Master Thesis

Feasibility of blended lifestyle coaching for people with diabetes type 2 in secondary care:

Perspectives of patients and healthcare professionals on CooL+Diameter

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Preface

This thesis was written as the final work for the completion of the Master Health Sciences at the University of Twente, within the specialization track of Innovation in Public Health. This thesis was part of the Diameter-1 study conducted in collaboration with Ziekenhuisgroep Twente (ZGT) and the University of Twente. With the results of this thesis I hope to contribute to further development of the CooL+Diameter program and integration into regular care.

At the beginning of this academic year I was fairly new to the field of Health Sciences, coming from a background in Public Administration. However, I have always been interested in the field of healthcare and I am so glad I made the choice 1.5 years ago to pursue this Master's degree. I have learned a lot over the past year and especially during the period of writing my thesis. It was very educational for me to help with some parts of the data collection in the hospital and having contact with patients and healthcare professionals. I am very grateful for this new experience.

I would like to thank my supervisors Annemieke Konijnendijk, Anouk Middelweerd and Eclaire Hietbrink for their time, critical and helpful feedback and suggestions. I would also like to express my gratitude to the patients and healthcare professionals that wanted to participate in the interviews and provide me with their thoughts on the CooL+Diameter intervention. Lastly, I would like to thank my family and friends for their unconditional support during this final period of my academic studies.

I hope you will enjoy reading this thesis!

Carine Gotink

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Abstract

Background: Diabetes Mellitus (DM) is causing a major challenge to public health with approximately 537 million diagnosed people worldwide. Ninety percent of people with DM are diagnosed with Type 2 Diabetes Mellitus (T2DM). Changing lifestyle behavior, such as a healthy dietary intake and increasing physical activity is the cornerstone of T2DM treatment. Several self-management interventions such as combined lifestyle interventions and eHealth are available to improve lifestyle behavior. However, long-term adherence to self-management behavior is lacking. Combining face-to-face coaching and the use of an app designed for self-monitoring and digital coaching could be of importance for the treatment of T2DM, however limited research has yet been performed on this combination. Ziekenhuisgroep Twente (ZGT) started with the two-year combined lifestyle intervention CooL led by a certified lifestyle coach. In addition, participants used the Diameter app for self-monitoring physical activity, nutritional intake and glucose values and digital coaching.

Aim: The aim of this study was to evaluate the feasibility of using the Diameter app in combination with the combined lifestyle intervention CooL to change lifestyle behaviors in people with T2DM in secondary care from the perspectives of patients and healthcare professionals.

Methods: The feasibility of the CooL+Diameter intervention was evaluated in a three-month period with a prospective longitudinal design using mixed-methods. Feasibility was assessed with acceptability, intervention usage, practicality, implementation barriers and facilitators and limited-efficacy testing. Five patients were included in the intervention. Measurements on glycemic regulation, body composition, health-related quality of life, physical activity and nutritional intake were performed at baseline and at the three-month follow-up. In addition, intervention usage was assessed using log-data. Lastly, semi-structured interviews with five patients and eight healthcare professionals were conducted at the end of the three-month intervention period.

Results: Patients accepted the use of CooL+Diameter and found the concept of using an app for self-monitoring and digital coaching a valuable addition to the CooL program. Insight in the effect of nutrition and physical activity on glucose values, getting feedback and becoming more aware were identified as the most helpful elements. Despite the overall acceptance of CooL+Diameter, the user friendliness of the Diameter app needs to be improved. Patients were satisfied with the use of the Fitbit and Freestyle Libre, but found it difficult to use the food diary and digital coaching and encountered several technical problems. This resulted in limited use of the Diameter app itself. However, despite the limited use of the Diameter and a small number of participants, glucose levels and BMI were significantly lower at follow-up compared to baseline. Hip and waist circumference also decreased compared to baseline.

Conclusion: Overall, CooL+Diameter was predominantly perceived as a feasible intervention for T2DM patients in secondary care by both patients and healthcare professionals. Future research should focus on improving the user friendliness of the Diameter, further personalization of digital coaching and integration of the Diameter app in the CooL program.

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Introduction

Diabetes mellitus (DM) is a chronic condition that is causing a major challenge to public health. Globally, approximately 537 million adults were diagnosed with DM in 2021, which accounts for 10.5% of the global population [1]. Without intervening, the prediction is that there will be 783 million people living with DM in 2045. This is an increase in prevalence of 46% [1]. In 2020, over 1.1 million people were living with DM in the Netherlands [2]. This high prevalence of DM causes a large clinical and economic burden [3, 4]. In 2018, DM had the highest clinical burden in the Netherlands, after coronary heart diseases and strokes [3]. Peters et al. [4] showed that in 2016 there was a substantial economic burden caused by DM in the Netherlands, with an estimated total cost of 6.8 billion euros [4].

The most common type of DM, accounting for approximately ninety percent of the total population diagnosed with DM, is type 2 diabetes (T2DM) [1,5]. Insulin resistance and dysfunctional insulin secretion causing high blood glucose levels are the main characteristics of T2DM [1,6]. Estimating average blood glucose levels over a period of 2-3 months is done by measuring glycated hemoglobin (HbA1c) (i.e., the amount of glucose that attaches to hemoglobin) [7]. Chronic high HbA1c levels can lead to several complications related to impairment or failure of organs, such as the kidneys, heart, blood vessels, nerves and the eyes [5-6]. The exact etiological causes for T2DM are unknown, however research has shown that there are certain risk factors for developing T2DM [5]. Individuals can have a genetic predisposition for developing T2DM [8]. If one parent has T2DM there is a lifetime risk of 40% for an individual to develop T2DM and nearly 70% if both parents have T2DM [9]. In addition, lifestyle and environmental factors such as physical inactivity, unhealthy diet, stress, disturbed sleep, social isolation, air pollution, noise pollution, sedentary lifestyle, smoking and a low socioeconomic status also play a major role in developing T2DM [6, 10-12]. These risk factors can result in obesity, high blood pressure and high blood lipid levels, which can lead to the development of pre-diabetes and eventually the diagnosis of T2DM [11-12].

A growing body of evidence shows that changing lifestyle behavior, such as a healthy dietary intake and physical activity, can result in remission (i.e., HbA1c levels below 48 mmol/mol and no medication usage for one or more years) or reversal (i.e., HbA1c levels below 53 mmol/mol and lowered medication usage for one or more years) of T2DM [13-15]. The Diabetes Remission Clinical Trial (DiRECT) demonstrated that 46% of patients following a dietary program (i.e., replacing food with shakes followed by reintroduction of a healthy dietary pattern) for weight loss in primary care achieved remission compared to 4% of patients in the control group [14]. Following a Mediterranean diet, which is characterized by eating seasonal and local products in a social environment, can lead to the postponement of diabetes medication usage by 4.8 years on average according to Esposito et al. [15, 16]. Improving physical activity has also led to reduced levels of HbA1c, especially in a structured training of both aerobic and resistance exercise [17]. Lifestyle changes have also shown improvements in perceived quality of life (QoL) and quality of sleep [18].

To be able to achieve lifestyle changes, patients need to actively take charge of their own health by undertaking the actions necessary to control and reduce risks of further progression of their disease. This is also known as self-management [19-20]. Adherence to self-management behavior, such as eating healthy foods and engaging in sufficient physical activity, is often a challenge for diabetes patients [21-23]. Recent numbers showed that only 33% of Dutch DM patients meet the physical activity guidelines (i.e., two strength exercises per week, 150 minutes of movement per week and limited hours of sitting per day) [24, 25]. Another study showed that adherence to a Mediterranean diet did not fall within acceptable levels [23]. Only 17% of the participants reached a high level of adherence [22]. Main barriers of proper self-management among DM patients are a lack of knowledge about their treatment, insufficient motivation to change their lifestyle and lack of a treatment plan tailored to the needs of the DM patient [26-28]. Gaining knowledge and skills improves empowerment of DM patients and is associated with better self-

management behavior, increased QoL and improved treatment satisfaction [26, 29].

Both in primary and secondary care, lifestyle changes are the cornerstone of T2DM treatment [30]. However, individual face-to-face consultations to discuss self-management with healthcare professionals in usual care may not always be feasible due to an aging population, capacity problems and increasing healthcare costs [31]. Therefore, facilitating self-management also asks for interventions beyond the clinical setting, in an at home setting with a personalized motivational approach [32, 33]. Various methods for self-management interventions are available such as small-group meetings and eHealth (i.e., digital technology that can deliver prevention, education, diagnostics, therapy and care) [32, 34]. Lifestyle interventions are mainly available for T2DM patients in primary care, while lifestyle interventions for T2DM patients in secondary care are scarce [35, 36].

Several diabetes self-management programs, based on peer-led small-group meetings focused on physical activity and dietary advice, have shown successful results [37]. The Action for Health in Diabetes (Look AHEAD) trial compared a four-year intensive lifestyle intervention (ILI) (i.e., frequent meetings supplemented with a meal plan and instructions to increase physical activity (assisted by a pedometer)) to a diabetes support and education intervention (DSE) (i.e., three informational meetings on diet, physical activity and social support a year). The results of the trial demonstrated that participants in the ILI can obtain long-term weight loss, lower HbA1c levels and can have a larger probability of partial remission compared to the DSE group [37-39]. However, these positive outcomes mostly related to participants who were recently diagnosed, had lower onset HbA1c-values and were not using insulin [37]. In the Netherlands, a few evidence-based lifestyle interventions, so-called combined lifestyle interventions (CLI), targeted at obesity and prevention of DM have been developed [40, 41]. Currently, there are four certified reimbursed programs in the Netherlands, including SLIMMER [42] , BeweegKuurGLI [43], Coaching op Leefstijl (CooL) [44] and Samen Sportief in Beweging [45, 46]. These two-year programs led by a lifestyle coach have a focus on weight reduction by sustained lifestyle changes in diet, physical activity and behavior [47]. Effect studies have shown positive results in weight loss and increased physical activity and quality of life. However, some of these results were very minimal, for example on average between 2-3 kilograms were lost at the end of the CLI and long-term effects are limited [48-52].

eHealth also has the potential to improve self-management among T2DM patients [34, 53] and has the ability to positively impact public health due to high capacity possibilities and low costs [54]. Wearable devices can be used to monitor real-time health-related data such as glucose levels and physical activity and gives the possibility to access objective health data on a daily basis by patients and healthcare professionals [33, 34, 55, 56]. Self-regulation techniques such as personal goal setting and coping strategies, can also be incorporated in eHealth applications [56]. A systematic review demonstrated positive results in increased physical activity, weight loss and improved diet in T2DM patients when using eHealth [55]. However, this systematic review also stated that effectiveness of eHealth varied among studies due to different outcomes, contexts and interventions [55].

The lack of long-term adherence to sufficient lifestyle behavior seems to be a barrier to the success of self-management interventions in T2DM patients [51, 52, 55]. Face-to-face coaching, in for example a lifestyle intervention program, next to using eHealth could be of importance for long-term positive effects [54]. In a scoping review, Obro et al. [57] demonstrated that health-coaching and mobile health (mHealth) benefit from each other. Data extracted from the mHealth application can be used to start a conversation and involve patients in their treatment [57]. However, barriers to combining health-coaching and mHealth were the lack of a coaching method, the lack of training or education of coaches, use of of-the-shelf technologies not tailored to a condition and limited physical coaching [57]. Antoun et al. [58] demonstrated in a meta-analysis that at six months combining a mobile app with a tracker and a behavioral intervention

(passive or human-based) resulted in a weight loss of 3.77 kilograms compared to the use of a mobile app alone with a weight loss of 2.80 kilograms. In a subgroup analysis only the combination of an app and human-based coaching was statistically significant with a weight loss of 2.63 kilos at six months [58].

Even though combining face-to-face coaching and eHealth have shown some positive results, combining eHealth applications, that include digital coaching and real-time monitoring, with face-to-face coaching for the treatment of T2DM has been limitedly studied. Research into combining face-to-face coaching and eHealth has been targeted mainly at the prevention of T2DM in a primary care setting [59, 60]. Next to this, eHealth and coaching was mainly incorporated into usual care and not set up as a separate lifestyle program [61]. Coaching is also not always performed by specifically trained professionals [62]. To address these gaps in the current T2DM treatment, this study will research the feasibility of combining a face-to-face coaching program with an eHealth application for T2DM patients in secondary care.

Feasibility studies can be used to test whether an intervention will be sustainable and to explore the potential efficacy of an intervention [63]. According to Bowen [63] feasibility of an intervention can be measured with several domains. In this study, the following domains will be used to guide the research sub-questions: acceptability, demand, implementation, practicality and limited-efficacy testing [63]. These domains can give insight into the experiences of patients and healthcare professionals about the combined intervention in its current context. The other domains focus on contextual changes and organizational settings which do not fit within the scope and timeframe of this research [63].

In this study, face-to-face coaching consists of the combined lifestyle intervention CooL which is led by a certified lifestyle coach. The CooL program is combined with a newly developed mobile app called the Diameter. The Diameter provides T2DM patients with coaching and feedback in their daily life [64, 65]. The aim of this study was to evaluate the feasibility of using the Diameter app in combination with the combined lifestyle intervention CooL to change lifestyle behaviors in people with T2DM in secondary care from the perspectives of patients and healthcare professionals. Since this study will focus on the perspectives of patients and healthcare professionals on the combined intervention (from now on 'CooL+Diameter'), the sub-questions are separated into these two perspectives.

<u>Patient perspective:</u>

Acceptability:

- To what extent do people with T2DM in secondary care accept the use of CooL+Diameter?

Demand:

- To what extent do people with T2DM in secondary care use CooL+Diameter?

Practicality:

- To what extent are people with T2DM in secondary care able to carry out the activities related to CooL+Diameter?

