

[]Omentrent hvor mange ganger måler du blodsukkeret i løpet av en vanlig dag/uke?

Vennligst skriv her:

Ganger per dag:

_____

Ganger per uke:

_____

[]
Hvor ofte teller/vurderer du karbohydrater eller kalorier før et måltid per dag/uke:

Vennligst skriv her:

Ganger per dag:

Ganger per uke:

[]Lager du regelmessige mål for egenbehandling av din diabetes?

Velg kun en av følgende:

- ◯ Ja
- ◯ Nei

[]Har du noen ganger hatt for lavt/høyt blodsukker?

Velg kun en av følgende:

- ◯ Ja
- ◯ Nei

[]Hvis ja, hvor mange ganger har du hatt det den siste uka?

Vennligst skriv her:

Antall ganger for lavt blodsukker:

Antall ganger for høyt blodsukker:

Spørsmål - Empowerment

[]Generelt sett tror jeg at jeg:

Vennligst velg passende besvarelse til hvert alternativ:

	Svært uenig	Litt uenig	Verken enig eller uenig	Litt enig	Svært enig
...vet hvilke deler av egen diabetes behandling som jeg ikke er fornøyd med.	◯	◯	◯	◯	◯
...kan få mine diabetesmål til å bli en gjennomførbar plan.	◯	◯	◯	◯	◯

	Svært uenig	Litt uenig	Verken enig eller uenig	Litt enig	Svært enig
...kan prøve ut forskjellige måter å overvinne hindringene for å nå mine diabetesmål.	○	○	○	○	○
...kan finne måter å ha det bedre på med diabetes.	○	○	○	○	○
...kjenner til de positive måter jeg kan meste diabetes-relatert stress på.	○	○	○	○	○
...vet hva som motiverer meg i min egen behandling av diabetes.	○	○	○	○	○
...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.	○	○	○	○	○

Spørsmål - Samarbeidsklima

[]

Vennligst velg passende besvarelse til hvert alternativ:

	1 - Helt uenig	2	3	4 - Verken enig eller uenig	5	6	7 - Helt enig
Jeg føler at helsepersonellet har gitt meg alternativer og valgmuligheter	○	○	○	○	○	○	○
Jeg føler meg forstått av helsepersonellet	○	○	○	○	○	○	○
Helsepersonellet uttrykker tillit til min evne til å gjøre endringer	○	○	○	○	○	○	○

	1 - Helt uenig	2	3	4 - Verken enig eller uenig	5	6	7 - Helt enig
Helsepersonellet oppmuntrer meg til å stille spørsmål	○	○	○	○	○	○	○
Helsepersonellet lytter til hvordan jeg kunne tenke meg å gjøre ting	○	○	○	○	○	○	○
Helsepersonellet prøver å forstå mitt syn før de foreslår en ny måte å gjøre ting på	○	○	○	○	○	○	○

Spørsmål - Trivsel og velvære

[]I de siste to ukene har jeg ...

Vennligst velg passende besvarelse til hvert alternativ:

	Hele tiden	Det meste av tiden	Mer enn halve tiden	Mindre enn halve tiden	Av og til	Aldri
Følt meg glad og i godt humør	○	○	○	○	○	○
Følt meg rolig og avslappet	○	○	○	○	○	○
Følt meg aktiv og sterk	○	○	○	○	○	○
Følt meg opplagt og uthvilt når jeg våkner	○	○	○	○	○	○
Følt at mitt daglige liv har vært fylt av ting som interesserer meg	○	○	○	○	○	○

Send undersøkelse.
Takk for at du fullførte denne undersøkelsen.

Appendix H

Mixed-method study: patient study-end (6-month) questionnaire

"FF-Q-set-2-study-end-6months"

FF-Q-set-2-study-end-6months

Dette spørreskjema tar ca 5 minutter å fylle ut. Tusen takk for at du deltar i studien og hjelper oss med denne forskningen!
Det er 11 spørsmål i denne undersøkelsen.

Spørsmål - Om systemet

[]Var informasjonen i systemet nyttig for deg? (Likert-skala, 5 verdier)

Velg ett av alternativene

Velg kun en av følgende:

- ◯ Nei
- ◯ Litt
- ◯ Noe
- ◯ Ja
- ◯ Ja veldig

[]Hvilke funksjoner brukte du i Datadelingssystemet sammen med din lege/sykepleier som var nyttig for deg:

Velg alternativene som passer

Vennligst velg alle som passer:

- ☐ Ingen
- ☐ Oversikten
- ☐ Personlige mål
- ☐ Identifiserte hendelser
- ☐ Detaljert visning (grafer og tabeller)
- ☐ Alle data i en graf
- ☐ Periodevisning (hver datatype i egne grafer over valgt periode)
- ☐ Døgnfordeling (hver datatype i egne grafer over 24 timer)
- ☐ Sum over tid (sum av hver datatype per dag over valgt periode)
- ☐ Liste av data
- ☐ Annet: _____

[]Bruk av systemet ga meg bedre forståelse for:

Velg alternativene som passer

Vennligst velg alle som passer:

- [ ] Personlige mål
- [ ] HbA1c
- [ ] Blodsukker
- [ ] Medisinbruk
- [ ] Kosthold
- [ ] Fysisk aktivitet
- [ ] Annet:

[]Planla du og din lege/sykepleier hva du skulle gjøre/fokusere på fram til neste konsultasjon?

Velg kun en av følgende:

- ○ Ja
- ○ Nei

[]Var anbefalningene fra din lege/sykepleier nyttig for deg etter denne konsultasjon?

Velg kun en av følgende:

- ○ Ja
- ○ Nei

[]Tror du anbefalingene du fikk er oppnåelige? Dvs. er du i stand til å gjennomføre det dere planla før neste konsultasjon?

Velg kun en av følgende:

- ○ Ja
- ○ Nei

[]Hva mer ville du gjerne hatt av funksjoner og/eller hvordan ville du endret systemet?

Vennligst skriv her:

Spørsmål - Samarbeidsklima

[]

Vennligst velg passende besvarelse til hvert alternativ:

	1 - Helt uenig	2	3	4 - Verken enig eller uenig	5	6	7 - Helt enig
Jeg føler at helsepersonellet har gitt meg alternativer og valgmuligheter	○	○	○	○	○	○	○
Jeg føler meg forstått av helsepersonellet	○	○	○	○	○	○	○
Helsepersonellet uttrykker tillit til min evne til å gjøre endringer	○	○	○	○	○	○	○
Helsepersonellet oppmuntrer meg til å stille spørsmål	○	○	○	○	○	○	○
Helsepersonellet lytter til hvordan jeg kunne tenke meg å gjøre ting	○	○	○	○	○	○	○
Helsepersonellet prøver å forstå mitt syn før de foreslår en ny måte å gjøre ting på	○	○	○	○	○	○	○

Spørsmål - Brukervennlighet

[]

1 = Helt uenig

5 = Helt enig

Vennligst velg passende besvarelse til hvert alternativ:

	1	2	3	4	5
Jeg kunne tenke meg å bruke dette systemet ofte	○	○	○	○	○
Jeg synes systemet er unødvendig komplisert	○	○	○	○	○
Jeg synes systemet er enkelt å bruke	○	○	○	○	○

	1	2	3	4	5
Jeg skulle gjerne hatt teknisk hjelp for å være i stand til å bruke systemet	○	○	○	○	○
Jeg synes de ulike delene i systemet henger fint sammen	○	○	○	○	○
Jeg synes det var for mye uoverensstemmelse mellom de ulike delene i systemet	○	○	○	○	○
Jeg vil tro at de fleste vil kunne lære seg dette systemet veldig raskt	○	○	○	○	○
Jeg synes dette systemet er veldig tungvindt å bruke	○	○	○	○	○
Jeg føler at jeg mestrer dette systemet veldig bra	○	○	○	○	○
Jeg trenger å lære meg mange flere ting før jeg kan komme i gang med å bruke systemet	○	○	○	○	○

Spørsmål- Empowerment

[]Generelt sett tror jeg at jeg:

Vennligst velg passende besvarelse til hvert alternativ:

	Svært uenig	Litt uenig	Verken enig eller uenig	Litt enig	Svært enig
...vet hvilke deler av egen diabetes behandling som jeg ikke er fornøyd med.	○	○	○	○	○
...kan få mine diabetesmål til å bli en gjennomførbar plan.	○	○	○	○	○
...kan prøve ut forskjellige måter å overvinne hindringene for å nå mine diabetesmål.	○	○	○	○	○
...kan finne måter å ha det bedre på med diabetes.	○	○	○	○	○
...kjenner til de positive måter jeg kan meste diabetes-relatert stress på.	○	○	○	○	○
...vet hva som motiverer meg i min egen behandling av diabetes.	○	○	○	○	○

	Svært uenig	Litt uenig	Verken enig eller uenig	Litt enig	Svært enig
...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.	○	○	○	○	○

Spørsmål - Trivsel og velvære

[]I de siste to ukene har jeg ...

Vennligst velg passende besvarelse til hvert alternativ:

	Hele tiden	Det meste av tiden	Mer enn halve tiden	Mindre enn halve tiden	Av og til	Aldri
Følt meg glad og i godt humør	○	○	○	○	○	○
Følt meg rolig og avslappet	○	○	○	○	○	○
Følt meg aktiv og sterk	○	○	○	○	○	○
Følt meg opplagt og uthvilt når jeg våkner	○	○	○	○	○	○
Følt at mitt daglige liv har vært fylt av ting som interesserer meg	○	○	○	○	○	○

Send undersøkelse.
Takk for at du fullførte denne undersøkelsen.

Appendix I

Mixed-method: HCP pre-study survey of FullFlow data-sharing system

"Spørsmål angående bruk av Full Flow systemet, 2019"

(Questions about using the FullFlow system, 2019)

Spørsmål angående bruk av Full Flow systemet, 2019

Rolle: Diabetessykepleier □ Lege □ Annet: _____

1. Tror du dette systemet vil være nyttig som del av konsultasjonen?

□ Ja □ Nei □ Vet ikke Evt. kommentarer:

2. Ville du hatt mer eller annen informasjon fra pasientene enn det systemet ser ut til å kunne gi deg? □ Ja □ Nei
Hvis ja, skriv litt om hvilken type informasjon du ville hatt:

3. Ville du foretrukket å fjerne noe av den informasjonen systemet kan vise deg? □ Ja □ Nei Hvis ja, spesifiser hvilken:

4. Har du noen kommentarer eller forslag til oss?

Tusen takk for at du tok deg tid til å svare!

Appendix J

Mixed-method study: HCP questionnaire after each consultation

"FF7 - Spørreskjema etter hver konsultasjon for helsepersonell"

(Questionnaire after each healthcare consultation)

FF7 - Spørreskjema etter hver konsultasjon for helsepersonell

Til utfylling etter hver konsultasjon der helspersonell har benyttet FullFlow-systemet.

