Designing an e-Health Program for Lifestyle Changes in Diabetes Care
A Qualitative Pre-Study in Norway

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Abstract
Type 2 diabetes mellitus (T2D) and prediabetes prevalence rates are high. Consequences are serious, but current treatment is often not efficient for achieving remission. Remission may be achieved through lifestyle intervention. Frequent follow-up is necessary, and health care personnel (HCP) lack resources, time, and often adequate knowledge. Self-management of T2D can benefit from better use of Information and Communication Technologies (ICT), which may improve patient involvement and follow-up, and can provide new tools for lifestyle change. Virtual follow-up through ICT with HCP may reduce costs and reach more patients. An electronic health (e-health) program for T2D and prediabetes will be developed in collaboration with users, as part of a plan for a large randomized controlled trial (RCT).

Keywords
Diabetes, type 2 diabetes mellitus, e-health, technology, lifestyle intervention.

1 INTRODUCTION

The prevalence of diabetes is increasing worldwide, where type 2 diabetes mellitus (T2D) accounts for approximately 90-95% of all cases (1). Additionally, many have prediabetes which is characterized by glucose levels higher than normal, but not high enough to meet the criteria of T2D (1). T2D is a chronic, metabolic disease characterized by elevated blood glucose levels caused by relative insulin deficiency. Risk factors include age, overweight or obesity, inactivity, and genetic predisposition (2). T2D, often in combination with obesity, affects morbidity, mortality, and quality of life, and the economic costs associated with T2D in Norway in 2019 was approximately 45,7 billion NOK (3). More than 50% of people with T2D have obesity (4), which can be treated with lifestyle intervention. Nevertheless, bariatric surgery is the most effective long-term treatment because long-term weight loss maintenance through lifestyle intervention only occurs in around 20% of cases (5, 6).

A weight loss of 5-10% is sufficient to achieve important health benefits, including reduced risks of developing complications and other co-morbidities in T2D (7-9). Larger weight losses may also reverse T2D (normalization of blood glucose and symptom relief without the use of medications) (7-9), and is possible to achieve for many. However, lack of thorough and sufficient follow-up tools and strategies often leads to weight regain and return of risk factors associated with overweight and obesity. Time since diagnosis is relevant, as people diagnosed early in the disease course are more likely to succeed with lifestyle changes (10). This confirms the importance of early and efficient intervention to improve chances of long-term health benefits.

According to national and international guidelines, newly diagnosed T2D should be treated with lifestyle intervention through dietary changes and increased physical activity (PA) level (11, 12). Two studies from Finland (13) and the USA (14) showed that lifestyle intervention emphasizing weight loss through a healthy diet and increased PA, can reduce the number of new T2D cases among people at risk of developing the disease by 58%. In the DiRECT trial from the UK, a structured weight loss program with a strict energy-restricted diet and intensive follow-up, administered by the primary health care provided remission of T2D in nearly half (46%) of the participants after one year, and 36% after two years (8, 15). Nonetheless, treatment through lifestyle intervention and follow-up offered to patients today is not sufficient to reach treatment goals regarding blood glucose control and other risk factors, and the majority of T2D patients also need blood glucose lowering medication (16). Bariatric surgery is used in obesity to reach substantial weight reduction, and a T2D remission rate of 25-75% is reported depending on surgical procedure and follow-up time (17).

The burden of T2D is considerable for both the individual and society. Lifestyle changes and weight reduction have great potential in preventing T2D, improving metabolic control among those who have the disease, and may provide remission. However, no present models uses this potential and offer long-term follow-up in the Norwegian health care system today. General practitioners lack capacity to provide such follow-up and may not have the necessary knowledge and they call for better options for lifestyle follow-up to offer their patients with prediabetes or T2D.

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Technological tools such as mobile phone-based applications with connected human sensors can contribute to, and potentially improve, self-management and follow-up of people with T2D (18, 19), and they have potential to prevent and provide support in the management of several chronic diseases (20). Such technology can provide tools for remote guidance from health care personnel (HCP) and may reduce costs and reach out to a larger group of patients. This technology also enables registration of food intake, PA, body weight, blood glucose levels, and more. In addition, video calls etc. with therapists or other HCP provides opportunity for follow-up without physical attendance. Few such technological tools, which provide lifestyle changes to prevent, treat and reverse T2D and emphasize long-term follow-up and contact with HCP, are available today.

A potential issue when designing and developing new e-health tools, is the probability that such tools are made for people in *least* need of them. This is referred to as the 'People Like Us' (PLU) problem (21) and point to the fact that people in greater need of help in their management and treatment of disease are in fact not the users in which these tools are tailored for. Furthermore, this could mean that the privileged gain even more access to health care services, and those in urgent need of such services are left out due to factors such as low health and technological literacy, motivation, and more. It is therefore necessary to recruit a diverse study sample including people with different needs and experiences in the design and development phase.