Implementation:

- What are the barriers and facilitators for the implementation of CooL+Diameter in secondary care according to people with T2DM?

Limited efficacy-testing:

- To what extent does CooL+Diameter show changes in glycemic regulation, body composition, physical activity, nutrition and quality of life between the start and end of the intervention?

<u>Healthcare professional perspective:</u>

Acceptability:

- To what extent do healthcare professionals accept the use of CooL+Diameter in secondary care?

Implementation:

- What are the barriers and facilitators for the implementation of CooL+Diameter in secondary care according to healthcare professionals?

Methods

Study design

The feasibility of the CooL+Diameter intervention was evaluated in a three-month period with a prospective longitudinal design using mixed-methods. The intervention CooL+Diameter included baseline assessments, continuous monitoring and postintervention assessments. Data was collected from January 2022 to June 2022. The study was approved by the Medical research Ethics Committees United (MEC-U) Nieuwegein, the Netherlands (R20.21) and the Behavioural, Management and Social Sciences Ethics Committee of the University of Twente (220569). All participants provided written informed consent.

Intervention

Researchers from the University of Twente, Ziekenhuisgroep Twente (ZGT) and Roessingh Research and Development have developed a mobile application targeted at T2DM patients, called the Diameter. In the present study, the combined lifestyle intervention CooL, led by a certified lifestyle coach, was combined with the Diameter for T2DM patients in secondary care.

Diameter

The Diameter consisted of two elements: monitoring and coaching. Monitoring included measurements of glucose values, physical activity and food intake. Glucose values were automatically measured in real-time by using the Freestyle Libre 2 glucose sensor (Abbott) or by entering fingerstick measurements manually in the Diameter. Results were shown in the Librelink app and Diameter. Physical activity was automatically measured by using a Fitbit Inspire 2 activity tracker (Fitbit Inc.) to assess daily step activity or by manually entering activities such as swimming, cycling or other activities. The Fitbit results were presented in the Diameter as a 24-hour daily step count graph and activities as active minutes. Food intake was registered by using a food diary. Data were presented as carbohydrates and kilo caloric intake as a total and per food or drink intake [64]. Coaching in the Diameter included four different components. Firstly, patients received evidence-based text messages focused on improving physical activity and/or dietary habits as push notifications in the Diameter twice a day for ten weeks. Secondly, patients were able to set weekly lifestyle goals (i.e., a step goal, a cycling goal or a nutritional goal). Thirdly, patients got weekly feedback to reflect on achieved or unachieved goals and a five-minute exercise for achievement of self-set lifestyle goals by a digital coach. Lastly, patients received a weekly e-mail with further elaboration on the information patients got in the daily text messages. The e-mails are based on effective behavioral change techniques, such as goal setting [64]. Figure 1 shows some example screens of the Diameter app.

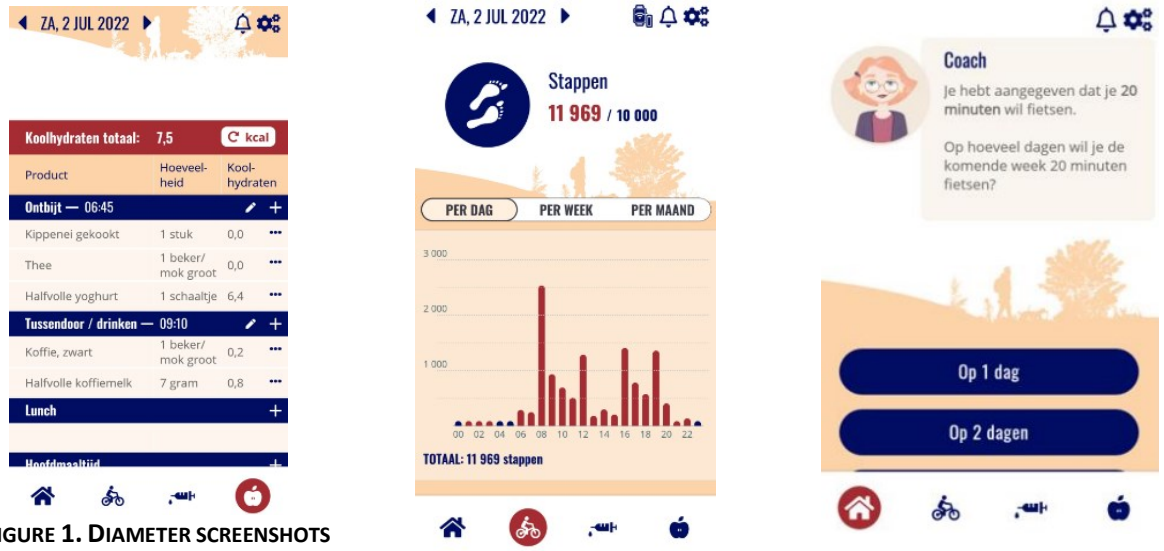

FIGURE 1. DIAMETER SCREENSHOTS

CooL intervention

Simultaneously, participants attended three group sessions and one individual session as part of the CooL program during the three-month intervention. These meetings were led by a certified lifestyle coach who also works as a diabetes nurse at ZGT hospital. During the group meetings, with a duration of 1.5 hours each, the participants first reflected with each other on the previous weeks. This was followed by education about a certain lifestyle topic accompanied by exercises. The three group sessions during this intervention had the following themes: 1) *"small changes, big effects: behavior change. Effect of nutrition on glucose regulation",* 2) "*Get moving: exercise and sports"* and 3) *"Delicious food provide structure: nutritious food".* Finally, the participants set new goals for themselves for the upcoming weeks. In the individual session the lifestyle coach and the participant evaluated lifestyle goals and refined them if necessary. Additionally, the lifestyle coach discussed the results from using the Diameter and accompanying tools with the patient [64, 66]. This study is part of the Diameter-1 study and is explained in more detail in appendix 1. An overview of the CooL+Diameter intervention is given in figure 2 [based on an unpublished model by E.A.G. Hietbrink].

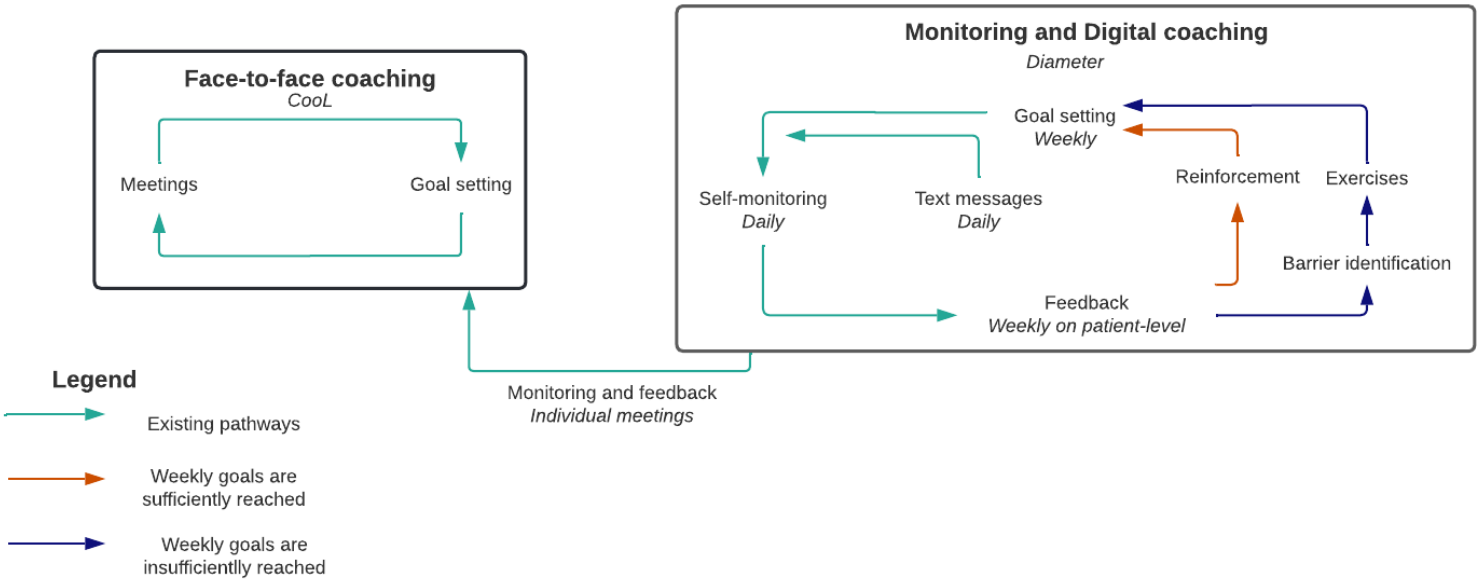

FIGURE 2. INTERVENTION OVERVIEW [BASED ON AN UNPUBLISHED MODEL, BY E.A.G. HIETBRINK]

Participants

Data were collected from patients with T2DM and healthcare professionals concerned with the treatment of patients with T2DM. People could participate in this study if they were 1) diagnosed with T2DM and were being treated at the outpatient clinic at ZGT hospital, 2) overweight with a Body Mass Index (BMI) of 25 or higher, 3) sufficiently motivated, 4) familiar with using an Android smartphone (version 5.0 or higher), 5) 18 years or older, 6) able to understand and weigh up information provided by the researcher and able to understand what the consequences of participation are and 7) able to provide a written informed consent [64, 66]. People were excluded if they were 1) dependent on renal replacement therapy, 2) diagnosed with severe general diseases or mental disorders, 3) drug abusive or 4) not proficient in the Dutch language [64].

Healthcare professionals were included if they were involved in the treatment of T2DM patients in secondary care. Lifestyle coaches were also included in the study population since a combined lifestyle intervention is supervised by a certified lifestyle coach.

The aim was to include six to twelve participants for each of the study population groups, patients and healthcare professionals. In a relatively homogenous group, six to twelve participants should be enough to recognize common perceptions and experiences and gain insight into the usability of a system, or in other words to reach data saturation [67, 68]. To apply data source triangulation the aim was to include healthcare professionals with different positions within T2DM care [69].

Procedure

Patients

Suitable patients with T2DM who are under treatment at the outpatient clinic for diabetes care at ZGT hospital were asked to participate in the CooL program during health visits. The sessions for the CooL program took place at ZGT hospital [64]. People who decided to participate in the CooL program were asked by the lifestyle coach, who also works as a diabetes nurse at ZGT hospital, to participate in the Diameter-1 study. Interested and eligible participants received an information letter. People who decided to participate in this study were asked to sign an informed consent.

Before the start of this study, patients who were interested in participating in the CooL program had an intake meeting with the lifestyle coach. The topics discussed in this meeting entailed: intended goals of the patient, motivation of the patient to complete the program, current lifestyle behavior, self-efficacy and social context (i.e., having support or not) of the patients [104]. After the intake session took place and the informed consent was received the first appointment for the CooL+Diameter intervention was planned [64].

An overview of the timeline of this study is given in figure 3. At the first appointment at ZGT hospital the participant received information from the researcher about the study and an instruction and explanation about the Diameter, Freestyle Libre and Fitbit. Additionally, participants downloaded the Diameter app on their own or borrowed Android smartphone. Furthermore, physiological and clinical measurements (i.e., HbA1c values, Time in Range, weight, height, waist and hip circumference) were assessed [64] (see table 2). After this, a two-week period of baseline measurements (T_0) started in the patient's home setting. This included blinded glucose measurements with the Freestyle Libre 2 and a reader, blinded nutrients intake using the Diameter app and non-blinded physical activity measurements with a Fitbit. Additionally, the patients were asked to fill in questionnaires about personal characteristics, openness to the use of new technology, current use of health apps and quality of life. Patients received these questionnaires through e-mail and filled them in digitally [64]. On the second or third day after starting baseline measurements patients were called by the researcher to ask if the Freestyle Libre and Fitbit worked properly and if the patient had questions about the Diameter or study in general [64]. In the following ten weeks three group sessions of the CooL program which took place at ZGT hospital were scheduled with an equal amount of time between each session. Simultaneously, the patient used the Diameter to receive digital coaching messages, set weekly lifestyle goals, receive weekly exercises, weekly informational e-mails and monitor physical activity and glucose values [64]. At the primary endpoint (T_1) in week thirteen or fourteen, the patient visited the outpatient clinic of ZGT hospital again. Another round of physiological and clinical measurements was conducted and patients were given two new Freestyle Libres [64]. One Freestyle Libre was used for T_1 measurement. The second Freestyle Libre was used for the next period of measurements of the Diameter-1 study [64]. Additionally, a semi-structured interview was conducted with the patients. Before interviews started patients were asked to read and sign the informed consent, specifically aimed at recording the interview (see appendix 4). These interviews lasted between twenty to thirty minutes and were held during the outpatient clinic visit for performing the T_1 measurements.