Det er 11 spørsmål i denne undersøkelsen.

Spørsmål

[]Klinikers ID *

Vennligst skriv her:

[]Pasientens HbA1c:

Kun tall er tillatt i dette feltet.

Vennligst skriv her:

[]Pasientens blodtrykk:

Vennligst skriv her:

[]Var informasjonen i Datadelingssystemet nyttig for deg? (Likert-skala, 5 verdier)

Velg ett av alternativene

Velg kun en av følgende:

- ○ Nei
- ○ Litt
- ○ Noe
- ○ Ja
- ○ Ja veldig

[]Hvilke funksjoner i Datadelingssystemet ble benyttet under konsultasjonen:

Velg alternativene som passer

Vennligst velg alle som passer:

- ☐ Ingen
- ☐ Oversikten
- ☐ Personlige mål

- [ ] Identifiserte hendelser
- [ ] Detaljert visning (grafer og tabeller)
- [ ] Alle data i en graf
- [ ] Periodevisning (hver datatype i egne grafer over valgt periode)
- [ ] Døgnfordeling (hver datatype i egne grafer over 24 timer)
- [ ] Sum over tid (sum av hver datatype per dag over valgt periode)
- [ ] Liste av data
- [ ] Annet:

[]Hvis du krysset av for "Ingen" i forrige spørsmål, Hvorfor brukte du ikke systemet?

Velg alternativene som passer

Vennligst velg alle som passer:

- [ ] For tidskrevende
- [ ] Tekniske problem
- [ ] Annet:

[]Hvilke ting ble diskutert under konsultasjonen:

Velg alternativene som passer

Vennligst velg alle som passer:

- [ ] Personlige mål
- [ ] HbA1c
- [ ] Blodsukker
- [ ] Medisinbruk
- [ ] Kosthold
- [ ] Fysisk aktivitet
- [ ] Identifiserte hendelser
- [ ] Annet:

[]I hvilken grad bidro informasjonen presentert av systemet til å kunne gi konkrete anbefalninger og planer til pasienten, sammenlignet med uten bruk av systemet?

Velg ett av alternativene

Velg kun en av følgende:

- ○ Ingen grad
- ○ Begrenset grad
- ○ En viss grad
- ○ Stor grad

- ◯ Veldig stor grad

[]Etter å ha brukt systemet, forstod du denne pasientens situasjon bedre?

Velg kun en av følgende:

- ◯ Ja
- ◯ Nei

[]Har du noen betenkeligheter med å benytte et system slik som dette?

Velg alternativene som passer

Vennligst velg alle som passer:

- ☐ Nei
- ☐ Ja, juridiske
- ☐ Ja, sikkerhetsmessige
- ☐ Ja, etiske
- ☐ Annet: [ ]

[]Hva mer ville du gjerne hatt av funksjoner og/eller hvordan ville du endret systemet?

Vennligst skriv her:

[ ]

Send undersøkelse.
Takk for at du fullførte denne undersøkelsen.

Appendix K

Identifying qualitative analysis gaps

"Qualitative evaluations of mHealth interventions: Current gaps and future directions"

Qualitative evaluations of mHealth interventions: Current gaps and future directions

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Abstract. Psycho-social factors are often addressed in behavioral health studies. While the purpose of many mHealth interventions is to facilitate behavior change, the focus is more prominently on the functionality and usability of the technology and less on the psycho-social factors that contribute to behavior change. Here we aim to identify the extent to which mHealth interventions for patient self-management address psychological factors. By understanding users' motivations, facilitators, and mindsets, we can better tailor mHealth interventions to promote behavior change.

Keywords Self-management, apps, behavior change, psycho-social factors

1. Introduction

Mobile health (mHealth) technologies (e.g., smartphone apps or wearables), affect patients' self-management (SM), clinical care, and health research. Especially for those with chronic health conditions like diabetes, mHealth enables patients to gather relevant data such as information about blood glucose, diet, and physical activity to better understand their health and make decisions about diabetes SM. With this knowledge at their fingertips, patients are now encouraged to participate in their care by sharing mHealth data with their healthcare providers (HCPs). As patients do this, HCPs will need to adjust their approach to patient care and guidance, and health researchers need to understand how mHealth technologies impact the ways patients and providers work together.

The purpose of most health and mHealth interventions for lifestyle-related health issues, e.g. diabetes, is to facilitate health management and, if necessary, behavior change. Research on mHealth interventions has focused on user experiences, with some pre-post measures of health behavior change, e.g. frequency of blood glucose measurements. However, less attention is placed on users' environments, motivations, or interactions with others [1]. Both internal (e.g., self-efficacy, sense of control, mindsets about health) and external factors (e.g., social connection, communication, and the patient-provider

relationship) influence the process of health behavior change. If we do not address these factors within mHealth intervention studies, we will not be able to understand the comprehensive impact of such technologies.

We propose that it is critical to design research questions that capture psycho-social factors in behavior change. Therefore, we have assessed the prevalence of questions related to these concepts in mHealth intervention studies, thereby revealing current gaps and future directions.

2. Methods

We aimed to identify articles that were published after the release of the 2015 Guidance for Industry and Food and Drug Administration Staff regarding how to address mHealth technologies [2]. These articles would thereby reflect the most updated efforts to assess new mHealth technologies, including those that address these new guidelines. We reviewed studies published in English between Jan. 1, 2015 and Jan. 18, 2019, describing mHealth interventions for patient self-management of WHO's listed major chronic non-communicable diseases (NCD) [3], as well as chronic mental illnesses. We searched Medline, PubMed, Google Scholar, and ProQuest Research Library for combinations of "mobile application" or wearable, and self-management or self-efficacy, and patient. We focused on qualitative questions asked in the following methods: study-specific questionnaires, interviews, and focus groups. Methods that described the purpose of the inquiry, e.g. satisfaction, without listing the questions themselves, were also included. Questions asked to both patients and HCPs were then grouped under emergent themes and then overarching categories: user experiences and four major psycho-social theories of behavior change: behavior change intentions, facilitators/barriers, measures of behavior change.

3. Results

The search resulted in 31 articles. Twenty-four articles included qualitative questions (Figure 1).

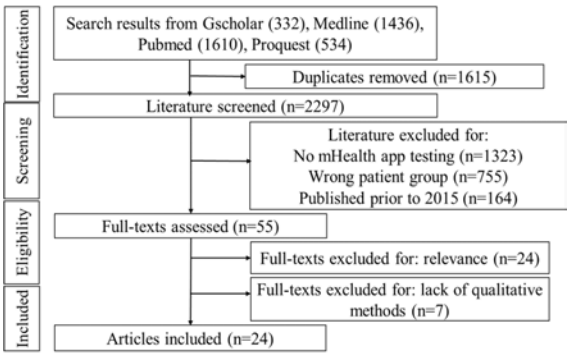

Figure 1. PRISMA diagram describing the selection of articles for data synthesis.

Emergent categories (n=18) were identified, and then grouped under broader categories (n=4).

Table 1. Behavior change categories, sub-categories and example questions identified within qualitative methods used in mHealth interventions

Categories [Refs]	Sub-categories (n=questions)	Example questions or statements
User Experience [4-21]	• Experience (n=43) • Usability (n=24) • App description (n=19) • Usefulness/efficacy (n=5) • Satisfaction (n=8) • Suggested improvements (n=4) • Questions described, not listed (n=5 articles)	• What were the main issues/difficulties you were facing when using the system? • The app had a remind/alert functionality • Overall, I am satisfied with how easy it is to use the App • (Nurse) Viewing daily measurements allowed nurses to recommend treatments
Measures of behavior (SM), health, or lifestyle change [5, 6, 10, 12, 22-24]	• SM behaviors or tasks (n=14) • General health (n=7) • General life and habits (n=6) • Mood (n=2)	• The Fitbit helps me be more active • How did you feel this morning when you woke up? • How healthy do you think your diet is? • I often forget pills or take them late
Behavior change intentions [4, 5, 8, 10, 11, 15, 19, 22, 25, 26]	• Intentions (n=27) • Expectations (n=20) • Questions described, not listed (n=1 article)	• (Provider) How confident are you that you will use the data from HeartMapp for decision making on patient care? • How likely do you think this app will help you lead a healthier lifestyle for better control of your diabetes • How comfortable would you feel sharing the information on this app with a family member or close friend?
Facilitators and barriers to behavior change [4, 6, 15, 22, 25]	• Self-efficacy/ autonomy (n=11) • Needs were/were not met (n=9) • App would facilitate control over SM (n=3) • Motivation (n=2)	• I know what helps me stay motivated to care for my diabetes • I am able to turn my diabetes goals into a workable plan • I can ask for support for having and caring for my diabetes when I need it

We identified 204 questions and six articles that did not list their questions but, instead, described the topic of their inquiries. *User experience* was the most represented category (n=103 questions in n=13 articles, and n=5 articles addressing this category). Other inquiries focused on motivation, goals, and control [22], daily or SM habits [23, 24], confidence in future use [25] and focus on intention of use [26]. It is important to note that articles cited under a category may contain few questions that address that category, e.g. Fortuna et al. only included one question that addressed the category *Facilitators and barriers* [4]. Two of the seven articles that used interviews included questions that expanded upon previous feedback, e.g. “Anything else?”, “What makes you say that?”. While it was most common that patients were the target of inquiries (n=192 questions addressed to patients), three studies queried HCPs on satisfaction, experiences, and expectations (n=13 questions, n=1 interview).

4. Discussion

The number of questions related to *Behavior change intentions* and *Facilitators or barriers to behavior change* (n=72), compared to those about *User experience* and *Measures of change* (n=132), demonstrates the weight of inquiry in research toward the latter. While psycho-social factors influence the use of mHealth, this review shows that there are relatively few assessments of these forces in mHealth studies. For example, by inquiring about motivation as well as intention and external support, studies could provide a greater understanding of not just how much something has changed after a study, but also why. We need to understand the context, i.e. motivations, facilitators and mindsets, to which we are introducing mHealth interventions to understand what makes mHealth-use relevant and sustainable. Inherent factors within patients and HCPs, such as perceived roles and responsibility within chronic health care, influence how these users choose to –or not to- use an mHealth intervention. By including questions that address psycho-social factors, in addition to those that measure objective or quantitative pre-post factors, we can begin to explain when, how and why users choose to engage with mHealth in such ways that do –or do not- lead to sustainable health behavior change.