An important term in the case of disease prevention and self-treatment is *self-management*, a process which facilitates achievement of knowledge and skills necessary to manage and take control over one's disease. This is especially important in the treatment of T2D (22). People must, according to Bandura (2004), *"learn to monitor their health behavior and the circumstances under which it occurs"* (23). This is possible using technological aids, and an easy-to-use e-health program providing sufficient tools and follow-up will be of great value to patients, relatives and care takers, HCP, and society as a whole in Norway.

This project is a collaboration between Oslo University Hospital (OUS), the University of Oslo (UiO), UiT the Arctic University of Norway (UiT), and ABEL Technologies AS, a technology company based in Tromsø, Norway. ABEL Technologies has developed a tool for lifestyle follow-up which has focused mostly on exercise and PA until now. They now wish to further develop this to target the health care sector including prevention and treatment of diseases.

2 AIMS AND HYPOTHESIS

The aim of this study is to gather information about what the user group (people with prediabetes and T2D) want and need from an e-health program, including essential functionalities.

The long-term aim is to use this e-health program in a large RCT planned to take place in Norway after the present pre-study is finished, to assess its effects in prevention, self-management, and remission of T2D, compared to the effect of not using such a program.

Based on findings from the literature and the clear need for improved options for preventing, treating, and reversing T2D, it is assumed that technology-based tools may be a more efficient way of deliver lifestyle interventions than options available today.

3 METHODS

3.1 Study design

This is a qualitative pre-study where study participants take part in physical and/or digital focus group meetings, where they will be encouraged to share information about what an e-health program should include, and how it should be designed and used. Questionnaires and audio recordings will be used to collect relevant information. Paper-prototyping (prototyping in paper format where the participants contribute to paper representations of how the functionalities should work and look like) will be used to involve the participants in the development of the program. During digital meetings, a safe communication platform (Whereby or similar) will be used, as well as a digital solution for prototyping. Whereby is currently used at the largest hospital in Norway (OUS) for video consultations with patients and is considered secure for such use.

3.2 Participants and recruitment

Approximately 32 adults (≥18 years) with prediabetes or T2D currently living in Norway will be recruited to this pre-study. Recruitment will mainly take place at the Norwegian Diabetes Association's web and Facebook page, in addition to flyers distributed by our collaborating partners at OUS and the University Hospital of North Norway (UNN).

Participants may sign up for the study in three ways: 1) through following a link which takes them to a secure web-based form: Nettskjema, 2) through scanning a QR code provided on the recruitment flyer which takes them to the same Nettskjema, or 3) by sending an e-mail to one of the researchers on the project, with instructions to only write the following: "I want to sign up for the study" or "I want to know more about the study". The person will then be contacted by the researcher by phone.

The web-based form (Nettskjema) contains information about the study and participation criteria. Information regarding age, gender, and education will be collected to ensure a representative group of participants. The qualified and chosen participants will then be able to read the informed consent form and take part in the study. Their e-mail addresses and phone numbers will be collected to enable further contact.

Inclusion and exclusion criteria

Inclusion criteria: HbA1c >48 mmol/mol for T2D, and elevated HbA1c above normal levels (>38 mmol/mol) or increased risk of developing T2D (e.g., first-degree relatives with T2D, elevated blood glucose levels) for prediabetes. Eligible participants must be willing to attend physical or digital meetings with other participants, and consent to audio recordings during meetings.

Exclusion criteria: health challenges which complicate ingesting a normal diet or being normally physical active (e.g., serious cardiovascular disease, lung disease etc.). Difficulties using mobile phones (e.g., reduced vision, motor ability etc.) and not able to communicate in Norwegian.

4 DETAILED PROTOCOL

4.1 Project description

In this pre-study, digital and physical focus group meetings including people with prediabetes and T2D will be held to inform the design and development of an e-health program in line with wishes and needs from a user perspective. These meetings allow the user group to contribute to the development process by sharing expectations about available functionality from an e-health program and suggest new ones. This includes factors associated with motivation and coping, what increases the likelihood of long-term use and thereby aiding in prevention, self-management, and remission of T2D.

Our aim is to develop treatment options using technological self-help tools in order to assess its long-term effect in a planned RCT in Norway, and to collect data to help answer research questions regarding the development of T2D; ranging from basic medicine related issues (importance of genetics, epigenetics, inflammation, adipose tissue changes etc.) to determining prerequisites for successful treatment with lifestyle intervention. This may provide knowledge needed for personalized treatment of prediabetes and T2D. One of the main aims of the e-health program is to tailor it to its users, building upon previous experience with tailoring of the Diabetes Diary self-management app (24). Tailoring is a process for creating individualized communications, and is used to *"determine the most appropriate information or strategies to meet the person's unique needs"* (25). Tailoring can lead to positive outcomes and benefits for health behavior when compared to non-tailored interventions (26, 27).