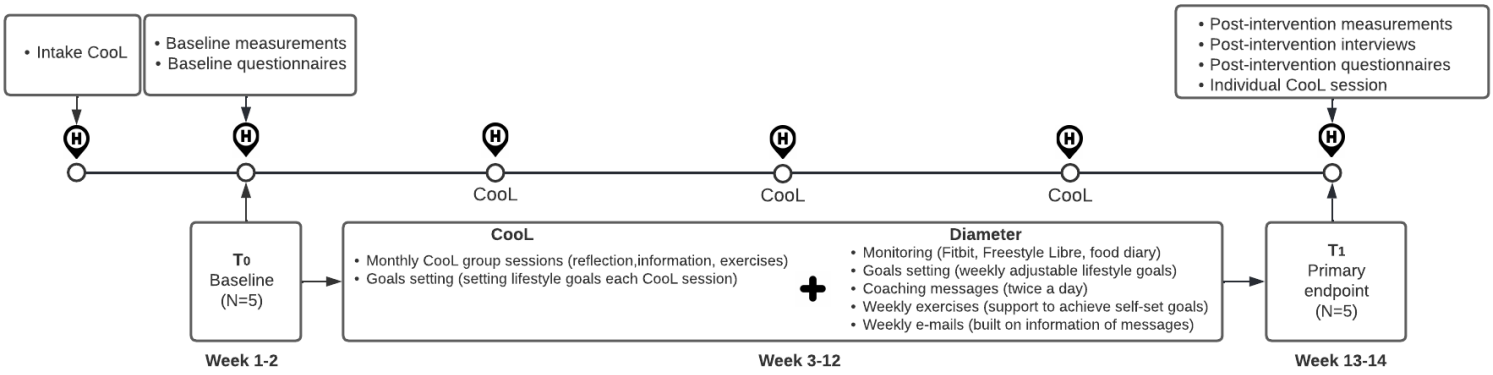

FIGURE 3. OVERVIEW OF COOL+DIAMETER TIMELINE

Healthcare professionals

Since the research is being conducted at ZGT hospital, healthcare professionals working at ZGT hospital in diabetes care and (distantly) involved in the Diameter-1 study were first contacted by the researcher via e-mail. Other healthcare professionals were contacted through purposive sampling [67]. After the healthcare professional gave approval for doing an interview with the researcher a date was scheduled. A week before the scheduled interview, the informed consent, and if necessary additional information about CooL and the Diameter (see appendix 7 and 8) was sent. The semi-structured interviews with healthcare professionals were conducted in a face-to-face setting and with the use of Microsoft Teams. Recordings of the audio were made during the interview. The interviews lasted between twenty to forty minutes per interview.

Measurements

To measure the feasibility of CooL+Diameter the following domains of feasibility were studied: acceptability, demand, practicality, implementation and self-efficacy [63]. Table 1 gives an overview of the operationalization of the used domains of feasibility and with which method the domain was measured. Data were collected from patients and healthcare professionals with quantitative methods using data from self-monitoring, log-data, and pre and post intervention questionnaires and measurements. Qualitative data was collected through semi-structured interviews.

Table 1. Overview of assessed domains of feasibility

Domain	Operationalization	Data collection method
Acceptability	*"The users' overall experience with a product, including perceived effectiveness, ease of use, and satisfaction of the experience" [70]*	Qualitative
Demand (Intervention usage)	*"The way in which an intervention and its various components are actually used in terms of frequency and duration" (based on [71])*	Quantitative
Practicality	*"One's capabilities to organize and execute the courses of actions required to produce given levels of attainments" [72]*	Qualitative
Implementation	*"The extent, likelihood, and manner in which an intervention can be fully implemented as planned and proposed" [63]*	Qualitative
Limited-efficacy	*"The extent to which a new idea, program, process, or measure show promise of being successful with the intended population" [63]*	Quantitative

Quantitative data

Quantitative data were collected with the Diameter, food diary, Fitbit and Freestyle Libre during the three-month intervention period. Next to this, clinical and physiological measurements (i.e., glycemic regulation and body composition) were conducted at baseline (T_0) and follow-up (T_1). Health-related quality of life was measured with a questionnaire at both measurement points. An overview is presented in table 2.

Table 2. Overview of quantitative data measurements

Domain	Measurement	Data collection	T_0	T_1
Demand	Intervention usage	Log-data		X
Efficacy-testing	Glycemic regulation	Freestyle Libre data	X	X
	Body composition	Physical examination	X	X
	Health-related quality of life	EQ-5D-3L questionnaire	X	X
	Physical activity	Fitbit data	X	X
	Nutritional behavior	Food diary	X	

Demand

Intervention usage

To assess intervention usage the log-data of the usage of the Diameter was analyzed. This contains data on: the number of coaching messages that were opened, the number of goals that have been set, the number of weekly interventions performed. In addition, log data (i.e., number of days that the diary was filled in and frequency of filling in the diary per day) was used to determine the usage of the food diary [64]. Usage of the Fitbit was measured by summing the days the Diameter was worn [64]. Since there is no algorithm available to estimate non-wear time for step count data, days with less than 1000 steps were left out. These lower step counts can possibly be due to the Fitbit not being worn, for example for recharging [73, 74]. Usage of the Freestyle Libre was analyzed by determining the amount of times patients scanned their sensor with their smartphone at baseline and follow-up [64].

Efficacy testing

Glycemic regulation

Estimated HbA1c levels and Time in Range (TIR) (i.e., the total time per day the glucose value was between 3.9 and 10.0 mmol/l) were measured with the Freestyle Libre 2 [64]. The Freestyle Libre glucose sensor is a waterproof adhesive medical device for continuous glucose monitoring. To measure glucose values from the interstitial fluid the Freestyle Libre sensor is inserted with a small needle on the upper arm. The sensor is worn for two weeks maximum. [64, 75]. The Freestyle Libre 2 measures glucose values every minute. With the Freestyle Libre 2 patients can scan their sensor with the Librelink app and see their glucose values in real-time [64, 76]. The Freestyle Libre has shown accurate results compared to standard methods of blood glucose testing (e.g., fingerstick measurements) [76]. However, accuracy on the first and last day is lower than on the other days [77, 78]. An algorithm will be used from which glucose measurements can be calculated [64].

Body composition

Total body weight was determined by the Bodyscan® Quadstad 4000. Body Mass Index (BMI) (kg/m^2) was calculated by using weight [kg] and height [cm] measurements. Next to this, waist and hip circumferences [cm] were measured using a tape measure to determine the distance around the smallest part of the waist and largest part of the hips [64].

Health-related quality of life

Health-related quality of life (HRQoL) was assessed using the EQ-5D-3L instrument. This is a generic instrument that has shown construct validity in DM patients and can be used to measure health status [79, 80]. The EQ-5D-3L consists of two elements: a questionnaire indicating the health state of a person and a visual analogue scale indicating a person's self-rated health (EQ VAS). The EQ-5D questionnaire is divided into five dimensions: mobility, self-care, usual activities, pain/comfort and anxiety/depression. Each dimension is assessed using a 3-point Likert scale including the following response options: (1) no problems, (2) some problems and (3) extreme problems [79]. The answers given to the questionnaire are used to describe a person's health status (e.g., 11111 indicates no problems in any of the dimensions). Additionally, a summary index score was calculated to demonstrate how good or bad a health state is in accordance with the preferences of the general Dutch population [79]. The EQ VAS asks the patients to rank their self-rated health on a scale from 'worst health you can imagine' to 'best health you can imagine' to (0-100). The result gives a quantitative measure of the patient's self-reported health judgement [64, 79].

Physical activity

Physical activity was measured by the data collected with a Fitbit Inspire 2. The Fitbit Inspire 2 is a wearable activity tracker that measures the amount of steps per minute by using a 3-axis accelerometer and an optical heart rate monitor [81]. Data gathered with a Fitbit can be synchronized to a smartphone. The amount of steps per minute and the amount of heart beats per minute were measured using an algorithm developed by Fitbit [64, 82]. To determine levels of physical activity the number of steps per day during the three-month intervention was studied [64]. In recent validation studies, different versions of the Fitbit have been tested and have shown accurate results for measuring step counts compared to manually observed step counts [82- 84]. However, studies have also shown that the Fitbit is less suitable for measuring time in physical activity intensity levels (e.g., moderate, vigorous or moderate-vigorous activity) [84-85].

Nutritional behavior

Nutritional behavior was measured with the use of the food diary (self-report) which was incorporated in the Diameter. To assess types of nutrition that has been eaten the amount of carbohydrates, fat, protein, sugar and kilocalories per day was calculated [64]. To assess whether patients ate these types of nutrition within recommended range, the recommended amounts of carbohydrates, fat, protein and sugar were calculated using the weight and recommended amount of calories a day [86]. To determine the recommended amount of calories per person per day a guideline provided by the Netherlands Nutrition Centre based on age, gender and level of activeness (active or less active) was used [86]. The level of activeness of a patient was assessed by comparing the minutes of moderate-vigorous physical activity to the Dutch guidelines for physical activity [25]. These guidelines recommend 150 minutes of moderate-vigorous movement per week. If patients had on average 150 or more minutes of moderate-vigorous movement per week patients were considered active [25]. If patients did not reach the threshold of 150 minutes of moderate-vigorous movement per week patients were considered less active. The recommended amount of carbohydrates, fat and protein is based on the recommendations of the Netherlands Nutrition Centre. The total amount of consumed kilocalories per day should consist for 40-70% of carbohydrates [87] and 20-35% should consist of fats [88]. On average people need approximately 0.83 grams of protein per kilogram of weight [89]. The World Health Organization recommends that less than 10% of the total consumed kilocalories consists of sugar [90]. Finally, kilocalories were converted to grams to assess if patients were eating the types of nutrition within recommended range [91, 92]

Openness to the use of new technologies

Openness to the use of technology was measured using a single-question based on Rogers' diffusion of innovations theory [93]. Answer options related to five different types of adopters of technology: innovators, early adopters, early majority, late majority and laggards [93]. Patients had statements to choose from ranging from ''I am usually ahead of others. I am always the first one to try new technologies" (innovator) to "I am usually behind of everyone else. I will start using new technology when this is necessary" (laggard).

Previous use of health apps

Previous use of health apps was measured by two questions. First, the current use of health apps was assessed with the following response options: 1) Yes, I am using one or more health apps, 2) Yes, I have used one or more health apps in the past, and 3) No, I have never used a health app. The second question assessed what type of health apps participants were using with four answer options: 1) food intake app, 2) physical activity app, 3) diabetes app and 4) other type of health app. If patients did not want to answer these questions they could choose the option: "I do not know or do not wish to say"

Demographics

Information on background characteristics such as, age (years), gender (female/male) and duration of T2DM (years) was collected at baseline with a questionnaire. With information on the medication history the patient it was determined if the patient was using insulin [yes/no]. With a physical examination and questions about medical history from the researcher complications [yes/no] of the patients were assessed [64].

Qualitative data

Qualitative data was collected through semi-structured interviews about the CooL+Diameter intervention from the perspectives of patients and healthcare professionals. Table 3 provides an overview of the measurements and the underlying theoretical frameworks.

Table 3. Overview of qualitative data measurements

Domain	Theoretical framework	Data collection	Participant group	T_0	T_1
Practicality	-	Interview	Patients		X
Acceptability	UTAUT2	Interview	Patients		X
	Unified TAM	Interview	Healthcare professional		X
Implementation	NASSS	Interview	Patients		X
	NASSS	Interview	Healthcare professional		X

Practicality

Practicality was measured with questions and prompts regarding the capabilities of the patients to carry out all the activities related to the Diameter (e.g., filling out food diary, wearing the Fitbit, checking glucose values) and the CooL program (e.g., setting goals, attending group meetings).

Acceptability

Patients' acceptability was measured based on the constructs as established in the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) by Venkatesh et al. [94]. The UTAUT2 constructs can predict the likelihood of a technology being accepted by its users [94]. The interview scheme was based on the following constructs of the UTAUT2: performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivation, habit and behavioral intention [95]. An explanation of these

constructs can be found in appendix 2.

The UTAUT2 is less suitable for measuring acceptability of healthcare professionals, since the UTAUT2 is based on the consumer use context, which is in this case the patient. For healthcare professionals, acceptability was measured based on the constructs of the Unified Technology Acceptance Model (Unified TAM) as established by Gagnon et al. [95]. This predictive model can be used to evaluate healthcare professionals' acceptance of an innovation. The interview scheme was based on the following constructs of the Unified Technology Acceptance Model: perceived usefulness, perceived ease-of-use, attitude, compatibility, subjective norm, facilitators and habit [95]. An explanation of these constructs can be found in appendix 2.

Implementation

The interview questions regarding implementation for both patients and healthcare professionals were based on the framework for non-adoption, abandonment, scale-up, spread and sustainability (NASSS) by Greenhalgh et al. [96]. The NASSS framework is an evidence-based theory-informed framework that can be used to assess the implementation of technology-supported programs in health and social care. The domains related to the NASSS framework can assist in identifying and addressing the challenges of implementation [96]. Six domains of the NASSS framework were used to gain insight into the barriers and facilitators of implementing CooL+Diameter. These domains included: the condition, the technology, the adopting person, value proposition, the organization and the wider system [96]. An explanation of these domains is presented in appendix 2.

The aforementioned theories were used to determine the topics for the interview. The topics used in the interview with patients are: acceptability, practicality and implementation of CooL+Diameter. Based on these topics interview questions were formulated and an interview guide was created (see appendix 3). An overview of the interview can be found in table 4.

Table 4. Overview of interview topics patients

Interview topics patients
1. Experiences with lifestyle monitoring (Diameter) • What is the patient's' opinion on the use of lifestyle monitoring? • Is the patient able to carry out activities related to lifestyle monitoring? 2. Experiences with digital coaching (Diameter) • What is the patient's opinion on digital coaching? • Is the patient able to carry out activities related to digital coaching? 3. Experiences with the CooL program • Is the patient able to carry out activities related to the CooL program? 4. Barriers and facilitators of CooL+Diameter • To what extent is using the Diameter of added value to the CooL program? • To what extent can the combined intervention contribute to obtaining patient'' lifestyle goals? • What are barriers to the use of CooL+Diameter? • What are facilitators to the use of CooL+Diameter?

Theories on acceptability and implementation were also used to create topics for the interviews with healthcare professionals and lifestyle coaches. Based on these topics, interview questions were created and assembled in an interview guide (see appendix 5 and 6). An overview of the interview topics is presented in table 5.