5. Conclusion

This review has demonstrated that while the qualitative questions asked in mHealth intervention studies do cover essential information, e.g. usability, there is a gap in our understanding of how and why users' choose to use mHealth interventions. By leveraging underutilized psycho-social factors, we can better understand the reasons for mHealth-use and study outcomes. Future studies could then tailor interventions to address end-user needs and more effectively optimize these technologies to facilitate health behavior change.

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Appendix L

Mixed-method study: patient focus groups discussion guide

"Discussion Guide (Patients) Full Flow Study-end Focus group"

Discussion Guide (Patients)
Full Flow Study-end Focus group

Spring 2020

Time		Activities or visual aids etc.
12h Introduction (over lunch)		
15-20	• Meet participants in the reception • Corona forhåndsregler: no hand-shake, hand wash, toilets • Confidentiality and consent forms, parking slips • 12h-15h, Audio recorded • Coffee and tea available outside + ice cream (if hypos) • Introductions, ice-breaker! • Honest responses :D • 45 min sessions a. How you chose to (or not) use the app **Diabetesdagboka** b. Experiences during the consultation with your **healthcare provider** after sharing your data c. Impressions of the **data-sharing system** d. **Improvements** that should be made • 10 minute breaks • Travel, reimbursement etc. • Explain briefly how a Focus group meeting works	- FOOD + Audio recorder - Put up all posters (tape) - Agenda (main titles on power-point) - Coins or something else for ice-breaker
I. We will start by getting to know how you used the app on your own – what were your priorities and how you chose to use it.		
- Underline that reasons for NOT using the system is as important! - RELATE TO POSTER (R2P) - Introduce the big screen posters at the front of the room and ask them to show and tell! Instruct: Initials - Yellow (used), green (liked), red (didn't like) (If they are shy, we can mark/draw for them)		
15-20	1. Who of you used the app, and for how long? Why or why not did you use the app for your self-management? 2. How did you use the app? a. If not, why? 3. Describe situations in which using the app was helpful or frustrating? Please explain. 4. Did the possibility of sharing your data change how you gathered data and what data you gathered? (how often, how careful your measurements were, added notes with your measurements etc.) a. If you didn't use the app very much- did being in the study change your self-management or anything else related to your diabetes health?	- **For Q1 Why did you use the app, Q2 and Q3.** Per types key words of responses in powerpoint to show everyone for each question - Meghan makes notes about who says what with initial first
II. Now we will talk about what it was like to share your data (or not) and how the conversation with your doctor went		

- R2P - Introduce the big screen posters at the front of the room of the patient and doctor together (blank screen)!		
10	5. Think about a time BEFORE this study you had a really successful conversation with your doctor (before sharing your data). What happened in that interaction?	- Meghan/Per put key words in the speech bubbles on the posters (if possible) or noted in the powerpoint
10 min Break (12:50)		
45	6. Who of you shared your data during the consultation? If not, why not? What were your intentions or hopes for sharing your data?	
	7. Before you went to the consultation, how did you expect sharing your data would or would not help? a. Follow-up: help yourself, help the doctor, help the discussion	- Per types key words of responses in powerpoint to show everyone for each question - Meghan makes notes about who says what with initial first
	- R2P - Introduce the big screen posters at the front of the room of the patient and doctor together (FullFlow system)!	
	8. Recall when you shared your data during the consultation- can you describe how the conversation progressed? a. If needed: what did you want to focus on, what questions did the doctor ask you, what information did the doctor bring up, e.g. lab results b. Ask if they sat on same side of table- eirik wants this for idea of "collaborating"	- Meghan/ Per put key words in the speech bubbles on the posters (if possible) or noted in the powerpoint
	9. Please explain how you felt when you shared your data during the consultation. a. If needed: e.g. did using the system make you feel anxious, comforted, etc. confident, engaged?)	- **For Q11 and 13.** Per types key words of responses in powerpoint to show everyone for each question - Meghan makes notes about who says what with initial first
	10. Was it easier for you to explain your situation (self-management, priorities, etc.) to your doctor when using the system?	
	11. Did you receive all of the feedback based on your shared data, that you hoped for from your doctor? a. Follow-up: How do you wish your doctor could have used your shared data?	
	12. Did using the system with your HCP change how you self-managed? a. If yes, How? b. If no, why not?	

	13. Ideally, how would you want your HCP to receive/use your data? And how to use the system in future consultations?	
10 min Break (13:45)		
III. We would also like to know your practical experience with the system and sharing your data during the consultation		
- R2P - Instruct to take some minutes to go up to the print outs of the system screens and mark with yellow, red and green what was used, didn't like and liked - (If they are shy, we can mark/draw for them)		
30	14. During the consultation, was the data or information presenting on the screen relevant to you?	- **For Q16.** Per types key words of responses in powerpoint to show everyone for each question - Meghan makes notes about who says what with initial first
	15. Was it easy to understand what was presented on the screen when you shared your data?	
	16. What was/were the most useful functions/features? What was the least useful/helpful?	
	17. Did the system help you to understand your diabetes health better?	
	18. How do you think this kind of system would affect medical services? a. Follow-up or if needed: would it change how you use medical services?	- Only if time and if they seem to have some good ideas
IV. Can you think of anything that helped you use the app and/or system, or made it difficult?		
	19. Did anything encourage you to use the app and/or system? a. If needed: e.g. Family/friends, automatic reminders, routines that you made?	- Per types key words of responses in powerpoint to show everyone for each question - Meghan makes notes about who says what with initial first
10-15	20. What aspects of your daily life made it difficult to use the app and/or system? a. If needed: e.g., too busy, forgot?	
	21. Do you need support to collect and share data? (in the most effective way? To be successful?) a. If needed: e.g. Training, family/friends, support services, encouragement from your doctors?	
5 min Break (14:25/30)		
V. Finally, we would like to know what you think about any improvements that could be made		
- R2P (if they want) - Instruct: if you wish (or if we need clarification) spend some minutes drawing in blue marker on ANY poster, any improvements you may have		
	22. (about the system they have been exposed to) Open-ended questions about what improvements should be made; pros and cons about the system a. If needed: specific potential facilitators, such as reminders, triggers to schedule an appointment, video visits, text messages, emails, chat, etc.	- Per types key words of responses in powerpoint to show everyone for each question - Meghan makes notes about who says what with initial first
	23. (things that could facilitate effective use, surrounding or within the app/system) If you could wave a magic wand and create anything in or around the app/system to make it	

	easier to use the system with your doctor, what would you change? a. Clarify if no response: not only about the system itself but support to use it, e.g. reminders from your doctor to collect and share your data, maybe connect to your appointment reminder (requires more integration/interoperability)	
VI. Wrapping up		
- Any forms that need to be filled out - Travel, reimbursement etc.		
10	Thank you – how their input is valuable	
	Filling out reimbursement forms etc.	

Appendix M

Mixed-method study: HCP focus group discussion guide

"Discussion Guide (HCPs) FullFlow Feasibility Study-End Focus Group"

Discussion Guide (HCPs)
FullFlow Feasibility Study-End Focus Group

Spring 2020

Time		Activities or visual aids etc.
Introduction (over lunch or after lunch?)		
15-20	1. Welcome and summary of why we are here (state our honest transparent intentions: we know that this is not the perfect system, but this is a way of starting to gather information and knowledge about how these should be made in the future so please give us your honest feedback) 2. remind of their own app and FF system 3. Give everyone some time to grab lunch 4. Go through the agenda so that everyone knows what to expect a. Main headings (as seen in the headings below) b. 45min sessions then 10min break 5. Round of introductions Ice breaker (if necessary and have time)	- FOOD - Agenda (main titles on power-point or printed) - Coins or something else for ice-breaker - Give people numbers to write on their paper poster and the order when speaking so that we can keep track (or Meghan keeps track)
I. We want to know how you usually meet your patients		
10	1. Think about a time you had a really successful conversation with your patient (before using this system). a. What happened in that interaction?	- Researcher to write down aspects of a good consultation (have a section of the wall with this so that we can reference and compare it to how the system was used to SEE visually where we could improve) - Perhaps: Unbiased opinions first and then say "patients said X" on high level and then have them comment/reflect
II. When you used the system, how was your experience?		
10-15	2. Who of you reviewed patient-gathered data using the tested system, during the consultation? a. If not, why not? b. What were your intentions or hopes for receiving patient-shared data in this way?	
	3. Did you believe that this would help the consultation and discussion with your patients?	

10 min Break		
20	4. *(prompt them: we want to focus on your experience here and then we will talk about the functionalities and system itself in the next section)* Recall when you used the system - can you describe how the conversation progressed? a. If needed: e.g. what did you want to focus on, what questions did the patient ask you, what more information did you need in addition to that presented by the system up, e.g. lab results, to provide feedback to your patient?	- Print outs of the screens or characters, figures so that they could interact with something while telling their experience
	5. Please explain how you felt using the system: a. were you confident in its functions and your ability to use it, was it frustrating? b. Did you feel motivated to review and give feedback based on the shared data?	
III. We would also like to know what you thought about the system itself		
25	6. Did the system present data or information that was relevant to you?	- Own-print outs so they can mark for themselves (yellow highlighter to illustrate what was used and a green highlighter for what you did like and red for not like) - Large print outs of the screens so that participants can interact with them while they explain their experiences, what they liked/didn't like etc. (don't mark the big ones until the "improvements section") - Perhaps: Unbiased opinions first and then say "patients said X" on high level and then have them comment
	7. Was it easy to understand what was presented by the system?	
	8. What was/were the most useful functions/features? What was the least useful/helpful?	
	9. How do you think this kind of system would affect medical services? a. E.g. would it change how you practice/your workflow etc.? EHR or the way you meet the patient?	- Perhaps: Unbiased opinions first and then say "patients said X" on high level and then have them comment
10min Break		
IV. What, if anything, did you learn? **V. How did you use that understanding to help your patient?**		
	10. Did the system help you to understand your patients' health/self-management progress better?	- Print out representations of patient self-management and post it on the wall (we put it on the wall) next to a

	a. If needed: Do you learn anything more about your patient's priorities, health, self-management by looking more detailed into the patient's own gathered data?	picture of the patient when they mention what they learned about their patient (give them the option of posting it too)
	11. Did you receive all of the data that you had hoped for from your patient? a. Did you receive enough data to provide feedback to your patient?	
	12. Did using the system help you provide feedback or make decisions about their health? a. If yes, how? b. If not, why not?	- Write around the patient what kind of feedback was given - Perhaps: Unbiased opinions first and then say "patients said X" on high level and then have them comment
10 min break		
VI.	**Can you think of anything that helped or discouraged you to use the system?**	
20	13. Did anyone or anything encourage you to use the system? a. If needed: was there anything in the time that we are living now, affect why they decided to use the system, e.g. all of the different mHealth sensors and apps out there or media, or your patients have brought data before/or asked for it before)	- Write on post-its or printed out images of things and post it around the large print-outs on the wall (green for things that helped and red for things that discouraged)
	14. Were there any aspects of your daily life and practice that discouraged your use of the system? a. If needed: What aspects of your clinical practice, standards or job expectations made it difficult to use the app and/or system? (e.g., too busy, forgot, too time consuming)?	
	15. Ideally, how do you want to use the data that patients share through the system?	
	a. Idealy, how do you want you and your patient to use the data-sharing system together in future consultations?	
	16. Do you need support to use the system and data that patients share? a. For example, training or guidelines?	
VII.	**Finally, we would like to know what you think about any improvements that could be made**	
30	17. Open-ended questions about what improvements should be made; a. pros and cons about the system b. specific potential facilitators, such as reminders, triggers to schedule an	- Give them some minutes to write or brainstorm and then either they or one of us write their feedback on the large print-outs what they think could be improved