4.2 Data collection

Participants will be asked to attend focus group meetings at the beginning of this study. Participants will be allocated to one of the following groups based on their disease status: T2D group or prediabetes group. The aim is to create three groups consisting of people with T2D, and one group consisting of people with prediabetes. Each group will have a maximum of eight participants. Two of the groups are planned to take place online (using Whereby or similar).

Given the short amount of time and possibilities (resources/funding etc.) available in this pre-study, it is expected that all important topics will be covered by including a variety of gender, age, and geographical spread across Norway. Data saturation is estimated to be reached at four focus groups (eight participants in each), based on previous research (28, 29). Several definitions of saturation exist, where one describes data saturation as the point at which "*new data tend to be redundant of data already collected. In interviews, when the researcher begins to hear the same comments again and again, data saturation is being reached"* (30).

Each meeting will last approximately 120 minutes (including a 15-minute break) and take place twice over a three-month period. The first half of the first meeting will be an introductory meeting where the participants get to know each other and are informed about the study, their role and what to expect from the future meetings. This part of the meeting will not be audio recorded in order for participants to share personal stories and experiences. If any personal information is shared during later meetings, such information will be censored from the transcript.

The following meetings will cover specific topics which are presented in the first meeting to allow preparation for the participants. All participants will be asked to fill out questionnaires regarding preferences, thoughts, and opinions on present and future e-health programs (for digital meetings a secure online form will be used [Nettskjema]). Participants will be asked to identify factors that can improve the usefulness and user experience in general, and which functions are excessive in an e-health program.

During meetings (except the first part of the introductory meeting) two audio recorders (Olympus WS-852) will be used (one for backup). Audio recordings will be saved on two encrypted memory sticks (Corsair Padlock 3) locked up in a separate cabinet until transcription is completed, and content will then be deleted by reformatting the memory sticks, and the memory cards on the audio recorders. Each participant will be assigned a unique identification code used in the transcripts, to deidentify all participants. An overview table containing participant's names and identification codes are kept locked up in a separate cabinet from the audio recordings. After deleting the audio recordings, only identification codes will be used. The table connecting participants to collected data will be deleted when relevant information has been retrieved and summarized, maximum one year after the end of the study.

Transcribing of audio recordings will be performed on an offline computer at UiT the Arctic University of Norway, by one of the researchers involved in the study, or by a certified company with education in the necessary security and privacy regulations. In the transcripts, unique identification codes will be used, and no sensitive or personal information will be transcribed. Any sensitive or personal information shared in meetings will be censored from transcripts.

Information, opinions, wishes, and needs provided by participants will be saved and used in publications, and to develop the e-health program. ABEL Technologies AS will be informed about the information that is relevant for developing the app with linked functionalities (no sensitive or other information about participants).

4.3 Dissemination

Results from this pre-study will be published as peer-reviewed article(s) and used in further research.

4.4 Ethics

This study was approved by the data protection officer at UiT the Arctic University of Norway and by the Norwegian Center for Research Data (Sikt, previously NSD). The Regional Committees for Medical and Health Research Ethics (REK) has been consulted and we received a conclusion that no application and approval was necessary for this study. Additionally, a risk assessment has been made guided by experts at UiT and has been accepted as sufficient to proceed with this pre-study.

Participation in this pre-study is informed and voluntary and all participants may withdraw from the study at any time without providing any reason(s).

5 SUMMARY

Prevalence rates of prediabetes and T2D are high and increasing worldwide. Consequences may be serious and impact morbidity, mortality, and quality of life, with economic costs exceeding 45 billion NOK in Norway in 2019. Lifestyle change is encouraged for people with prediabetes and T2D, and remission may be achieved. Moderate weight loss (5-10%) can induce important health benefits, but long-term weight maintenance is difficult and only successful in around 20% of cases. GPs and other HCP need new tools to prevent, treat and reverse T2D in Norway, and worldwide. Technological tools such as mobile phone-based applications and services can be valuable and may improve self-management and follow-up in people with T2D, encouraging and providing new and innovative ways for self-management.

The aim of this pre-study is to prepare for the design of a comprehensive e-health program for lifestyle change in this target group, through qualitative focus group meetings, including adults with prediabetes or T2D. Both digital and physical meetings will be arranged, using questionnaires, paper prototyping, and audio recordings to gather information relevant to design an e-health program tailored to the needs of people with the disease.

The long-term aim is to use these results in a large RCT, planned to take place in Norway in 2024, to collect data to help answer research questions regarding the development and treatment of prediabetes and T2D.

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