Table 5. Overview of interview topics healthcare professionals

Interview topics
1. Opinion and experiences with lifestyle coaching for T2DM patients by healthcare professionals • What is healthcare professionals' opinion on the use of lifestyle coaching as part of T2DM treatment? 2. Opinion and experiences on the use of eHealth for T2DM patients by healthcare professionals? • What is the healthcare professionals' opinion on the use of eHealth as part of T2DM treatment? • To what extent is the Diameter of added value for T2DM patients? 3. Combining CooL and Diameter • To what extent can CooL+Diameter contribute to obtaining lifestyle goals by T2DM patients? • Will the use of CooL+Diameter be of added value in secondary care? 4. Implementation of CooL+Diameter • What are facilitators for using CooL+Diameter in the care of T2DM patients? • What are barriers for using CooL+Diameter in the care of T2DM patients? • To what extent will changes in the care process be needed to implement this CooL+Diameter? • How would CooL+Diameter be perceived by other healthcare professionals • To what extent does the organization facilitate integrating CooL+Diameter in the regular T2DM care path?

Data handling

Personal details of the respondents were anonymized. Qualitative and quantitative data were saved under a code, which was only known by the researcher to protect anonymity of the respondents. Interviews for both the patients and healthcare professionals were recorded and transcribed verbatim. A first transcript was created by using AmberScript. The audio files and transcriptions were saved on the server of the University of Twente, which can only be accessed by the researcher. After audio files and transcriptions were uploaded to the server, they were deleted from the recording device and Amberscript website.

Data analysis

Quantitative data

Data analysis was performed in R (version 4.1.1) and IBM SPSS (version 28). Demographics, openness to the use of new technologies and previous usage of health apps were presented using descriptive statistics (i.e., standard deviations, means, frequencies and percentages). To analyze intervention usage, nutritional behavior and physical activity during the three-month intervention descriptive statistics (i.e., means, frequencies, line charts and bar charts) were used. To analyze the potential differences in HbA1c, TIR, BMI, waist and hip circumference and HRQoL between baseline (T_0) and follow-up (T_1) descriptive statistics and paired samples t-tests were conducted. Since the sample size was below thirty a Shapiro-Wilk test and scatterplot was used to test for normal distribution. A Wilcoxon signed-rank test was used for variables that were not normally distributed [97]. A p-value below 0.05 (two-tailed) was seen as statistically significant.

Qualitative data

Qualitative data were analyzed using a hybrid approach of thematic analysis. The hybrid approach of thematic analysis is characterized by both inductive and deductive coding and theme development [98]. In this study the thematic analysis process as demonstrated by Bingham and Witkowsky [99] was used. First the researcher got familiar with the data by organizing it. After this step, the codes were inductively coded, by the means of open codes. This was followed by axial coding to identify patterns within each interview and between the interviews. Eventually, the theoretical frameworks used to set up the interview guides

were used to deductively create overarching themes. The initial process of inductive coding was used to keep an open view on the data and to limit the possibility of overlooking concepts due to standardized categories. However, deductive coding helped to focus on the relevant topics and to relate findings to literature [99].

The interviews were analyzed during the data collection process, which allowed for changes in the interview guide to clarify and adjust questions based on information from earlier interviews [100]. This is also known as the method of constant comparison [101]. After the first interviews with both patients and healthcare professionals the interview guides were adapted to clarify some questions. To analyze the data the computer program Atlas.ti (version 22.1.3) was used. A fellow student of the researcher reviewed two of the randomly selected transcripts independently. The researcher and fellow student discussed and compared the codes they generated. When codes differed between the researchers, discussion followed until consensus was reached.

Results

In total, five participants participated in the combined intervention and completed the baseline questionnaire and measurements (see table 6). Four out of five participants were female and the average age was 55 years. Participants were living with T2DM for 12.6 years on average. Three out of five participants used insulin next to drug treatment and two out of five participants suffered from complications due to their illness. None of the participants perceived themselves as a laggard. One participant identified as an innovator, one participant identified as an early adopter, two participants were in the early majority and one patient was in the late majority. Three out of five participants used or previously used health apps at baseline. Apps that were used are nutrition apps (1/3), diabetes apps (2/3) and other apps such as apps for medication usage and brushing your teeth (1/3). None of the participants used apps for physical activity.

Table 6. Baseline characteristics of participants in the CooL+Diameter intervention

Characteristics	**N=5**
Female; n (%)	4 (80)
Age (years); mean (SD)	55 (8.6)
Duration of T2DM (years); mean (SD)	12.6 (5.4)
Insulin (yes); n (%)	3 (60)
Complications (yes); n (%)	2 (40)
Openness to new technologies	
Innovator; n (%)	1 (20)
Early adopter; n (%)	1 (20)
Early majority; n (%)	2 (40)
Late majority; n (%)	1 (20)
Laggard; n (%)	0 (0)
Previous experience with health apps (yes); n (%)	3 (60)
Type of health app[a]	N=3
Nutrition app; n (%)	1 (33.3)
Physical activity app; n (%)	0 (0)
Diabetes app; n (%)	2 (66.6)
Other; n(%)	1 (33.3)

[a] More than one answer option possible.

Quantitative results

Intervention usage

Of the sent coaching messages during the three-month intervention, 38.6% (108/280) was opened by the participants. There were large differences between participants. One participant opened 77% (84/108) of all the opened messages. Three participants opened 4 or less messages. One participant opened 16 messages. Participants set a total of 14 goals during baseline and follow-up of which 8 were set by one participant. The other participants set 3 or less goals during the intervention. Participants wore the Fitbit (>1000 steps per day) 75 out of 84 days on average. All participants wore the Fitbit until the follow-up measurement moment. Nutrition was reported on 20 days on average and there were on average 17.27 logs per day. One patient did only log nutrition four times in total, due to not being able to find foods and managing the food diary digitally. Therefore, this patient was left out. One participant logged approximately 30 nutritional intakes per day, whereas two other participants logged approximately 11 nutritional intakes per day. The fourth participant logged around 15 nutritional intakes per day. At follow-up patients scanned their Freestyle Libre sensor 4.7 times per day on average compared to 4.05 scans per day on average at baseline. Four out five patients scanned their Freestyle Libre sensor more times per day at follow-up than at baseline. One patient scanned her Freestyle Libre sensor fewer times at follow-up.

Intervention effects

Participants (N=5) had a significantly lower HbA1c value at T_1 (40.2±6.80) compared to T_0 (41.0±6.72); p<0.05). Body mass index was also significantly lower at three months (40.2±6.80) compared to baseline values (41.0 ±6.72; p<0.05) (see table 7). Time in Range decreased between baseline and follow-up and no significant change was observed (p = 0.06). At baseline the median of Time in Range was 75% compared to a median of 49% at follow-up. Hip and waist circumference stayed the same for two out of five participants and reduced for three out of five patients at the three-month follow up. However, no significant change was observed (p= 0.09 and p=0.14, respectively). Health-related quality of life did also not show significant changes. The average index scores of HRQoL (0.76) remained the same at baseline and follow-up. Fewer patients experienced problems with pain (2/5) and anxiety (1/5) at the three-month follow-up compared three out of five and two out of five participants at baseline, respectively. However, one patient experienced extreme pain resulting in a higher index score at T_1. The same amount of patients experienced some problems in activity (1/5) and mobility (3/5) at both baseline and follow-up. None of the patients experienced problems with selfcare. Four of the five participants rated their own health higher at the three-month follow up compared to baseline. On average patients rated their health at 83.0 at follow up compared to 74.2 on average at baseline. One patient rated their own health one point one point lower at follow-up (79) than at baseline (80).

Table 7. Outcomes at baseline (T_0) and 3-month follow-up (T_1)

	T_0	T_1	P-value[a]
HbA1c (mmol/mol)[b], mean (SD)	75.6 (9.45)	64.6 (4.10)	**0.04**
TIR (%), median (IQR)[c]	75.0 (45.0)	49.0 (42.0)	0.06
BMI (kg/m^2)[d], mean (SD)	41.0 (6.72)	40.2 (6.80)	**0.01**
Hip circumference (cm), mean (SD)	139.0 (14.4)	138.0 (14.0)	0.09
Waist circumference (cm), mean (SD)	141.0 (7.94)	138.0 (7.33)	0.14
EQ-5D-3L index score, mean (SD)	0.76 (0.14)	0.76 (0.22)	0.99
EQ-5D-3L VAS score, mean (SD)	74.2 (8.26)	83.0 (9.30)	0.13

[a] P-value is the result of paired samples t-test and Wilcoxon signed-rank test between baseline and follow-up
[b] Hemoglobin A1c
[c] Time in Range
[d] Body Mass Index

Physical activity

Participants took 7633 steps per day on average. The participants reached on average on 74 out of the 84 days more than 6000 steps. Average daily step counts between 7000 and 8000 steps were most frequent. The average step count of 10.000 steps was reached on 6 out of 84 days. During baseline (week 1-2) participants reached a step count of 7338 per day on average. In the last week of the intervention the daily step count shows a slight decrease compared to baseline with 7255 per day on average. The number of steps per day per participant throughout the three-month intervention are presented in figure 4. Participant 2 had the highest average daily step count with 15.068 steps per day and patient 4 had the lowest average daily step count with 3829 steps per day.

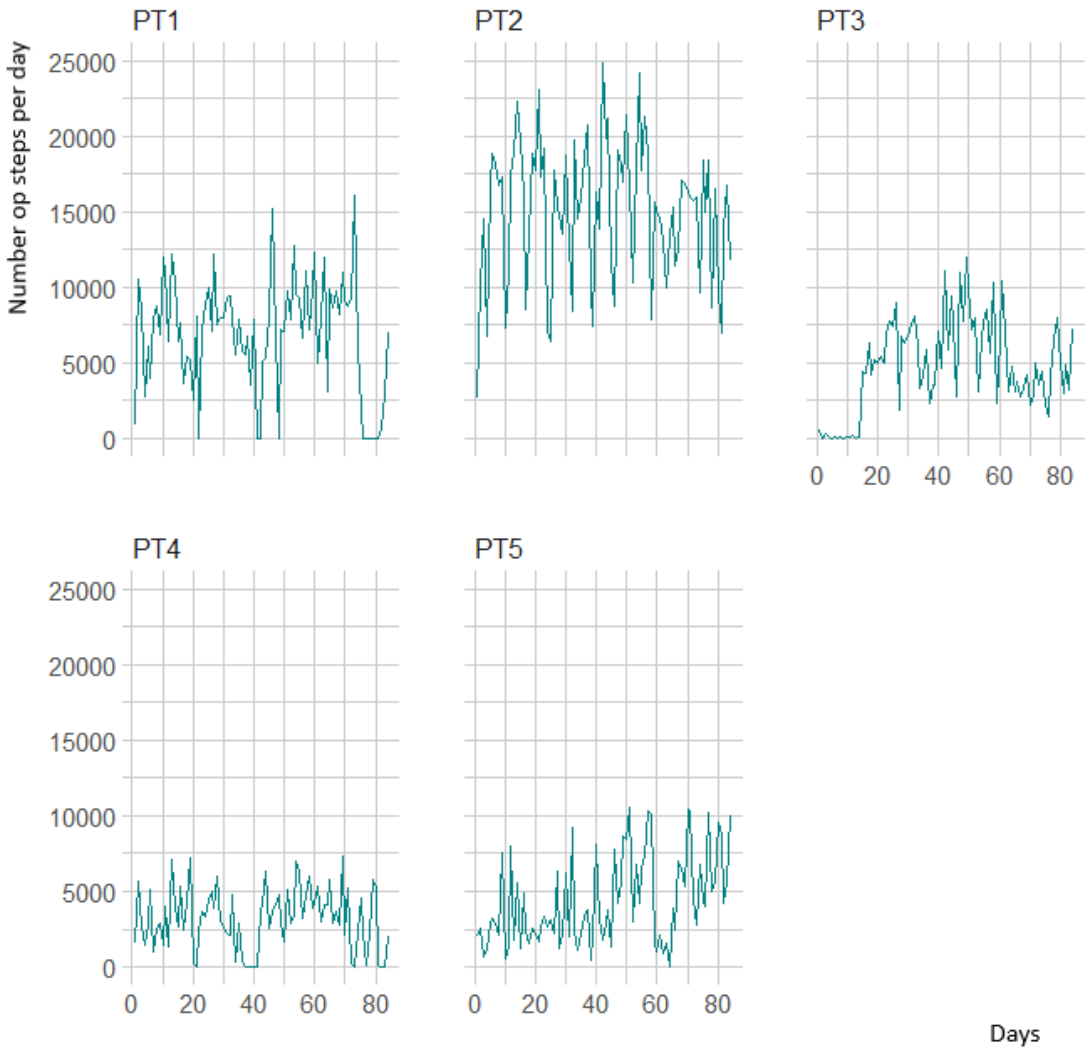

FIGURE 4. NUMBER OF STEPS PER DAY PER PARTICIPANT DURING THE THREE-MONTH INTERVENTION (N=5).

Nutritional behavior

Four out of five patients filled in the food diary for at least six days. One of the patients filled in the food diary on two days, but with very few data entries due to problems when filling in the food diary (e.g., not able to find certain foods and able to manage the food diary digitally). Therefore, this patient was left out in the analysis of nutritional behavior. Based on age, gender and level of activeness the recommended calorie intake was 1800, 2000, 1800 and 1900 kilocalories for the four participants per day. On average, patients consumed 1523 kilocalories per day. Figure 5 shows per nutritional component (i.e., carbohydrates, protein, sugar and fats) how many times patients stayed within target values and adhered to the nutritional guidelines and how many times patients did not stay within target values and therefore did not adhere to the nutritional guidelines during the first six days of the intervention. One of the patients stayed within het own target values of 180-315 grams of carbohydrates for five of the six days. The other patients ate less grams of carbohydrates than their recommended target values (ranging between 180-350 grams) on each of the six days. Two patients ate too little or too much protein on each of the six days. One patient adhered to nutritional guidelines of protein on one of the six days and another patient on four of the six days. All patients consumed too many grams of fat on each of the six days, except for one patient

who stayed within her target values (ranging between 42.2 – 73.8 grams of fat per day) on two of the six days. Two patients ate too much sugar on each of the six days. One patient ate less than 10% of her recommended caloric intake in sugar on four out of the six days and another patient on two out of the six days.