	appointment, video visits, text messages, emails, chat, other information that should be presented to be useful	- Sketching or paper prototypes what they would change if they want - Perhaps: Unbiased opinions first and then say "patients said X" on high level and then have them comment
	18. If you could wave a magic wand and create anything in or around the app/system to make it easier to use the system with your patient (as you describe above), what would you change? a. What would help you to use the system more efficiently/effectively/ or support to use the system at all? b. Think of external things – outside the system, that would help: e.g. Training, support services, encouragement from your superiors?	- Have post-its or paper to post on the wall when they mention a support service that could help (perhaps the researchers do this as the patients talk about it) - Perhaps: Unbiased opinions first and then say "patients said X" on high level and then have them comment
VIII. Wrapping up		
10	Thank you – how their input is valuable Filling out reimbursement forms etc.	- Any forms to be filled out

Appendix N

Mixed-method study: study-administration platform

"The need for updated evaluation approaches for e-health and m-health interventions - a dynamic concept for more efficient trials"

The need for updated evaluation approaches for e-health and m-health interventions - a dynamic concept for more efficient trials

Norwegian Centre for E-health Research

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Background

Clinical trials are notorious for falling behind schedule and over budget. In fact, nearly 90% of clinical trials fail to reach intended outcomes on time. Today, mobile health (m-health) technologies, e.g. apps for diabetes self-management, provide additional challenges by developing faster than clinical trials are able to evaluate them. Therefore, approaches to assess m-health self-management interventions, especially randomized controlled trials, must adapt.

Method

A review of traditional e-health and m-health assessment studies revealed that tested interventions were often outdated by the time trials ended, thus reducing their quality and potential impact. Major bottlenecks were identified and a holistic platform for electronically supporting study management was proposed. Specific technological functionalities were designed through collaboration between researchers, patients, medical experts, and improved through consultation with our hospital's research unit, the regional ethical board (REK) and Norwegian Data Protection Authority (Datatilsynet).

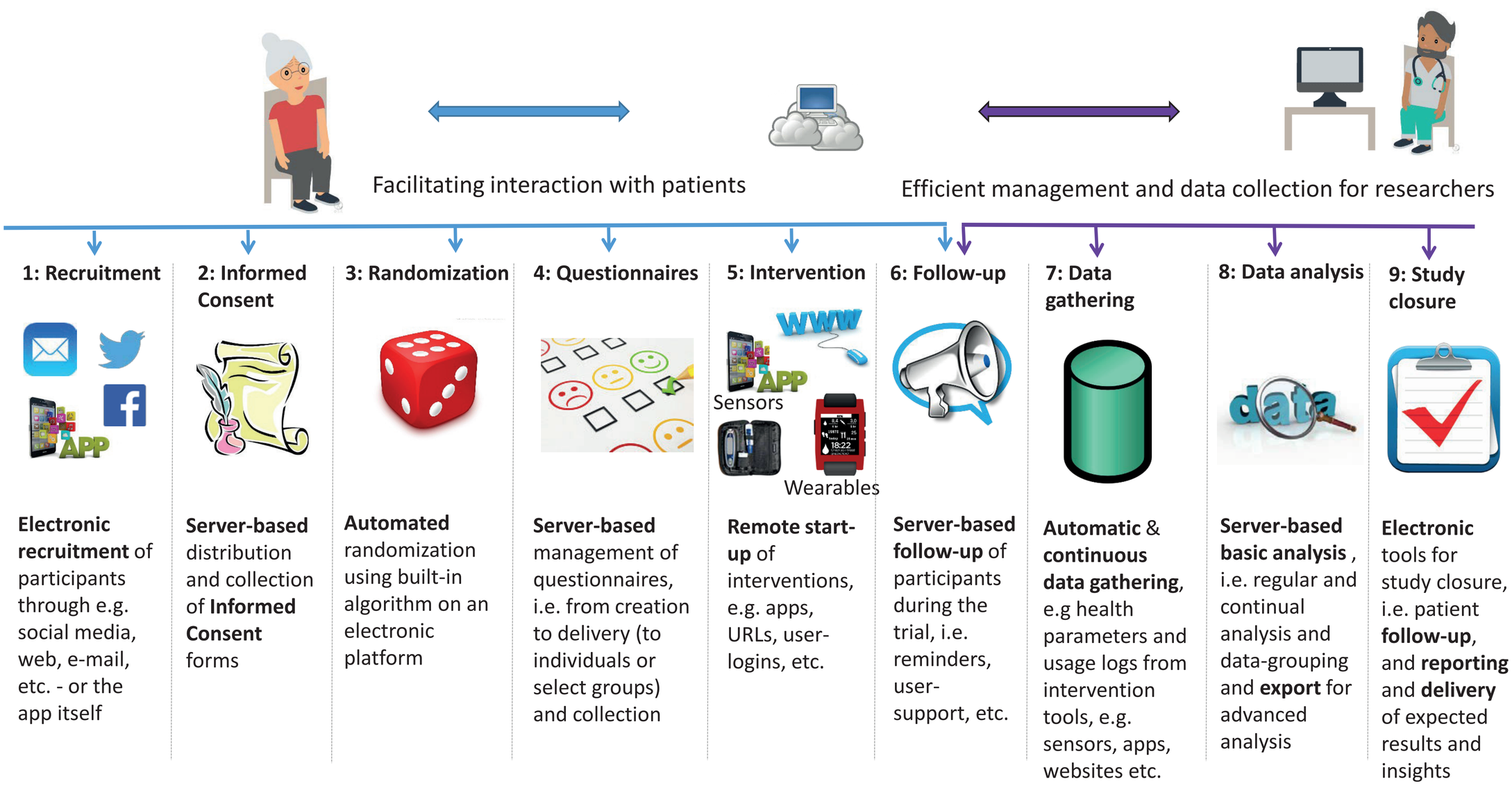

Figure 1. Visual representation of the elements in the proposed e-health and m-health research evaluation concept.

Results

An electronic study-management concept was developed. Modules with functionalities specific to major trial stages (Figure 1), several of which have been separately tested with success, facilitate a new holistic system for evaluation of e-health and m-health trials. The concept is acknowledged by Datatilsynet and REK (ref. 2013/1906/REK sør-øst B), and is currently under test as part of the "Tailoring Type 2 Diabetes Self-Management" project.

Conclusion

We expect this concept to enable researchers to more efficiently handle the administrational-, patient-, and data-related tasks of m-health and e-health interventions. By utilizing this concept in an ongoing clinical trial, we will demonstrate the potential of evaluating m-health technologies as disease and self-management treatment interventions.

ehealthresearch.no

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Appendix O

Mixed-method study: HCP pre-study survey results and Experience with study-admin platform

"Healthcare Personnel's' Expectations of a System for Sharing and Using Patient-gathered Data" (pg. A-148)

"Lessons Learned From Using a Remote Study-Management Platform: Use in an mHealth Diabetes Study" (pg. A-149)

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Advanced Technologies & Treatments for Diabetes CONFERENCE

19-22 FEBRUARY, 2020 I MADRID, SPAIN

430 / Abstract ID 826

HEALTHCARE PERSONNEL'S EXPECTATIONS OF A SYSTEM FOR SHARING AND USING PATIENT-GATHERED DATA

INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES

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Background and Aims: Personal health-sensors and devices are quickly entering the marked, answering the needs of people with diabetes' self-management. This has led to an increasing amount of patient-gathered health data, which we foresee will be important in meetings between healthcare personnel and patients. Building on the previous FI-STAR project, we address this issue in the current FullFlow project.

Methods: Prior to testing an in-house developed system that allows people with diabetes to share their self-gathered data during consultations, we queried healthcare personnel (n = 17; 12 GPs, 4 nurses, and 1 nutritionist) about their perceptions of, and suggestions for, the proposed system.

Results: All the healthcare personnel informants reported that they expected the designed system to be useful during consultations. Ten of them gave specific suggestions about how they expected the system to function, including: 1) possibilities for remote consultations; 2) support for keeping track of types of carbohydrates, not only amount; 3) support for keeping track of lipid levels; 4) automatic data transfer from apps, e.g. Strava, and devices, e.g. glucose meters and insulin pens; 5) support for all kinds of mobile phones; 6) integration of this system's functions with electronic health record systems; 7) highlighting changes since last consultation; 8) transfer of consultation notes and hospital system information into the patients' app to provide them with tailored recommendations for follow-up at the next consultation.

Conclusions: Healthcare personnel are positive to a system for using patient-gathered data, and they contribute with creative and specific suggestions for how such systems should work.

431 / Abstract ID 955

THE TELECONSULTATION AS AN EXPERIMENTAL EXCHANGE OF INFORMATION BETWEEN GENERAL PRACTITIONERS AND HOSPITAL SPECIALISTS

INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES

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Background and Aims: People with diabetes have a 15–25% risk of developing a foot ulcer during their lifetime. In Tuscany, out of an estimated population of over 100,000 diabetics there is an expected incidence of 2,000 new diabetic ulcers per year. In order to create a timely and better management of the patient suffering from skin lesions on the lower limbs, it is essential to promote synergy and communicative interaction between health professionals in the area and those in the hospital.

Methods: Starting from June 2019, a teleconsultation project between the Department of General Medicine and the Foot Clinic of the San Giovanni di Dio Hospital in Florence will be tested within the northwest area of the Vast Tuscany Center Area.

Results: Through the web telemedicine platform, GPs will be able to transmit requests for advice, images of skin lesions, relevant clinical information and the patient summary of subjects at risk . The teleconsultation service will send to the Foot Clinic specialist chosen by the GP, a notification on their mobile phone with the aim of reducing response times to a minimum.

Conclusions: The immediacy of the exchange of clinical information between GPs and hospital specialists allows the creation of an integrated management model based on the centrality of the person. Sending the report of the specialist visit directly to the GP through web platform, allows to eliminate misunderstandings and facilitates the continuity of assistance, producing in the end a greater participation of the patient in the care process.