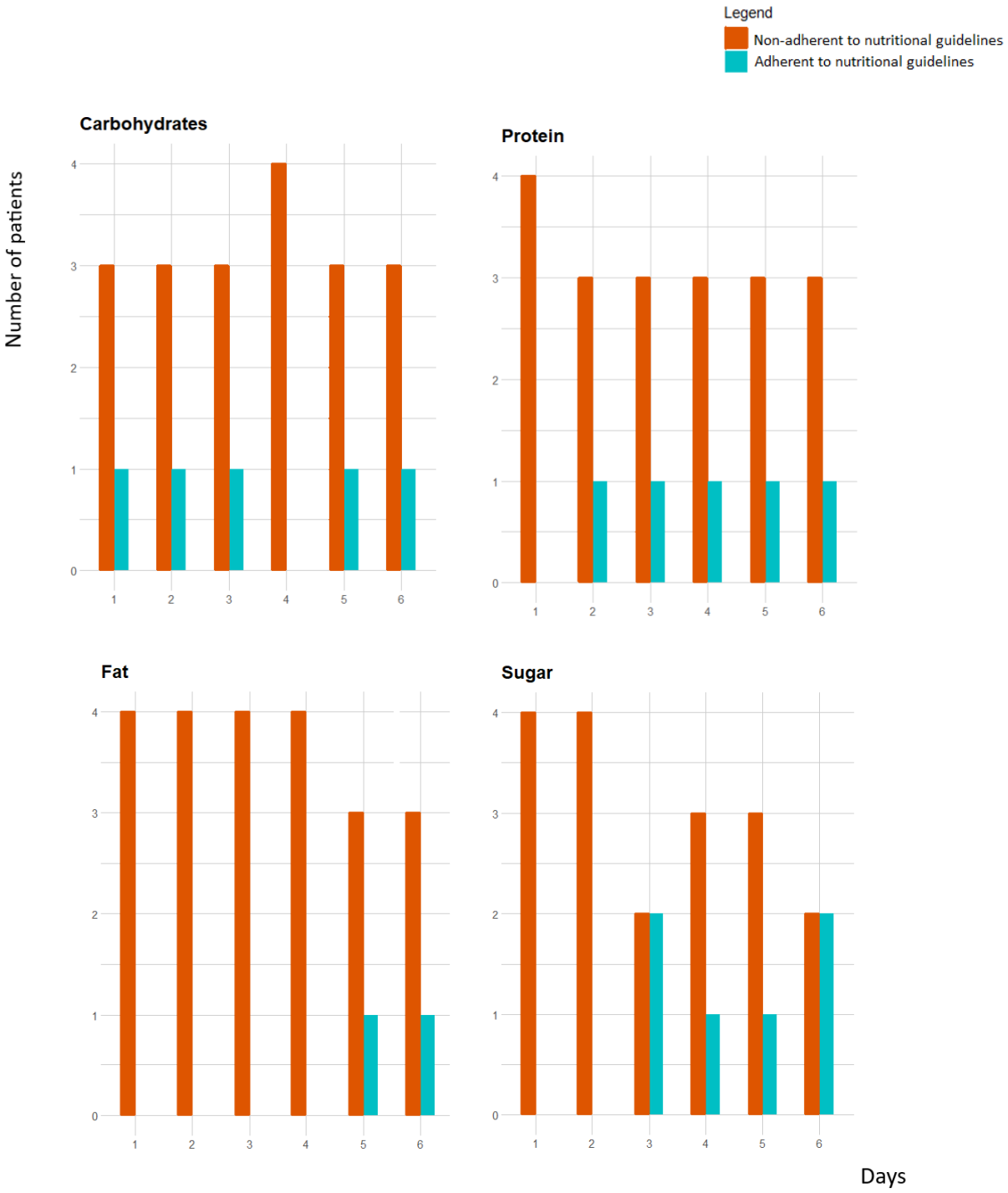

FIGURE 5. THE AMOUNT OF TIMES A PATIENT CONSUMED A NUTRITIONAL COMPONENT WITHIN RECOMMENDED VALUES (N=4)

Qualitative results

In total thirteen people were interviewed: five patients and eight healthcare professionals. The patients that were interviewed were involved in the CooL+Diameter intervention. The demographic details of the interviewed patients were presented previously in table 6. Furthermore, one internist, two nurse practitioners, two diabetes nurses/lifestyle coaches, one diabetes nurse, one lifestyle coach and one dietician participated in the interviews. One of the lifestyle coaches, who is also a diabetes nurse, was involved in the CooL+Diameter intervention as the CooL lifestyle coach. The results of the interviews are structured according to the domains of feasibility: practicality, acceptability and implementation [63]. Theoretical constructs were used to organize the codes.

Practicality

Patients were asked during the interview how they perceived the practicality of the activities related to CooL and the Diameter (i.e., were patients able to carry out all activities related to the combined intervention). Wearing the Fitbit, checking their physical activity, scanning their Freestyle Libre sensor to retrieve blood glucose values and going to CooL sessions were easy tasks to do for patients. Three of the patients found it challenging to keep track of their nutrition. This was mainly due to patients not being able to find certain ingredients in the food diary, forgetting what they ate during the day and the amount of effort it takes. Another challenge three of the patients experienced were difficulties in setting realistic goals for themselves. Some patients indicated that goals proposed by the Diameter were not suitable for the patients, because the goal was not realistic to them and that they needed help from the lifestyle coach to set attainable goals.

Acceptability

To structure the acceptability (i.e., the experiences of patients and expectations of healthcare professionals) about the CooL+Diameter intervention the UTAUT2 model [94] and Modified TAM model were used [95]. When possible, similar constructs of these two models were combined. Table 8 gives an overview of the codes related to experiences and expectations of CooL+Diameter. None of the codes fitted under the constructs of price value and attitude.

Performance expectancy/perceived usefulness

In general, patients experienced the combined intervention, CooL+Diameter, as useful. Three patients saw it as an opportunity to receive additional care, next to their usual care at the outpatient clinic of ZGT hospital. Both nurse practitioners mentioned that this combined intervention would give some patients in secondary care an opportunity for a new or other treatment option. This is especially useful for patients whose health has declined or not improved for a longer period of time, according to the nurse practitioners.

All healthcare professionals explained that the Diameter could serve as a daily coach in between CooL sessions, but also in between appointments in usual secondary care. One of the lifestyle coaches, who also works as a diabetes nurse explained that:

"I always tell people that you should look at it like a circle. Someone with diabetes has diabetes 365 days a year, 24 hours per day. In this time they see healthcare professionals, if we sum it, barely three days a year. So, if there is digital support, that stimulates patients 365 days a year I think that is of added value"
- Lifestyle coach/diabetes nurse

Table 8. Acceptance of patients and healthcare professionals of CooL+Diameter

Themes and codes	Definition of code	Patient[a] (N=5)	Healthcare professional[b] (N=8)
Acceptability CooL+Diameter			
Performance expectancy/Perceived usefulness			
Additional care	Patients having more treatment options	5 (3)	7(2)
Daily coach	Having a daily coach to use in between CooL and usual care		12 (5)
Insights	Seeing effects of nutrition and physical activity on glucose levels	26 (5)	39 (8)
Feedback	Seeing immediate results of lifestyle behavior	27 (4)	14 (7)
Awareness	Patients becoming aware of own lifestyle behavior	16 (5)	10 (4)
Conversation starter	Discussing lifestyle with patients based on data	3 (2)	18 (7)
Patient centered advice	Data gives the opportunity to give tailored advice to patients		4 (2)
Setting goals	Using the Diameter to achieve goals set in CooL	3 (2)	2(1)
Reminder	Triggering to stay on track and take action	6 (3)	
Tools	Using the Fitbit and Freestyle Libre sensor	8 (5)	
Empowerment	Patients having control over own diabetes	3 (3)	
Improving health	Improved health since starting CooL+Diameter	5 (1)	
Education	Gained knowledge about changing lifestyle	17 (5)	
Motivational incentives	Stimulation to achieve lifestyle goals	9(3)	10 (6)
Effort expectancy/Perceived ease-of-use			
Technical issues	Technical bugs in the Diameter	2 (2)	
Time intensity	Intensiveness of CooL+Diameter for patients	5(3)	7 (1)
Information	Multiple ways of receiving information about lifestyle	2 (1)	
Social influence/Subjective norm			
Social support	Feeling supported by others to improve lifestyle	5 (3)	
Facilitating conditions/Facilitators			
Collaboration	Discussing results CooL+Diameter with HCPs[c]		3 (1)
Hedonic motivation			
Fun	Enjoying the use of CooL+Diameter	3 (2)	
Habit/Behavioral intention			
Routine	Using the Diameter and tools automatically	15 (5)	
Compatibility			
Integration	Integrating lifestyle parameters and coaching in usual care		26 (4)
Remote coaching	Coaching patients outside CooL sessions		3 (1)
Aftercare	Getting guidance on lifestyle after CooL has ended	4 (1)	

[a]The total number of times a code was mentioned by patients and (#) the number of different patients that mentioned the code (N=5).
[b] The total number of times a code was mentioned by healthcare professionals and (#) the number of different healthcare professionals that mentioned the code (N=8).
[c] Healthcare professional

All patients and healthcare professionals mentioned that measuring lifestyle behavior (i.e., nutrition and physical activity) was beneficial for creating insight in the patient's body and the effects lifestyle behavior has on blood glucose values. According to most patients and healthcare professionals, getting continuous feedback on nutritional values and physical activity is beneficial to show a patient in what area a patient is doing well and in what areas a patient can improve. This makes patients aware about their own lifestyle behavior. As one patient stated:

"It are facts, it is not like: 'I think so much or I expect that much', it is displayed and that means when I am doing well 'Yippee, I have done more than I expected', but also 'You think you have done a lot, but that is not becoming clear on here [Diameter]'" – PT1

The lifestyle coaches stated that they currently have no insight in actual behavior of the participants. One of the lifestyle coaches advises participants to use different apps for lifestyle improvement, such as apps to track nutrition (e.g., de Eetmeter) and apps for collaborative exercising (e.g., Ommetje). However, it would be much easier for the lifestyle coach if these elements were combined in one app, such as the Diameter, and data could be accessed by the lifestyle coach. Access to the self-monitored data gives an opportunity to discuss progress with participants in CooL sessions and in usual care according to the healthcare professionals and patients. Based on the data it becomes clearer what goes well and what areas of lifestyle behavior need improvement. This gives an opportunity for more tailored advice. As one of the diabetes nurses explained:

"I think it makes the conversation easier, because you can show what happened and then you can discuss specific points instead of asking: 'What are you eating?', 'What are you doing with exercise?', 'How many steps do you walk?' and 'How many carbs do you eat?' It makes it more efficient" – Diabetes nurse

Using the Diameter next to CooL could also be beneficial for setting realistic goals. As one of the lifestyle coaches explained:

"It is important that you show people that they have to make small goals. Using the Diameter can help them with that. So, if participants see that they do 3000 steps per day right now, then the next goal is 3500 steps a day or they see that they eat 300 grams of carbohydrates per day right now, then the goal for the next month is to eat 200 grams of carbohydrates per day on five days during the week. It makes it easier to constantly set new individualized goals" – Lifestyle coach/diabetes nurse

Going to the CooL sessions and self-monitoring behavior stimulates motivation and works as a reminder to stay on track with their lifestyle behavior changes, according to three patients. All participants found the tools accompanying the Diameter (i.e., Freestyle Libre and Fitbit) very helpful and it helped them to set lifestyle goals. One patient explained that he felt much more in control over his diabetes when he was using the Freestyle Libre sensor. Another patient experienced progress in health, because due to insights from the Freestyle Libre medication could be lowered for this patient.

All patients felt like they gained knowledge during the intervention. The patients found the CooL sessions useful to learn about their own condition and how to take action on lifestyle behavior. One patient found some information she received in the CooL sessions about nutritional values in certain products eye-opening. Two patients and the majority of the healthcare professionals also stated that the Diameter could be a motivational element to the CooL program. Seeing progress and discussing this progress in a group setting, such as the CooL sessions, can stimulate patients in improving their health. For example, by setting up physical activity competitions (e.g., tracking who reached the highest number of steps) with fellow CooL participants. One patient also found it useful to set a goal every Monday and to get a fresh start every week. This patient also noted that the vibrations of the Fitbit helped her to stay motivated.

Effort expectancy/ Perceived ease-of-use

All patients found the Diameter difficult to use, due to technical problems and limited possibilities in the app. Two of the patients experienced some technical difficulties, such as bugs and connection problems with Bluetooth, when using the Diameter. One patient mentioned that it was difficult to change data in the

app. Receiving information about lifestyle through various ways (i.e., CooL sessions, e-mails, messages in the Diameter) was perceived as useful by one patient:

"Personal coaching tends to stick a little bit better than just reading something, but on the other hand, with reading you can read back information very quickly" – PT1

Three of the patients and one of the lifestyle coaches did note that the CooL+Diameter program is quite intensive. All together, the Diameter, the CooL program and the patient's own health process take up quite a bit of time and can feel as a burden according to the lifestyle coach who was leading the CooL sessions in the CooL+Diameter intervention.

Social influence/Subjective norm

CooL sessions were also deemed helpful because it gave patients the opportunity to talk about lifestyle and share problems with each other. Talking and sharing problems with other CooL participants gave three patients a feeling of understanding and knowing that they were not alone. Even though one of the patients understood that digital messages are automatized, it still gave the patient a feeling that she was not on her own in this process.

Facilitating conditions/facilitators

The lifestyle coach who was leading the CooL sessions in this intervention mentioned that because the intervention took place in the hospital it was easier to consult other healthcare professionals about the results of the intervention and health-related issues of patients. These health-related issues concerned for example, changing or lowering the medication of patients.

Hedonic motivation

A few patients noted that it was fun to monitor lifestyle. One patient also mentioned it was fun to get digital messages. Patients also mentioned that they found the CooL sessions interesting and liked to attend the group meetings.

Habit/Behavioral intention

Wearing the Fitbit, checking their physical activity and scanning their Freestyle Libre sensor to retrieve blood glucose values became routine tasks to the patients. Patients indicated that they wanted to keep using the Freestyle Libre and Fitbit in the future. However, patients were worried about the costs of the Freestyle Libre. Most of the patients did not have the intention to keep using the Diameter in the future, due to limited user friendliness.

Compatibility

One of the healthcare professionals mentioned that lifestyle parameters, just like other parameters such as blood pressure and taking medication, should be integrated in usual care in the future. This healthcare professional also stated that lifestyle coaching should be continued in usual care when the CooL program has ended. One of the patients also found it important that after the CooL sessions are finished there is still some form of care related to lifestyle. One of the lifestyle coaches also mentioned that having access to data through the Diameter could also be helpful for coaching participants remotely in between sessions.

Satisfaction

At the end of the interview with patients, patients were asked to grade the two different elements of the Diameter (i.e., self-monitoring and digital coaching) combined with CooL on a scale from one to ten.

Patients awarded the combination of self-monitoring and CooL a 9.0 on average. Digital coaching combined with CooL received a 7.4 on average.

Figure 6 shows a visual overview of the codes and themes that came forward during the interviews about acceptance of CooL+Diameter. The different colors represent a division in whether the code was mentioned by patients, healthcare professionals or both. Furthermore, the larger the circle, the more the code was mentioned during the interviews.

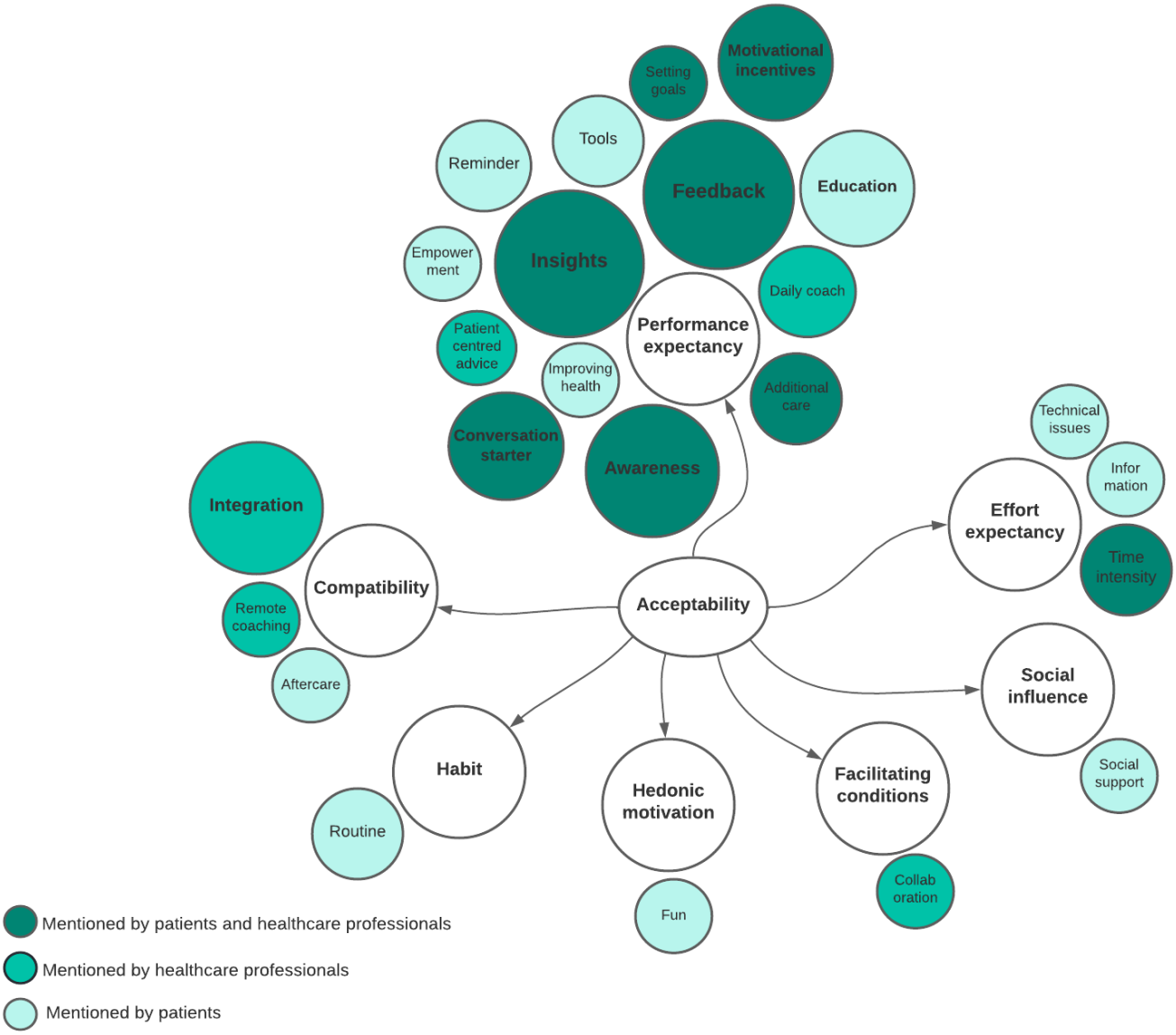

FIGURE 6. VISUALIZATION OF CODES AND THEMES BELONGING TO THE ACCEPTABILITY OF COOL+DIAMETER (N=13)

Implementation

Several barriers and facilitators were mentioned for the implementation of CooL+Diameter during the interviews with patients and healthcare professionals (see table 9). The NASSS framework [96] was used to structure the barriers and facilitators into different domains [96]. None of the codes fitted in the last domain: embedding and adaptation over time.

Table 9. Barriers and facilitators to implementing CooL+Diameter

Themes and codes	Definition	Patient[a] (N=5)	Healthcare professional[b] (N=8)
Implementation barriers CooL+Diameter			
Condition			
Complications	Severity of complications patients		10(5)
Technology			
User friendliness	Limited ease-of-use of the Diameter	13(5)	22(6)
Completeness food diary	Lack of available ingredients in the food diary	5 (3)	
Reliability	Careful with judging self-monitored data		3 (2)
Information	Length and negative tone of digital coaching	5 (2)	
Standardization	Digital coaching not fitted to personal situation	2 (1)	3 (1)
Look Diameter	Unattractive look of the Diameter	4 (1)	
Operating system	Diameter not available in all operating systems	5 (2)	
Integration	Limited integration of Diameter in CooL program	15 (3)	
Value proposition			
Costs	Costs of using CooL+Diameter	8(3)	6(3)
Reimbursement	Limited reimbursement of lifestyle coaches		10(3)
Adopters			
Digital skills	Limited digital skills of patient		10(5)
Age	Older age of the patient		9(4)
Educational level	Limitations due to educational levels		8(3)
Illiteracy	Illiteracy of the patient		4(1)
Motivation	Lack of motivation of patient to change lifestyle		28(6)
Coping issues	Patients with coping issues		2(1)
Adherence	Patients' inability to adhere to T2DM treatment		9(5)
Personal circumstances	Personal difficulties of the patient		8(3)
Confrontation	Patients being confronted with own lifestyle behavior	1 (1)	3 (3)
Obsessive behavior	Patients being continuously busy with lifestyle		1 (1)
Privacy concerns	Concerns about privacy patients	3 (1)	6(2)
Skepticism	Skepticism among HCPs about lifestyle interventions		9(3)
Organization			
Time	Lack of time to implement CooL+Diameter		21(5)
Wider system			
Scalability	Limited scalability of CooL+Diameter		13(2)
Execution difficulties	Unclear division of responsibilities		8(4)
Implementation facilitators CooL+Diameter			
Condition			
Personal context	Adjustments to personal situation patient	4(2)	13(5)
Technology			
Flexibility	Flexible structure of the CooL program		7(3)
Education	Lifestyle coaches having sufficient knowledge about T2DM		7(3)
Training	Following a training about CooL+Diameter by HCPs[c]		8 (7)
Technical support	Having technical support when necessary		2 (2)
Adopters			
Professional guidance	Help from a healthcare professional to improve lifestyle	15(5)	

Social support	Having support to improve lifestyle behavior	2(2)	4(1)
Organization			
Logistics	Having the means to implement CooL+Diameter		15(7)
Data availability	Availability of information CooL+Diameter in IT system		10(4)
Wider system			
Collaboration	Collaboration between HCPs and lifestyle coaches		12(2)

[a]The total number of times a code was mentioned by patients and (#) the number of different patients that mentioned the code. (N=5)
[b]The total number of times a code was mentioned by healthcare professionals and (#) the number of different healthcare professionals that mentioned the code. (N=8)
[c]Healthcare professional

Condition

One of the barriers that came forward related to whether CooL+Diameter was perceived as a suitable intervention for T2DM in secondary care. Healthcare professionals think that this intervention is mostly suitable for patients in primary care. Healthcare professionals stated that this has mainly to do with the characteristics related to the condition of patients in secondary care. Patients in secondary care often suffer from complications such as neuropathy, high blood pressure, kidney problems and eye damage. This makes participating in an intensive program such as CooL+Diameter difficult according to some of the healthcare professionals. Three of the patients and the majority of the healthcare professionals found it important that the combined intervention is adjusted to the personal context of the patient. The internist-nephrologist suggested that a "light approach", where only the Diameter is used, might be more suitable for some patients in secondary care. One of the nurse practitioners explained:

"There will be patients that have had diabetes for a long time and who had a lower leg amputation or another complication. You will have to set different goals for physical activity for them than for people who have just been referred and who are trying to reverse their diabetes" – Nurse practitioner

Technology

The most frequently mentioned barrier by every patient and the majority of the healthcare professionals was user friendliness of the Diameter. All five patients did not experience the Diameter as user friendly. Patients mentioned that they found it difficult to fill in the food diary due to missing ingredients in the Diameter. Healthcare professionals also mentioned that filling in the food diary should cost limited time and be intuitive in use. Other barriers of using the Diameter related to the reliability of the data, especially when it is self-reported data such as the food diary. One of the healthcare professionals mentioned that in the beginning data is often less reliable, because people tend to make more of an effort in the beginning of something new, but after a while this levels out. Other barriers of the Diameter were related to the digital coaching element of the Diameter. The majority of the patients found the length of the e-mails too long and the tone of the e-mails sometimes too negative. One of the patients said:

"Then I get messages stating 'What If you have had a bad day and have eaten chocolate or you have eaten something bad', but I am thinking to myself I am doing so well and I do not want to see these kind of messages because I am not doing those kind of things" (PT4).

The statement above also relates to the lack of personalization that patients experienced when using the Diameter, mainly in the digital coaching messages and e-mails. One of the patients and one of the healthcare professionals mentioned that standardization of digital coaching is a downside, because it makes the digital coaching messages less engaging. According to one patient, the look of the Diameter

could also be upgraded to make it look more appealing and interactive. Some of the patients who used an iPhone in daily life mentioned that it would be easier for them if the Diameter was also compatible with other operating systems than Android.

One of the most frequently mentioned barriers by patients was the limited integration of the Diameter in the CooL program. Patients mentioned that they sometimes received overlapping information in the CooL sessions and through the digital coach of the Diameter. Patients told that during the group sessions the Diameter was not discussed. However, results of self-monitoring were discussed with the five patients who were participating in the CooL+Diameter intervention in the individual sessions with the lifestyle coach. The three interviewed lifestyle coaches do not expect difficulties when integrating the Diameter in the CooL program. The lifestyle coaches explained that the CooL program has a flexible approach, which allows the lifestyle coach to make changes to the program according to own insights. However, two of the lifestyle coaches and one of the diabetes nurses did outline the importance of education and knowledge about diabetes for the lifestyle program. One of the lifestyle coaches said that some kind of extra module about diabetes should become available for lifestyle coaches. Additionally, seven healthcare professionals found it useful if there would be a small training or simple manual about the use of the combined intervention. Next to this, a few healthcare professionals stated that technical support would be helpful when problems with the use of the Diameter occur.