432 / Abstract ID 790

A COMBINED BIOFEEDBACK-VIRTUAL REALITY SMARTPHONE APPLICATION TO COPE WITH FEAR OF HYPOGLYCEMIA

INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES

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Background and Aims: Fear of hypoglycemia (FOH) refers to phobic avoidance reactions associated with hypoglycemia. FOH is associated with poor glycemic control and its consequences, necessitating the development of effective methods to address this condition. We present a pilot study, combining biofeedback (BF) with a virtual reality (VR) smartphone application.

Methods: Patients with type 1 diabetes suffering from FOH as evaluated by the "Hypoglycemia Fear Survey-II" questionnaire [composed of two subscales; Behaviors (HFS-B) and Worries (HFS-W)] were randomly assigned to either treatment with BF or BF+VR. All participants were instructed to use a smartphone application daily for two weeks. They were exposed to virtual stimuli: mild low glucometer readings (85–125) and practiced reducing their physiological arousal using a galvanic skin response (GSR)

biofeedback system. In the BF+VR arm successful relaxation was reinforced by exposure to their own virtual smile; this stimulus has the potential of activating brain reward mechanisms. Primary outcome was defined as the change in the HFS-Worries scale.

Results: Five participants were recruited and randomly assigned to receive BF+VR (n = 3) or BF alone (n = 2). Participants demonstrated a significant improvement in their HFS score (an average reduction of 7.4 points from a baseline of 83.4), mostly attributed to a reduction in the HFS-Worries subscale (5.8 points). This improvement was durable for a 2 month period. There was no clear trend towards superiority of the BF+VR over BF alone.

Conclusions: The results of this feasibility study, using a smartphone-based virtual reality application to treat FOH, call for a larger randomized controlled trial.

433 / Abstract ID 537

INTERVENTION STUDIES NEED TO ADAPT TO ADDRESS PATIENT NEEDS FOR DIABETES SELF-MANAGEMENT

INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES

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Background and Aims: Research on health technologies traditionally report clinical measures. However, with mHealth and online resources for diabetes self-management, individuals are calling for more, diverse evidence. We compare two reviews to determine to what extent mHealth and online intervention studies address patient-reported needs.

Methods: A systematic review (Review 1) searched for reported outcomes of mHealth and online intervention studies (PROSPERO registration: CRD42018115246). A literature review (Review 2) searched for patient-reported needs for diabetes self-management. Both covered articles published between 2015 and 2019. For ease of comparison, the co-authors categorized the results.

Results: Reviews 1 and 2 resulted in n = 31 and n = 21 articles, respectively. Main categories of reported outcomes were: support from/access to resources, usability/suitability, patient empowerment/engagement, clinical outcomes, and data protection. Main needs categories were: support/access to services, information, coping and patient engagement/empowerment, and technology. Thus, the research outcomes and patient needs were in general very different. For example, under the category *support/access to services*, reported intervention outcomes included *peers, coordinated-care services* and *relevant information*. However, specific patient-reported needs included *resources and services to self-management activities*, e.g. gyms, *feedback on self-management performance* and *reminders*.

Conclusions: A reason for these differences is that research interventions occur within closed and controllable systems, whereas patient-reported needs result from experience in the real-world, with a multitude of resources. Future interventions can address this by include more contextual information, e.g. about participants' access to resources, as baseline measures. In doing so, we can provide evidence of the relationship that these resources have on the success of the intervention.

434 / Abstract ID 541

LESSONS LEARNED FROM USING A REMOTE STUDY-MANAGEMENT PLATFORM: USE IN AN MHEALTH DIABETES STUDY

INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES

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Background and Aims: The use of an online study-management system can help to ease the burden of both participation in, and administration of, mHealth interventions. We describe the benefits and challenges of using such a platform to manage an intervention (FullFlow Project) involving both patients and their providers in the testing of an mHealth data-sharing system.

Methods: Our remote study-management platform consists of: a website used to monitor status and message the participants, a local server for automatic data-collection and analysis (Piwik, now Matomo) and an open source survey tool (LimeSurvey). Patient recruitment was initiated through health providers and continued through the platform. Two researchers and one developer administrated the study.

Results: The **benefits** of this platform included security and efficiency in distributing study-information and messages, as well as supporting participants from a single platform, based on open-source systems. For example, if a participant was not actively engaged in the intervention, we could then send messages specific to their situation. In the platforms' current implementation, we have experienced three main challenges: 1-Participant follow-up requires manual tracking and initiation of messaging; 2-Data-collection requires manual review of data and interaction logs, from separate sources; and 3-Data-analysis requires specific programming to combine the differently structured output from each data source.

Conclusions: Future improvements to the system can include automation of tasks and additional software that can facilitate the organization of these data for analysis. For example, automatic merging of data-sources and generation of simple reports would make the system more efficient, which is especially important for mHealth interventions.

435 / Abstract ID 743

ONTOLOGY-BASED MODELING OF MEDICAL PROFILES OF DIABETIC PATIENTS

INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES

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Appendix P

Clinicians' mHealth preparedness

"The Evolution of Clinicians' Preparedness for mHealth Use (2013-2017) and Current Barriers"

The Evolution of Clinicians' Preparedness for mHealth Use (2013-2017) and Current Barriers

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Abstract

Clinicians now insist that health authorities and researchers provide practical evidence and strategies for reacting to and handling patient-gathered data (PGD) and mobile health (mHealth) devices. With diabetes as a use-case, we present a summary of our own studies and a narrative scientific literature review to exemplify the progress of clinicians' perceptions of mHealth. We then compare these results to a narrative review of official clinical practice guidelines related to mHealth use (2013-2017) to demonstrate similarities and differences between what clinicians perceive as opportunities for mHealth and what health authorities are providing. Review of mHealth studies revealed that clinicians have become more willing to accept mHealth technologies and use patient-generated data over time. However, review of clinical practice guidelines revealed several barriers to using mHealth in clinical practice. Results of this comparison indicate 1) the need for a balance of clinician and patient participation and feedback during mHealth studies, and 2) health authorities' lack of sufficient guidance to clinicians for practically using mHealth in their daily practice.

Keywords:

Clinicians, Diabetes, Mobile Health, mHealth, mDiabetes, Consultation.

Introduction

Traditionally, medical devices for diabetes self-management and treatment were validated by health authorities. As such, clinicians were provided with structured guidelines and protocols for how to instruct their patients to use such technologies and relate to the subsequent gathered data. More and more commonly patient-operated mobile health (mHealth) tools enable patients to become more knowledgeable of their own health challenges and more in control of treatment priorities by providing them the means to better understand their own disease. As such, the novelties of mHealth throw a completely different spin on the priorities of patient care; clinicians are now expected to adapt not only to patients' new capacity to self-manage but also analyze larger patient-generated data sets.

Considering the lack of validation and testing within clinical settings, it is understandable that many medical personnel are concerned with various factors surrounding the clinical integration of e.g. mHealth apps [1]. Furthermore, because most often apps are designed for use by patients only, and not clinicians [2], initial evaluation studies within the medical realm focused upon answering questions relevant to individual patient users and not medical practice [3, 4]. Only until more recently was the concept of medical integration and evaluation considered [5]. Thus, medical personnel are now reacting to changes within two different environments: 1) the rapid increase of patient-centered mHealth, for example mobile diabetes (mDiabetes) tools, within the commercial sector as well as 2) pressures from patients to integrate such technologies within the medical sector.

The purpose of this paper is to identify the change in clinicians' perceptions related to mHealth between 2013 and 2017. By comparing this progress to the guidelines provided by regional and national health authorities, e.g. government agencies and those who create medical standards, we identify and emphasize the lack of necessary support for clinicians as well as the importance of including them in the planning and implementation of mHealth within clinical practices. This is especially important in primary health care, where research activities and partnerships with general practitioners' (GPs') offices are not as common as they are amongst health care personnel at hospitals.

Methods

Three narrative reviews were conducted. The first two were of health research literature, published between 2013 and 2017, that described mHealth interventions in which patient-gathered data were shared with clinicians. These were then compared to the third, which was a review of best practice recommendations produced by healthcare authorities, during the same period, regarding how clinicians should use patient-gathered mHealth data.

The first review was of mHealth interventions completed at our own University Hospital of North Norway's (UNN) Norwegian

Centre for E-health Research (NSE). These activities began with the REgioNs of Europe WorkING together for HEALTH (RENEWING HEALTH) Norwegian Pilot study (2013) [6, 7] in which individuals with Type 2 Diabetes were encouraged to discuss their use of an mHealth app for diabetes self-management, called the Few Touch Application (FTA), during consultations. During the 2014 annual Diabetes Research Conference in Oslo, Norway, we surveyed clinicians about their perceptions of a "clinician interface" of the patient-operated Diabetes Diary smartphone app. The next study that was conducted, concerning clinicians' use and relation to mHealth, was the Norwegian diabetes pilot of the international FI-STAR study [8]. Two GP's and a specialist participated in a clinician workshop in October 2016 to reflect upon what is needed to share patient-gathered mHealth data during consultations. In 2017 we invited patients and clinicians to participate in a co-design workshop, in both peer and joint sessions, to design their ideal mHealth data-sharing system, and indicate their preparedness for relating to mHealth. Workshops were audio-recorded, transcribed and translated into English.

To contextualize our own reports, we conducted a second narrative review of literature describing clinicians' perceptions of mHealth and patient-gathered data reported from similar studies within Europe and America. PubMed and Google Scholar were used to search scientific literature produced between 2013 and 2017. The following search strategy was used for PubMed: *clinician, practitioner, provider, or nurse AND barriers, concern, motivations, perspective, opinion, viewpoint or outlooks AND apps, mHealth, mobile health, wearables, or sensors*. The following search strategy was used for Google Scholar: *combinations of clinician, practitioner, provider, or nurse AND apps, mHealth, mobile health, wearables, or sensors*. Resulting articles were exported to the Systematic Reviews web app, Rayyan [9], for sorting and selection. Analysis included screening for reports of clinicians' firsthand experience with mHealth data presented by patients during clinical interventions. Author MB collected and reviewed the full-text of the publications, where data extraction included clinicians' perceptions of using mHealth in clinical practice, which were categorized as either perceived benefits or barriers. Benefits can be seen as clinicians' willingness to use mHealth, while concerns and needs represent the uncertainty toward using mHealth that needs to be resolved. Inclusion criteria were that literature must i) be published between 2013-2017 in English, ii) describe patient-operated mobile apps as part of the intervention, iii) describe studies included inquiry and reported responses of health care providers within America or Europe. Publications were excluded if i) they did not survey health care providers as part of the study, if ii) no abstract was found to support initial review processes, if iii) it only included "medical devices" [10], if iv) the intervention primarily provided basic mobile phone functions, e.g. SMS, from health providers for patient self-management.