Value proposition

Costs were identified, by both the patients and the healthcare professionals, as a barrier to implementing CooL+Diameter. For patients, the concerns were mainly about the price of the Freestyle Libres, since these are not being reimbursed for most of the patients. Healthcare professionals also stated that secondary care is expensive, and it will therefore be more expensive to have this CooL+Diameter in secondary care than in primary care. The lifestyle coaches also stated that sufficient reimbursement for CooL sessions is necessary. According to the lifestyle coaches reimbursement is currently insufficient to devote time to integrating the Diameter in the CooL program. The lifestyle coaches explained that lifestyle coaches only get reimbursed for a certain amount of time. Including the Diameter in the CooL program will take extra time and as one of the lifestyle coaches explained:

"That is where the big bottleneck lies, not necessarily the time I can invest, but what the compensation is for that time" – Lifestyle coach

Adopters

More than half of the healthcare professionals found that digital skills were necessary to use the Diameter. From experiences in the past, the healthcare professionals explained that the older generation is generally less digitally skilled, which makes the CooL+Diameter intervention less suitable for them. Three healthcare professionals also mentioned that the educational level of the patient is important. Patients need to be able to interpret the information in the app and comprehend the information given in the CooL sessions. Literacy was also mentioned as a barrier. One nurse practitioner mentioned that the group of illiterate patients is quite large and stated that using an app would not be attainable for them. Additionally, all patients stated that they needed some form of professional guidance when using the Diameter and accompanying tools. One of the patients noted:

"If you give people a [Freestyle] Libre, it is also good that at least at some point [people] who can interpret it professionally explain it, because then it gets extra value I think" – PT1

A frequently mentioned barrier by healthcare professionals was lack of motivation among T2DM patients. Patients need to be willing to change their lifestyle behavior before they can start with an intervention like CooL+Diameter. Healthcare professionals also noted that patients should not have coping issues or treatment adherence difficulties. Personal circumstances, such as a divorce, debt or dealing with illness in the family also make it difficult for patients to succeed in these kinds of interventions according to healthcare professionals. The internist-nephrologist outlined the situation in secondary care as follows:

"I think this [CooL+Diameter] may be appropriate for a small niche. I think in secondary care there are a lot of people not suitable for a very intensive program, because they just do not have the motivation or are not able to. These are people who often have had diabetes for a long period of time, are more seriously ill, less fit and are of older age" - Internist-nephrologist

Another barrier mentioned by both patients and healthcare professionals was that self-monitoring lifestyle behavior can be confrontational for patients. Especially when patients have a wrong perception of their own health as stated by two of the healthcare professionals. On the other hand, the dietician stated that self-monitoring nutrition and physical activity can also lead to obsessive behavior, where a patient loses him or herself in the results and numbers. Social support from family members was mentioned as a facilitator by both patients and healthcare professionals. One of the nurse practitioners explained that it is necessary that all family members join in on changing their lifestyle, otherwise it will not work.

One of the healthcare professionals pointed out that for certain patients privacy would be an issue due to certain beliefs and that these patients would not be willing to use the Diameter. One of the patients stated:

"In the beginning I had the feeling of 'big brother is watching you', because someone is looking at what you are doing. If I am eating something which is unhealthy, but I do not register it, you can still see in the computer that I have had something that apparently makes my sugar go up" – PT4

Later, the patient did not feel this way anymore since the data could also be useful to the lifestyle coach to give advice. Three healthcare professionals mentioned that there is some skepticism among other healthcare professionals about lifestyle programs, since effectiveness of lifestyle interventions has so far been limited. However, most of the interviewed healthcare professionals thought that the intervention would be positively received by healthcare professionals they are working with.

Organization

Seven healthcare professionals stated that lack of time was a barrier to implementing the combined intervention. When lifestyle parameters will also be included in regular consults with diabetes nurses, nurse practitioners and internists the consult will take longer. However, one of the nurse practitioners did mention that it was important to allow time for lifestyle in consults.

There were also several logistical facilitators mentioned for the implementation of the combined intervention. One of the lifestyle coaches mentioned that patients need to be in the possession of a smartphone and there needs to be an internet connection at the CooL session location. Healthcare professionals also mentioned that it would also be beneficial if the data retrieved from the Diameter could be easily accessible in for example the electronic patient dossier.

Wider system

One of the barriers to implementing the CooL+Diameter intervention mentioned by two of the healthcare professionals is scalability which refers to problems with the labor and time intensiveness of GLIs and

scarcity of GLI coaches to help all eligible T2DM patients. Three healthcare professionals pointed out execution difficulties with implementing CooL+Diameter in secondary care. Half of the healthcare professionals mentioned that there need to be clear guidelines about referring to a GLI. One of the diabetes nurses who also works as a lifestyle coach stated that it should not be the case that patients in secondary care need to be sent back to primary care for a referral. According to one of the diabetes nurses, responsibilities for the patient are currently not clearly set out for patients who are involved in a GLI, but who are also still under secondary care supervision. This diabetes nurse stated that it would only be feasible to have an in-house lifestyle coach (i.e., in the hospital) if eligible patients from different specialisms would be combined. However, collaboration with one external lifestyle could also be a suitable option. What is of most importance, according to the diabetes nurse, is that lifestyle coaches and healthcare professionals in secondary discuss the trajectory of patients with each other. As one of the diabetes nurses stated:

"What if you are in secondary care, who is responsible for what? We are responsible for the blood sugar, but if the patient does not consult us, because the patient thinks he is in the program, well that is going to be tricky" – Diabetes nurse

Figure 7 gives a visualized overview of the codes and themes retrieved from the interviews about the implementation barriers and facilitators of CooL+Diameter. The orange colors show barriers and green colors show facilitators of the implementation of CooL+Diameter. The darkness of the color represents the division in whether the code was mentioned by patients, healthcare professionals or both. In addition, the larger the circle, the more the code was mentioned during the interviews.

FIGURE 7. VISUALIZATION OF CODES AND THEMES BELONGING TO THE IMPLEMENTATION OF COOL+DIAMETER (N=13)

Discussion

This study aimed to evaluate the feasibility of the CooL+Diameter intervention to change lifestyle behaviors in people with T2DM in secondary care through the perspectives of patients and healthcare professionals. Guided by the feasibility domains of Bowen [63] the acceptability, intervention usage, practicality, implementation and limited efficacy of CooL+Diameter were evaluated. In general, patients and healthcare professionals found the CooL+Diameter intervention feasible. Patients and healthcare professionals accepted the use of CooL+Diameter and thought the concept of using an app combined with face-to-face coaching was useful. However, the main barrier to the implementation was user friendliness of the Diameter app. This resulted in patients using the app limitedly, however patients did value the use of the Fitbit and Freestyle Libre sensors. Despite patients using the Diameter limitedly, statistically significant results were found for BMI and HbA1c-values.

Principal findings and explanations

Acceptability

Overall, the patients and healthcare professionals accepted the use of CooL+Diameter. For the different components of the Diameter in combination with CooL, the patients rated the combination of self-monitoring and CooL with a 9.0 on average and the combination of digital coaching and CooL with a 7.4 on average. Patients were mostly satisfied about the accompanying tools (i.e., the Fitbit and Freestyle Libre sensor) and the CooL sessions. Patients were less satisfied about the use of the Diameter app. A meta-analysis on the use of mHealth for chronic disease management shows a similar outcome [102]. Patients and healthcare professionals generally accept the use of apps. However, similar problems that also arose in this study came forward in this meta-analysis as well, such as difficulties with understanding and using mHealth apps. This included for example technical difficulties [102].

Healthcare professionals and patients experienced having insights into the effects of nutrition and physical activity on glucose levels, getting continuous feedback, and becoming aware of their own lifestyle as most useful. This is similar to findings in the systematic review by Carter et al. [103] which mentioned that the use of mHealth, such as wearables, to self-monitor increased awareness of physical activity among participants which resulted in opportunities to reflect on their lifestyle and how they could make changes to improve lifestyle [103]. In other previous research self-testing blood glucose values and seeing direct feedback on lifestyle modifications has been related to empowerment of patients' self-management [104, 105]. Current secondary diabetes care is mainly focused on glucose lowering medicinal treatment [36]. However the healthcare professionals indicated that lifestyle parameters, such as physical activity and dietary intake, should also be embedded in regular secondary diabetes care. Healthcare professionals and lifestyle coaches indicated that with the use of the Diameter and the accompanying self-monitoring devices they can give more patient-centered advice, since the objective data immediately shows where there is room for improvement. This makes the conversation between patient and healthcare professional or lifestyle coach easier.

Intervention usage

Usage of the Diameter and accompanying tools showed mixed results. Engagement with digital coaching was limited. Log-data of the coaching component showed that 38.6% of the messages were opened and only 14 goals were set. These results do not match with findings in a randomized controlled trial (RCT) performed by Nelson et al. [106] which reported a mean response rate of 81% over the course of 12 months. In this RCT diabetes patients received (daily) tailored self-care messages to which patients had to reply with short answers [106]. A possible explanation for this difference in engagement might be that

patients did not perceive the Diameter as user friendly. For example, some patients had difficulty with opening the app and therefore chose to not use the app and only use the accompanying tools (i.e., Fitbit and Freestyle Libre) which they found easy to use. This ease-of-use of the Fitbit and Freestyle Libre might be an explanation for good adherence to using these tools. Patients wore the Fitbit on 75 out of 84 days on average and scanned the Freestyle Libre sensor regularly. This is in compliance with other studies that show high adherence rates. Whelan et al. [107] showed that in a 6-week intervention the Fitbit was worn on 40 out of 42 days on average.

Practicality

Patients found some activities related to CooL+Diameter easy to carry out, such as wearing and using the Fitbit and Freestyle Libre sensor. This can possibly be explained by the earlier mentioned ease-of-use patients experienced, which is also supported by other research on the ease-of-use of both devices [108-109]. Keeping track of nutrition was challenging to some patients. During the three-month intervention patients filled in the food diary 20 days on average with 17.27 logs per day on average. Patients explained that it took a lot of effort to keep the food diary up-to-date and was sometimes forgotten. Chen et al. [110] also showed that there was a 42% decrease of food recordings from the first till the seventh day of recording, most likely due to fatigue. Patients also indicated that not all ingredients could be found in the food diary, which made it difficult to pick the right products. This is in concordance with findings by Rebro et al. [111] which showed that numbers of logged nutrition and complexity of reported nutrition decrease over time when using a food diary. Patients indicated that they experienced difficulty when having to set lifestyle goals for themselves and need help from the lifestyle coach to set realistic goals. Previous research has shown that working collaboratively on goal setting increases communication between the healthcare professional and patient and can potentially lead to better glycemic control [112].

Implementation

Patients and healthcare professionals mentioned several barriers and a few facilitators for the implementation of CooL+Diameter. Healthcare professionals were mainly concerned if CooL+Diameter would be suitable for T2DM patients in secondary care, since T2DM patients in secondary care tend to be more severely ill and are more likely to suffer from complications than patients in primary care [114]. These complications can potentially make it more difficult to participate in a program like CooL+Diameter. Healthcare professionals indicated that most of the patients who are suitable for this intervention are treated in primary care. In 2020 89% of T2DM patients were treated in primary care [114]. However, healthcare professionals did indicate that CooL+Diameter, or a slimmed down version of the intervention where only the Diameter is used would be valuable for some patients in secondary care.

The Diameter was not easy to use according to the patients. This was mainly due to technical problems such as bugs and connection issues. Patients also mentioned that the look of the Diameter was not appealing and difficult to navigate. A systematic review also mentioned that technical issues such as an unclear interface were seen as a barrier to implementation of mHealth for the purpose of treatment adherence [102]. Patients also noted that the food diary was incomplete which made it difficult to pick the right products. Some patients also stated that they found the tone of the e-mails sometimes too negative and too extensive, which made patients reluctant to read them. Patients were also worried about the costs of the Freestyle Libre. Only DM patients with an intensive insulin scheme (i.e., with 4-5 insulin injections per day) are eligible for reimbursement of the Freestyle Libre [115, 116]. Most patients did not inject this amount of insulin per day, which makes them ineligible for reimbursement. Limited reimbursement of Freestyle Libre sensors might lead to less eligible patients for the CooL+Diameter program.

Lack of time was also seen as a barrier to the implementation of CooL+Diameter. When using the

results of the Diameter more time needs to be invested in consults and CooL sessions to discuss the lifestyle parameters, however there is not always sufficient time. In addition, lifestyle coaches stated that the current reimbursement is too little to add the use of the Diameter to the CooL program. Both healthcare professionals and patients stated that some form of aftercare would be valuable after the intervention has ended. Schmidt et al. [117] showed that when an intensive lifestyle intervention, focused on physical activity and nutrition, ended only a few participants continued with the new lifestyle behaviors they had learned. Previous research showed that low energy, personal circumstances, physical problems and having to carry one alone were main barriers to continue [117].

Healthcare professionals also emphasized the importance of motivation among patients to change lifestyle behavior. However, since motivation of the participants is assessed before they are accepted in the CooL program this should not be a barrier for integrating the Diameter in CooL [66]. Another main barrier to the implementation of CooL+Diameter mentioned by all patients was the limited integration of the Diameter in CooL in the current program. However, the lifestyle coaches indicated that if this combination would be implemented that this would cause no difficulties due to the open nature of the CooL intervention. There are no strict guidelines for the CooL sessions and the Diameter could be easily added [66].

Limited-efficacy testing

Most of the measured outcomes showed a positive difference between baseline and follow-up. Levels of HbA1c and BMI were significantly lower at follow-up compared to baseline. Hip and waist circumference also decreased compared to baseline. Additionally, the EQ-5D-3L VAS score also showed positive results at follow-up compared to baseline. These results did not show statistically significant results. However, these results had low p-values (ranging from 0.09 to 0.14) and the sample size was small (N=5), which does indicate that these outcomes might be clinically relevant. Studies combining a combined lifestyle intervention such as CooL and an app for self-monitoring and coaching are limited. However, a systemic review and meta-analysis by Antoun et al. [58] showed that combining a mobile app with a behavioral intervention (such as a human coach) resulted in a weight loss of 3.77 kilograms at six months compared to 2.8 kilograms weight loss for the use of an app without the behavioral intervention [58].

An unexpected result was the decrease of time in range between baseline and follow-up. Since the HbA1c-levels did decrease between baseline and follow-up the expectation was that time in range would increase [118]. However, research has shown that the time in range value can still vary greatly even if the uncertainty of the predicted time in range is very small [119]. The amount of steps per day was relatively high with on average 7633 steps per day. However, the step count did not show a clear trend in increased physical activity over the three-month period for each individual patient. On each of the days nutrition was measured most of the patients did not meet the nutritional guidelines for carbohydrates, protein, fat and sugar. On average patients consumed 1523 calories per day, which is much lower than the nutritional guidelines generally recommend (i.e., 2000 kcal for females and 2500 for males) [86]. This can be due to underreporting of nutrition or specific diets that patients follow [120-122].