- The third review was of official recommendations produced by health authorities related to how healthcare practitioners should react to, or use patients' own-gathered mHealth data or tools during consultations. Guidelines were searched for in European, Norwegian and American health authorities' websites including The World Health Organization (WHO), the European Commission (EU), Health Care Information and Management Systems Society (HIMSS), and the Norwegian Health Directorate, using versions of the following terms: *"clinical practice guidelines", recommendations AND Europe, Norway, America AND mHealth, mobile health, apps.* Analysis included screening for any recommendations related to how clinicians themselves should react to and\or use patient-gathered data and mobile health technologies in daily clinical practice. This did not include recommendations for health facility managers or security systems. Data extraction included recommendations for how clinicians could relate to mHealth during consultations. These recommendations were then compared to the clinicians' needs to relate to, as presented in the previous two narrative reviews. Inclusion criteria were as follows: must mention daily medical activities performed by health professionals related to patient-operated mHealth technologies or their self-gathered data. Guidelines must also be published open-access between 2013-2017 within governmental, health authorities' and/or organizational reports. In focusing on publically available documents, we stress the importance of ease of access and use of these clinical practice guidelines for health care personnel themselves. Documents were disregarded if they i) provided no recommendations directly to health care practitioners for mHealth-use, ii) Only described design and/or evaluation guidelines for mHealth interventions studies, iii) Merely commented on issues related to mHealth-use during clinical practice, without direct input from clinicians themselves, iv) Only described appropriate use of clinicians' own mobile device during working hours.

Results

First, we summarized the clinician-related responses to mHealth interventions for our research activities, annually between 2013 and 2017. Table 1 summarizes the results related to clinicians' perceptions of the mHealth tools that were presented to them, both from previously published and unpublished (UP) reports from our studies.

Table 1- Own research: clinicians' perceptions related to use of mHealth tools and patient-gathered data (PGD)

Ref.	Benefits	Concerns and needs
2013		
UP	• PGD would be useful (n=17/23) • Would give recommendations based on PGD (n=17/23)	• Unclear financing (n=12/23) • Would require re-organizing services (n=11/23) • Training/supporting patients (n=11/23)
2014		
UP	• Better preparations of consultations (n=15/15) • Better able to help patients (n=13/15) • More effective communication with colleagues (n=9/15)	• More knowledge required about "patient compliance" (n=12/15) and "Integration into EHRs" (n=12/15) • Clinicians would need more "direct experience" (n=13/15) and training via "seminars" (n=13/15)
2015		
[11]	• Comfort with the system increase over time • Increase understanding of the patient situation • Graphical displays of data improved understanding of patient situation	• Not all patients present data, which is needed for clinicians to provide guidance

2016		
[12]	• Easier to present PGD • Eager to discuss app data as graphs and trends • Patients reflect on data • Patients can and should take initiative during consults	• Must operate with existing medical technology • Data can be "noisy" • Patients need intensive training about how to collect data for medical purposes • Not all patients present data
2017		
[13]	• Can base discussion and advice on personalized data • Result in more concrete discussions • Patients can become more engaged in their health • Specific information will save time	• Patients don't always present their data • Must be easy to collect data • Chance of data overload • Could be too time consuming • Clinicians still need to learn more about mHealth tools

Second, we summarize results of both narrative literature reviews of mHealth intervention studies and official clinical practice guidelines in order to contextualize our own findings and gain a greater understanding of the overall needs expressed by clinicians within the evolving field of mHealth.

The keyword searches in PubMed and Google Scholar results in 71 and 64 results, respectively. Initial review of titles and abstracts was based upon the inclusion criteria as described in the Methods section. 129 publications were excluded because medical practitioners were not directly surveyed and/or because the intervention did not involve patient-operated mHealth tools, leaving only 6 publications for full-text review (see Figure 1). Responses were then separated into benefits and barriers for relating to mHealth tools during clinical practice (see Table 2).

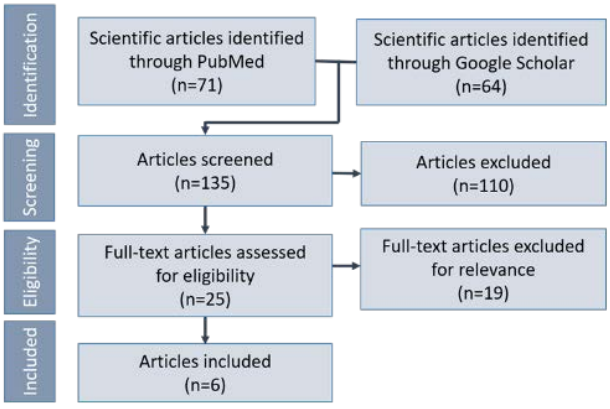

Figure 1- PRISMA flow diagram describing selection of scientific literature for review

Three of the reviewed publications reported clinicians' perspectives on the potential use of mHealth in general, while the remaining three papers reported clinicians' perspectives of a presented or tested mHealth system. The paper by Bonilla et al. [14] reported percentages of respondents' perceptions for each question, which allowed the authors of this paper to highlight how clinicians' perceptions differed between certain benefits and barriers. Table 2 summarizes the overall results of these six publications, ordered by publication year.

Table 2- Scientific literature search results: clinicians' perceptions related to use of mHealth tools and patient-gathered data (PGD).

Ref.	Benefits	Concerns and needs
2013		
[15]	• Simple to use • Positive for patient care process • Monitoring patient progress • React to problems in real time	• Rapid technology progress • Unclear impacts of technology • Content/data overload • Too time consuming • May increase clinical workload • No operational support/guidelines
2015		
[14]	• Tailored patient care • Supplementary patient support • Improved data accuracy • Increased amount of valuable data	• Cost • Time consuming to operate • Validity of applications • Reliability of patient-provided data • Risk of misinterpretation • Safety/privacy
[16]	• Tailor patient care • Improve communication • Fosters trust • Monitoring patient progress • Reinforce motivation and autonomy • Increase legitimacy of own clinical practice • Improve clinical workload/workflow	• Lack of direct view of patient data • Limited data flow and interoperability • Limited functionalities for follow-up • Technology limited to specific device • Competition with traditional care
2016		
[17]	• More possibilities for teaching patients • Increase admin efficiency • Increase consultation efficiency • Supplementary patient support	• No operational support/guidelines • Limited data flow interop. • Time consuming • Tech. integration would compete with other priorities • No guidelines for handling sensitive information
[18]	• Would recommend apps • Comfortable exchanging info via technology • Monitoring patient progress • Improve communication • Must be endorsed by experts	• Discomfort using electronic communication with patient • Lack of sufficient evidence
2017		
[19]	• Understand patient situations • Records symptoms • Medical adherence tracking & alerts	• No operational support/guidelines

Results from review of clinical practice recommendations

Ref.	Recommendations
	2015
[20]	Proposes Continua as the standard for welfare technology
[21]	**Guidelines for recommending apps to patients:** • Tailor app recommendations to patients and discuss consent regarding use of data and limits to consent • Discuss effective apps with colleagues • "Adhere to legislation and regulation (if existing) and/or professional obligations" • If the app is used for monitoring, the physician should instruct the patient how to respond to the information provided • Clinicians should look for the following characteristics before choosing an app: • Endorsement by professional or reputable health organization • Usability and evidence of impact - clinicians may also test the app themselves before recommending it • Reliability of information: inquire about how the patient intends to use the app to determine if the information provided is appropriate • Privacy/security: inform patients of added security risk of using apps, and even recommend apps with additional levels of authentication vs. apps without • Avoids conflicts of interest and fragmentation of health information
[22]	• Do not use medical apps that do not have a CE Mark, or if they do not "meet the requirements of the medical device directives and regulations" • "Exercise professional judgment before relying on information from an app"
[23]	• Clinicians should differentiate medical and non-medical mobile apps – differentiating characteristics are provided
	2016
[24]	• Clinicians should tailor recommendations to the disease and the mHealth apps/PGD presented by patients – example scenarios provided
	2017
	• None found

N=16 documents were identified from the search of clinical practice guidelines for mHealth. We excluded one document because it was not in English, and two documents because they were behind a pay-wall, leaving 13 for full-text review. We excluded 8 recommendations that do not offer practical solutions for clinicians in their every-day practice (see Figure 2).

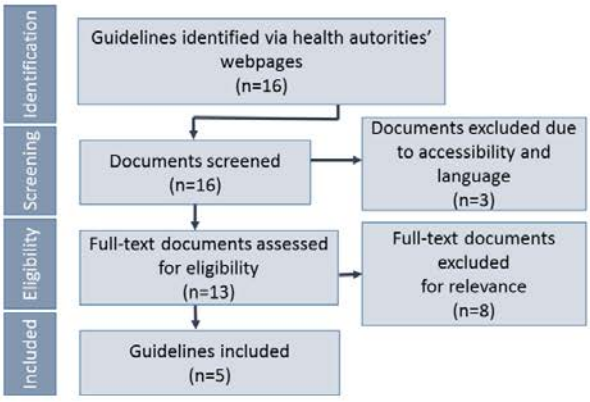

Figure 2 – PRISMA flow diagram describing selection of clinical practice guidelines for review.

Table 3 summarizes the recommendations provided by health authorities for how clinicians should relate to mHealth and patient-gathered data (PGD). This enabled us to compare if such recommendations meet clinicians' needs, as presented by the concerns and needs reported in Tables 1 and 2.

Table 3 – Health authorities' clinical practice recommendations for clinicians' use of mHealth and PGD.

Discussion

Clinicians have traditionally relied upon health authorities and management to provide guidance regarding clinical practice. As demonstrated, with the introduction of mobile health technologies to the options of patient self-management aids, clinicians have been and continue to be at a loss for answers. Despite these initial limitations, clinicians are acknowledging the benefits of these technologies more and more over recent years, especially since patients require more frequent support than the medical system is able to provide. Given the diversity of mHealth-generated data, health authorities and facility managers must provide support and suggestions for how care providers should relate to such technologies within differing clinical specialties in order for integration of mHealth to be successful.

The results of this paper also suggest an answer to the looming question; are the recommendations provided by regulatory bodies evolving quickly enough to meet the needs to clinicians in the rapidly changing environment of mHealth? Comparison of clinicians' perceptions of mHealth over time and guidance produced by regulatory bodies demonstrate that health and care authorities are beginning to propose the type of specific suggestions for relating to mHealth that clinicians need. However, the majority of the official activities under-way involve preparation for secure technological integration on the back-end. There have been few guidelines or recommendations for how clinicians can use data gathered by mHealth tools such as apps and sensors in daily practice. Questions remain regarding how patient-gathered lifestyle and health data should be weighted and considered along-side clinically generated information, e.g. lab results, to inform and generate actionable health recommendations. In addition, it is unclear which data is appropriate for providers to register and store within their own EHR systems. Health providers are responsible for judging which information is medically necessary and relevant for clinical decisions versus which information is sensitive to the individual and, therefore, should not be shared with the rest of the coordinated care team. This task is made exponentially more difficult with the added volume and detail of patient-gathered data, and our current research project *Full Flow of Health Data Between Patients and Health Care Systems* will address this in the coming clinical study of a mHealth system during clinical practice in Norway.

Conclusion

We have seen a development in mHealth where mobile technology, such as apps for mobile phones, smartwatches, and patient-operated sensors, have led to a situation in which patients are bringing new and more data into the clinical settings. mHealth is a rapidly developing field and clinicians need sufficient guidance to respond to the frequent changes and challenges that this new environment calls for. As this paper demonstrates, while official guidelines published by health authorities reference standards for back-end requirements for technological communication between EHRs and mHealth devices, they do not provide sufficient support for clinicians' in

their daily struggle to relate to mHealth. Therefore, the authors advocate for a greater voice and active involvement of health professionals in the development of any new processes, protocols or official standards, regardless of their specialty, to relate to mHealth successfully on a daily basis. It is time to integrate mHealth learning into medical and continued-education for practicing clinicians.

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Appendix Q

Patients' reported needs vs. research outcomes

"Do diabetes mHealth and online interventions evaluate what is important for users?"

Do diabetes mHealth and online interventions evaluate what is important for users?

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Abstract
Research often presents patient needs from perceptions of healthcare professionals and researchers. Today, patients can formulate tailored questions and seek solutions for what they need to self-manage in many ways. We aimed to compare reported outcomes of mHealth and online intervention studies for diabetes self-management to patient-reported needs, from a systematic review and a literature review respectively. Although we found similarities between the reported outcomes and the patient-reported needs, research has yet to meet all patient needs. Comprehensive methods for development and testing of interventions should be explored to meet the specific needs of patients.

Keywords
mHealth, diabetes, online, evaluation, patients, needs.

1 INTRODUCTION

Evidence for models of diabetes self-management focus on medical devices and clinically relevant measures, and not those that are reportedly relevant for the patients who are the intended users [1,2]. Technology such as mHealth and online tools and services intend to aid patients' diabetes self-management (SM) and provide additional support and information to that from traditional diabetes care and medical technology. In fact, patients with diabetes, have expressed impatience and dissatisfaction with the medically approved technology-based solutions, leading to the rise of the Do-It-Yourself (DIY) movement of hacking technologies to provide the functions and support that patients need [3]. However, the tradition within health intervention research has been to mostly focus on addressing and reporting clinical evidence and outcomes such as change in hemoglobin A1c and cholesterol levels, and not so much on other patient-relevant factors [2]. This raises the question: to what extent is mHealth and online intervention research targeting what is important for the patient and their needs in diabetes care?

"Patient needs" are often described in scientific literature as activities or actions that patients have to take to achieve good diabetes health. In other words, it is often focused on what healthcare professionals (HCPs) and researchers, not patients, perceive as patient needs [4]. When reported, patient needs are usually inferred from patients' feedback about their experience with mHealth or online interventions as part of an intervention study [5,6]. However, these do not comprehensively cover the overall needs for aiding their self-management.

2 METHODS

We compare results from two reviews: Review 1 identified reported outcomes of mHealth and online intervention studies for diabetes SM, and Review 2 identified patient-reported needs and facilitating factors for diabetes SM. While performed separately, categorization of the results for each review were discussed and agreed upon by all co-authors.

2.1 Search strategy for Review 1 - reported outcomes of mHealth and online interventions

The first review was a systematic literature review, with the overall aim of identifying methods and evaluation criteria used during mHealth and online interventions for diabetes SM. Several categories of information were extracted from the resulting literature. However, for the purpose of this paper, we will focus on reporting only a selection of the extracted data, i.e. reported outcomes. The following are examples of terms within titles and abstracts of literature found in CINAHL, EMBASE, MEDLINE and Web of Science, and published between Jan 1, 2015 and June 21, 2018 for the search strategy: *[mHealth or web-based]* AND *[self-assessment OR self-care]* AND *[assessment OR guidelines]*. The detailed search strategy is published along with the protocol of the systematic review in PROSPERO (Registration number: CRD42018115246). Articles were included if: they reported a relevant framework, guideline, questionnaire or other relevant criteria for evaluating mHealth or online interventions for patients – with all types of diabetes. Articles were excluded if: the evaluation only included medical measurements or did not include patients. Articles with only abstracts available, reviews, and dissertations were also excluded. Data extraction was performed by two co-authors (PR, MB). The main author (DL) performed inductive qualitative analysis and grouping of the outcomes. All stages from search strategy to data extraction and synthesis were contributed to and approved by all co-authors.

2.2 Search strategy for Review 2 - patient-reported needs

The second review was a literature review aimed at identifying patient-reported needs related to the facilitation and performance of SM activities, including but not limited to those based on the use of mHealth technologies and online SM aids. Our search strategy included combinations of the following terms in titles and abstracts searched within Google (grey literature search) and PubMed that were published between Jan. 1, 2015 and August 17, 2019: *[patient-reported needs OR want OR information needs OR*

needs OR unmet needs] AND *[patients]* AND *[diabetes OR mHealth OR online]*. Literature, news articles and other resulting publications were included if they reported needs and wishes for SM and SM aids by patients with diabetes. Literature was excluded if the feedback was from non-patients, or from patients during development or testing of a specific app or online intervention only. This is because we aimed to identify unbiased feedback about needs for SM and factors that facilitated SM, without the context of development or testing of an app for a purpose that was chosen by the researchers, not the patients. Data extraction included patient-reported needs and facilitating factors related to diabetes self-management. Co-author (MB) performed inductive qualitative analysis and grouping of the needs.

2.3 Comparison of reported outcomes vs. patient-reported needs

We performed a comparison based on the individual topics, i.e. reported outcomes and patient-reported needs, independent of the previously established categories. Comparison of the individual topics was discussed and agreed upon by all co-authors. By comparing individual reported outcomes and patient-reported needs, we were able to identify which patient needs are addressed by intervention studies and which still need to be addressed in the future.

3 RESULTS

3.1 Results from Review 1 – reported outcomes of mHealth and online interventions

The search strategy resulted in the identification of n=1681 mHealth and online intervention studies. After removing duplicates, most were excluded because no evaluation was reported, the focus of the study was not on diabetes or apps and online interventions, was not in English, not peer-reviewed or published before 2015. The selection process is described in Figure 1.

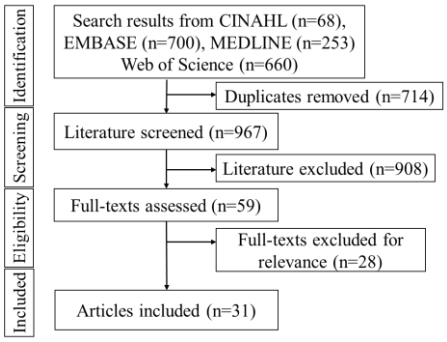

Figure 1 is a PRISMA flow chart diagram of Review 1.

The analysis of mHealth and online interventions studies resulted in six categories, each with outcomes reported from evaluations. The *Usability and Suitability of apps and interventions* category (see Table 1) had the most reported outcomes. Of these, the most commonly reported outcome was the Features and functions of an mHealth or online intervention. The Features and functions included the different types of tools for self-management such as diabetes diaries and glucose monitors, their characteristics and the users' experiences with these tools. mHealth and online interventions tend to focus on their effect on self-management, self-efficacy and autonomy, and clinical health measures such as hemoglobin A1c and blood pressure. See Table 1 for the full list of reported outcomes.

Reported Outcomes	Refs
Usability and Suitability of apps and/or online interventions	[5, 7-32]
• Tailorability	
• Features and functions	
• Ease-of-use	
• Challenges of use (from HCPs and patients)	
• Suggestions for development and improvement	
• Feasibility of integration into care practice	
• User interface design	
Effect on patient empowerment and engagement	[5-7, 10-12, 14, 17-20, 22, 25-29, 31, 33-35]
• Self-management	
• Self-efficacy and autonomy	
• Motivation	
• Usage patterns	
• Adherence	
Effect on clinical health measures	[6, 7, 9, 12, 14, 16, 18, 20, 22, 26, 29, 34]
• Quality of life	
• Psychological symptoms	
• Physical symptoms	
• Clinically measured data	
• Changes in patient-recorded health measures	
Data protection	[11, 13, 15, 17, 22, 32]
• Security and privacy	
• Security regulations (or national standards)	
Support from and access to	[6, 9-11, 13, 14, 17, 18, 20, 24, 25, 27-29, 31, 33, 35]
• Peers	
• Family	
• Coordinated healthcare services	
• Relevant diabetes information	
Other	[9, 28]
• Cost of development	
• Recommendation of technical solutions to patients by HCPs	

Table 1 Results of Review 1, reported outcomes from mHealth and online interventions.

3.2 Results from Review 2 - patient-reported needs

The search strategy in PubMed and Google resulted in 160 manuscripts with references to "patients' needs" for diabetes self-management. Review of the titles, abstracts and brief descriptions, followed by review of full texts, resulted in the exclusion of 139 manuscripts, largely because the needs were not directly reported by patients, or were not related to diabetes. Figure 2 details the identification and selection of included literature.

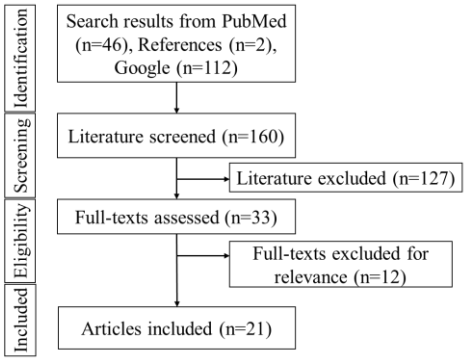

Figure 2 is a PRISMA flow chart diagram of Review 2.

Four categories of needs were identified from the qualitative assessment of reported patient needs. The most commonly reported needs were related to *Support and access to services,* including both Emotional and practical tailored support from family, peers and HCPs to encourage and guide SM. The second group of most common needs were related to *Coping, patient engagement and empowerment*. Patients saw the importance of being motivated and having confidence in their ability to perform SM tasks. This included being able to determine the best action in different situations, e.g. vacation, or if they needed to adjust how they managed their disease, e.g. because their metabolism and other factors changed as they grew older. While patients reported that they needed routines and more structure in their SM, they also wanted more relaxed and less strict SM goals, e.g. they did not like to feel ashamed or defeated by not reaching a diabetes-related goal. Because this review focused on general SM needs and facilitators of SM, fewer articles (n=6) described needs specifically related to mHealth or online interventions.

Further, many of the reported needs were inter-related. For example, patients wanted information about how their lifestyle choices affected their diabetes health, and vice versa. This information could be provided by HCPs' feedback about their SM performance, or from visualization of previously registered lifestyle and health data in an app (seen under *Support and access to services* and *Technology needs*, respectively, in Table 2). Table 2 provides more detail of the categorized needs that patients reported.

3.3 Comparing review results: Research foci vs. patient needs

When comparing the topics of the reported outcomes of mHealth and online interventions and the patient-reported needs (see Venn diagram, Figure 3), we found many commonalities. The green section of the Venn diagram (B) illustrates these commonalities, with some individual topics such as Relevant diabetes information, and Feasibility of integration into care practice, reported as outcomes of interventions covering a variety of individual topics from the patient-reported needs.

The yellow section of the Venn diagram (A) illustrates only reported outcomes from the mHealth and online interventions such as Cost of development, and Challenges to use from both HCPs and patients. The blue section of the Venn diagram (C) which illustrates only patient-reported needs, include individual topics such as Access to updated research results and policy changes related to diabetes SM, and How to cope with negative feelings and stress related to SM.

Patient-reported needs	**Refs**
Information needs	[36-46]
• Clinical tests and disease function • Options, risks, symptoms of treatments and medications • How lifestyle impacts disease • How disease impacts life • Population level disease info • Information for family and friends • Quality, reliable, tailored education and information • Awareness of updated research and healthcare policies	
Support and access to services *(HCPs, peers, family)* ***needs***	[36-45,47-56]
• Sharing data, e.g. from app to HCP, and from electronic health records to patient • Emotional and practical tailored support • Feedback on SM performance and reminders • Variety of always-available health services/SM aid options • Resources and services that facilitate SM activities, e.g. gyms	
Coping, patient engagement and empowerment needs	[37, 39-42, 44-46, 49-53]
• Participation in own healthcare decisions • Motivation • Self-efficacy • Self-control/discipline, e.g. daily routines • SM plan/goals that are not too strict • How to adjust SM to e.g. different situations, as disease progresses • How to cope with negative feelings, stress, insecurity about disease • Avoid burden of disease for self and family • Balancing life and SM responsibilities	
Technology needs	[36, 41, 47, 48, 50, 56]
• Simple and relevant visualization • Automatic entry of different types of data • Access to previous activity records • Ease-of-use, e.g. always available	

Table 2 Results of Review 2, patient-reported needs.

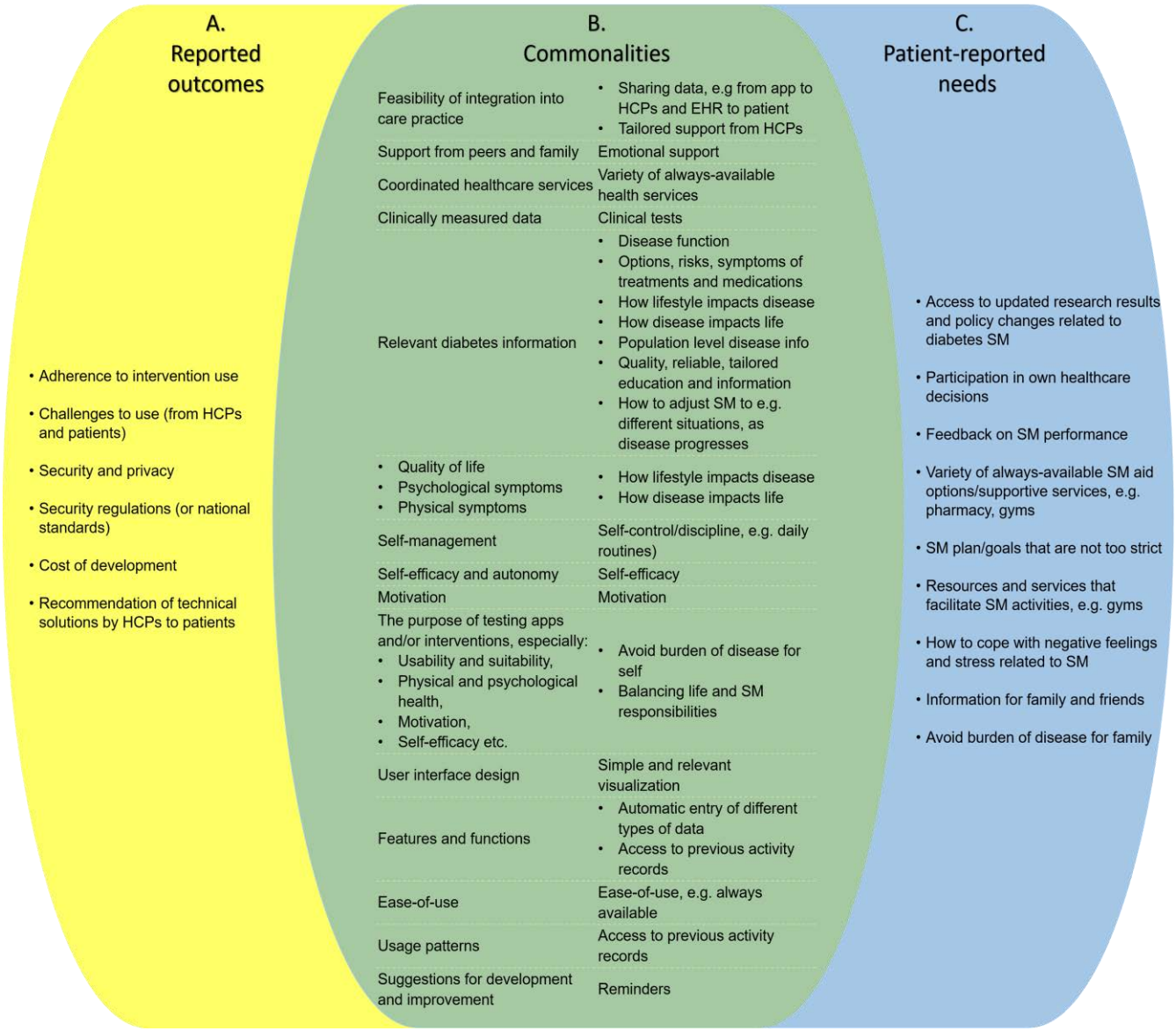

Figure 3 Venn diagram comparing results of both reviews, based on individual topics: **A.** topics that only appeared in reported outcomes, **B.** topics that appeared in both reported outcomes and patient-reported needs, and **C.** topics that only appeared in patient-reported needs.

4 DISCUSSION

The reported needs of patients and the reported outcomes of research did overlap a lot. There are still however, patient-reported needs that research has yet to address in order to optimize the self-management of diabetes patients.

4.1 Patients want to share data

The patients' need to share their own gathered health data from apps with HCP has little representation in research outcomes. Only recently have technology developers, health authorities and researchers accepted the need to address both patients' and healthcare practitioners' use of these technologies, for example in consultations [57]. As a new and emerging field, patient-generated health data integration faces challenges in the every-day clinical setting, as well as from continuous development and use [58]. In addition to its significant effect on patients' health, patient-generated data integration improves communication between HCPs and patients [58]. With input from HCPs about this shared data, patients could receive more supportive and tailored services, e.g. medication advice, and tools for coping with emotional and psychological distress. With the continuous advancement in technology, more of the already existing and future diabetes interventions could incorporate this function to help improve SM activities. This is especially true for diabetes, which is the fastest growing target audience for both individual and integrated mHealth systems [59].

4.2 Patients want more information

The patient-reported need for Awareness of updated research and healthcare policies is among those needs not well-represented in the reported outcomes from mHealth and online intervention studies. Considering the importance that some categories of patients place in the digital sources of information [60], patients must be given the opportunity to access and understand research that pertains to their disease condition. We must also acknowledge that because

this information is published in a language and platform, e.g. scientific journals, that target researchers, not patients, it is understandable that patients do not feel that they have access to this information. If researchers would be more active in their production of popular science articles, participation in social media or blogs, this information could be more accessible and understandable for patients.

Patients also reported a strong need for evidence, information and support. Some important questions to ask regarding these topics are: for which patient group is the evidence, i.e. reported outcomes, relevant? And, are there factors or needs that precede patients' needs for SM? For example, Majeed-Ariss et al. report the needs of a group of British-Pakistani women who struggle with receiving health information and recommendations in English [51]. In this case, there was a fundamental barrier, i.e. communication, which needed to be overcome before these women could be expected to perform recommended SM activities, let alone to achieve diabetes health goals.

4.3 Involving Patients in SM interventions

Platforms or devices addressing the majority of the patient needs in mHealth and online interventions should be a priority for researchers. Similarly to Majeed-Ariss et al. [51], Berkowitz et al. [54] report that, in addition to healthcare services, patient needs include community resources and access to gyms that serve to lower the barriers to performing SM activities. Because patient needs relate to both medical and non-medical factors, research should involve patients from the beginning of SM aid-development to the identification and organization of a preventative or related service and support network, e.g. family and peers. Designing mHealth or online interventions that allow for personalization or tailoring based on each individual's needs at their stage of SM or disease progress, can be another way for research to significantly address patient-reported needs for SM.

4.4 Limitations

Based on experience in the field of mHealth development and evaluation, which iteratively involves patients, we know that data and personal security and privacy, as well as clinical efficacy of SM aids are both important to patients [61]. However, because Review 2 focused on general SM needs reported by patients, with less emphasis on needs from mHealth or health technologies, these were not included in the extraction of patient-reported needs.

Due to the differences in aims and the kind of data we hoped to extract from the two reviews used in this paper, the time span of the searches, the databases accessed, and the type of review (systematic versus non-systematic review) were different. In addition, the reviews were limited to articles published in English language.

5 CONCLUSION

There are many patient-reported needs not addressed in today's diabetes mHealth and online intervention studies. In order to meet the needs of patients, facilitate the expectations and treatment goals of care teams and improve overall health and wellbeing for those living with diabetes, comprehensive interventions and methods for developing and testing mHealth and online interventions should be further explored. With today's technologies, it is more feasible and possible to realize the potential of patient empowerment and improved self-efficacy via mHealth and online interventions. Patients' desire to share information with their HCPs can reinforce the potential of collaborating with their healthcare teams as opposed to only following directions. Therefore, the more we know about the challenges that patients face, the specific needs for patients' self-management, and the ability of health services to support these needs, the more effectively we can develop tools and services, and provide relevant interventions for both patients and HCPs.

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7 ACKNOWLEDGEMENT

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