Strengths and limitations

One of the strengths of this study is the mixed-methods design. Each of the feasibility domains asked for a different measurement approach. Acceptability, implementation and practicality were measured using interviews. Interviews can give in-depth insight into the experiences, barriers and facilitators related to CooL+Diameter [123]. To measure intervention usage and limited efficacy quantitative methods were used. With these quantitative methods of measurement changes between baseline and follow-up could be assessed [123]. With these methods of measurement, the end-users, patients and healthcare

professionals, were involved in the assessment of the intervention. Involvement of end-users in the developmental phase to explore the needs of end-users can enhance the uptake of innovations, such as eHealth applications like the Diameter [125]

Another strength of this study is that the methods of measurements are based on theory. Interview questions were based on different theories regarding intervention acceptance and implementation of interventions. Using the UTAUT2 model [94], modified TAM model [95] and NASSS framework [96] to form an interview guide provided a more systemic approach to make sure topics were not missed. The quantitative measurements were also assessed on validity. The Fitbit has shown accurate results in other studies regarding daily step count [82-84]. The Freestyle Libre has also proven to show accurate results of glucose levels compared to regular methods of blood glucose testing [77-78]. The instrument to measure HRQoL, the EQ-5D-3L, has demonstrated construct validity, making it a reliable instrument to use [80].

One of the limitations of this study is that CooL+Diameter consists of several different components (i.e., face-to-face coaching, self-monitoring, digital coaching). This makes it difficult to assign the results to the combined intervention as a whole, since it could also be the case that only certain components of the intervention cause positive results. However, this study was of exploratory nature, meaning that the positive results found in this study can be used to further investigate the different elements of CooL+Diameter to assess which (combination of) elements cause positive effects.

Another limitation was the amount of participants in the CooL+Diameter intervention. The target sample size of 6-12 participants was met for the healthcare professionals [67]. With the inclusion of five patients the target sample size was not met. This was mainly due to the other participants in the CooL group not having an Android phone. Due to this small sample size, findings are of exploratory nature and can not be generalized. However, the results did show common perspectives in the interviews and a few statistically significant outcomes which implies a sound foundation for further research. There is also the possibility that selection bias may have occurred when participants were included in the study [125]. Only participants already enrolled in the CooL program were asked to participate in this study. One of the inclusion criteria of the CooL intervention is having sufficient motivation to complete the program [66]. Including only participants from this CooL group may have therefore resulted in more positive outcomes. In addition, none of the participants perceived themselves as laggards towards the use of new technology. This may indicate that this group of participants is more open to the use of technology than others, which might give a more biased result. Additionally, some of the healthcare professionals were (distantly) involved with the Diameter-1 study, which was helpful since they had more insight into the intervention. However, involvement in the research of the Diameter could also have biased their responses.

Furthermore, a limitation of this study was that during the three-month intervention period only three CooL group sessions took place. Only certain topics were discussed in those CooL sessions. This resulted in patients not having enough experience about the CooL intervention to provide a full picture of their experiences with the intervention.

Lastly, for the measurement of nutritional behavior the patients self-reported their nutrition. However, nutrition is often not very accurately reported by people. Even the six-day period which was used in this study can show a decline in numbers of foods logged and the complexity of foods that are logged due to fatigue of the participant [111]. This potential lack of compliance can generate less reliable results of nutritional behavior. Another limitation regarding nutritional behavior was that only data from baseline were available. Therefore, potential nutritional behavior changes between baseline and follow-up could not be analyzed.

Implications for practice and future research

User friendliness of an application, such as interface appearance and presentation of information, can have an impact on user engagement [126]. Since the Diameter app was not perceived as user friendly by the patients in this study, further development of the Diameter app should focus on a more user friendly design. In addition, having T2DM is of heterogeneous nature, meaning that experiences of having T2DM are not the same for every T2DM patient [127] In order to help as many T2DM patients as possible it can be of importance to adjust lifestyle interventions to the personal context of the patient. More tailored support can help patients stay more motivated to change and maintain their lifestyle [117]. In the Diameter-1 study the Diameter will also be evaluated as a stand-alone app [64]. Using this slimmed down version of the intervention, where only the Diameter is used can make this treatment option more approachable to some patients. Additionally, it would also be valuable if more tailoring of digital coaching is possible in future versions of the Diameter [118]. This could be of importance for people with T2DM who have limited options for physical activity, due to for example an amputation, since certain lifestyle goals may not be feasible. Furthermore, future research of the implementation of CooL+Diameter in primary care may also be of importance, since the majority of people with T2DM are being treated in primary care [114]

This study included only a small sample size and was of exploratory nature. To enhance generalizability of the combined intervention, further research with a larger sample size is necessary. It is also recommended that in future research a control group will be added. In this control group only the use of the Diameter will be tested. Comparing the results of the combined intervention (CooL+Diameter) and the stand-alone intervention (Diameter) can show potential differences between the two groups. In future research of the Diameter-1 study, patients using the Diameter as a stand-alone app and the Diameter in combination with the CooL program will be studied [64]. Additionally, a longer intervention period could be valuable to test long-term effects and study maintenance of lifestyle changes. For the potential reimbursement of the Diameter and accompanying tools and the reimbursement lifestyle coaches receive, future research should also focus on the cost-effectiveness of CooL+Diameter.

Furthermore, the development of an integrated program where CooL and the Diameter are seen as one intervention might be valuable. Currently, the Diameter and CooL are perceived as two separate interventions, which results in no linkages as well as overlap between the two interventions. Combining the two interventions in an integrated program can lead to more opportunities to discuss the objective results generated with the Diameter. Having objective results can also be valuable for regular consults with healthcare professionals. Getting continuous support and monitoring of lifestyle parameters, also after the intervention has ended, can give reassurance about the status of their condition and help with motivation to maintain lifestyle changes [117].

Conclusion

This study aimed to evaluate the feasibility of using the Diameter app in combination with the combined lifestyle intervention CooL to change lifestyle behaviors in people with T2DM in secondary care from the perspectives of patients and healthcare professionals. Overall, CooL+Diameter was perceived as a feasible intervention for T2DM patients in secondary care by both patients and healthcare professionals. Patients and healthcare professionals found the concept of using an app with features of digital coaching and self-monitoring tools a valuable addition to the CooL program. Both patients and healthcare professionals perceived the insight in nutrition and physical activity on glucose levels, getting continuous feedback and becoming aware of the health status of patients the most valuable elements of CooL+Diameter. Even though the CooL+Diameter intervention was accepted by both patients and healthcare professionals, improvements need to be made on the user friendliness of the Diameter app. Patients were satisfied with the use of the Fitbit and Freestyle Libre, but found it difficult to navigate the food diary and digital coaching and encountered technical problems while using the Diameter. This resulted in limited use of the Diameter app itself. However, despite the limited use of the Diameter and a small number of participants, the results of this study showed statistically significant and clinically relevant results.

Future research should focus on improving the user experience of the Diameter and further personalization of digital coaching. Furthermore, integration of the Diameter app in the CooL program would be valuable to enhance discussion of the self-monitored results between the patients and lifestyle coach and/or healthcare professional, which can be helpful to set more tailored lifestyle goals.

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Appendices

Appendix 1 – Overview of the Diameter-1 study

This study is part of the Diameter-1 study, which evaluates intervention usage, acceptability and effects on clinical and psychological outcomes of the Diameter app. The Diameter app will be evaluated in three different phases [64]. First a small pilot study at ZGT hospital has been performed to test the proposed research protocol. In the following phase a feasibility study was conducted to evaluate intervention usage and acceptability of the Diameter in combination with standard of care at ZGT hospital. Additionally, some of the participants took part in the CooL program. In the third and last phase a small study will be performed to explore the acceptability of the Diameter as a stand-alone tool in primary care. The present study is part of the second phase of the Diameter-1 study [64]. Table 10 presents a brief overview of phase two [64].

Table 10. Overview of the Diameter 1-study

Time	Procedures
Week 1-2 (baseline measurements): T_0*	• Blinded glucose measurement (Freestyle Libre 2) • Blinded nutrition intake measurement (Diameter) (6 days) • Non-blinded physical activity measurement (Fitbit) • Measurements of clinical and physiological outcomes • Digital questionnaires
Week 3-12: Diameter*	• Monitoring of physical activity and glucose • Daily digital coaching messages • Weekly exercises • Weekly goal setting • Weekly digital coaching e-mails
Week 13-14 (primary endpoint): T_1*	• Measurements of clinical and physiological outcomes • Measurements of behavioral outcomes • Nutrition intake measurement (6 days) • Questionnaires • Interview (10-15 patients) about experiences with the Diameter
Week 15-24: Diameter Light	• Monitoring of physical activity, glucose and nutrition • Weekly exercises • Weekly goal setting
Week 25-26 (follow-up): T_2	• Measurements of clinical and physiological outcomes • Measurements of behavioral outcomes • Questionnaires
Week 34 (follow-up: T_3	• Only for CooL participants: Data from the patient record (clinical and physiological outcomes)

* Parts of phase two that are included in the present study

Appendix 2 - Explanation of theoretical constructs

Unified Theory of Acceptance and Use of Technology 2 (UTAUT2)

Acceptability can be seen as the extent to which an intervention is judged as suitable, satisfying, or attractive to both deliverers of the intervention as to recipients of the intervention [63]. Venkatesh et al. [130] developed a theory based on several models focused on information technology acceptance. This resulted in the Unified Theory of Acceptance and Use of Technology (UTAUT). Venkatesh et al. [130] hypothesize that the UTAUT is based on four constructs that influence user acceptance and usage behavior. These constructs are: performance expectancy, effort expectancy, social influence and facilitating conditions [130]. These four constructs influence behavioral intention to use technology or the usage of technology [94]. Later, Venkatesh et al. [94] developed an updated version of the UTAUT, namely the UTAUT2. This expanded theory adds factors that are more applicable to a consumer technology use context, whereas the original UTAUT was developed to explain employee technology acceptance and use. The three constructs that were added on to the model are: hedonic motivation, price value and habit [94]. Since UTAUT2 is based on a consumer use setting, this theory can be used to measure the acceptance of the Diameter combined with CooL from the perspective of the patients. The different constructs and overview of the model of the UTAUT2 can be found in table 11 and figure 8 below.

Table 11. Constructs of the UTAUT2

Construct	Definition
Performance expectancy	"the degree to which an individual believes that using the system will help him or her to attain gains in jobs performance" [129].
Effort expectancy	"the degree of ease associated with the use of the system" [129].
Social influence	"the degree to which an individual perceived that important others believe he or she should use the new system" [129]
Facilitating conditions	"the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of the system" [129]
Hedonic motivation	"the fun or pleasure derived from using a technology" [94]
Price value	"consumers' cognitive trade off between the perceived benefit of the applications and the monetary cost for using them" [94]
Habit	"the degree to which behaviors are fulfilled automatically due to learning experiences" [94]

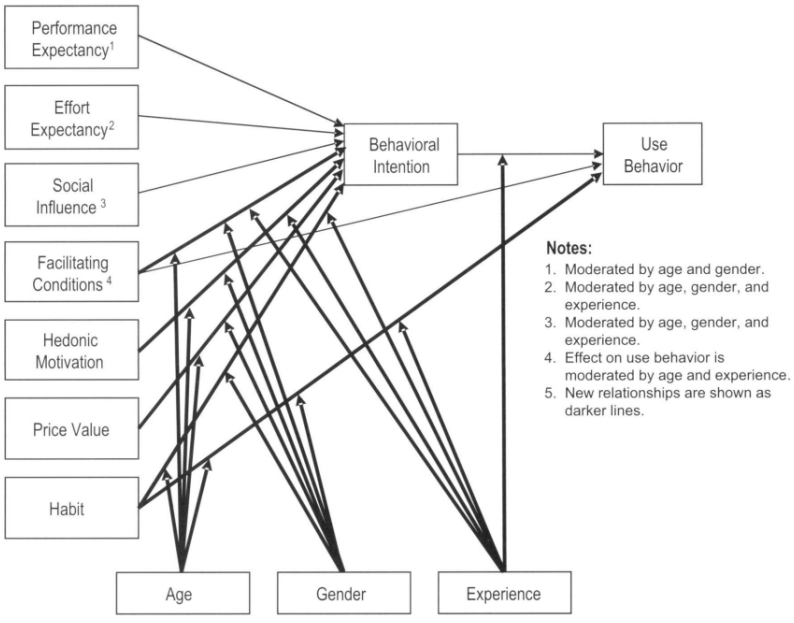


FIGURE 8. UTAUT 2 MODEL [94]

Modified Technology Acceptance Model

For the acceptability of a technology from the perspective of healthcare professionals other measurement tools exist [95]. These tools for technology acceptance are adapted to the professionals' perspective. Gagnon et al. [95] developed a questionnaire based on the Technology Acceptance Model (TAM). Gagnon et al. [95] modified this model in order to evaluate the acceptance of a telemonitoring system from the perspective of healthcare professionals [95]. The dimensions of the original TAM model consist of perceived usefulness, perceived ease of use, attitude and intention to use [95]. Gagnon et al. [95], added based on other theories, the following dimensions: habits, compatibility, facilitators and subjective norm. The different constructs and overview of the modified technology acceptance model can be found in table 12 and figure 9 below.

Table 12. Constructs of the Modified Technology Acceptance Model

Construct	Definition
Perceived usefulness	"The degree to which a person believes that using a particular system would enhance his or her job performance" [130]
Perceived Ease-of-Use	"The degree to which a person believes that using a particular system would be free of effort" [130]
Habit	"The extent to which behavior has become automatized" [95, 131]
Subjective norm	"The extent to which an individual believes that people who are important to him or her will approve his or her adopting a particular behavior" [95]
Facilitators	"The degree to which an individual believes that an organizational and technical infrastructure exists to support the use of the system" [95, 131]
Attitude	"The extent to which an individual perceives consequences of adopting the technology as positive or negative" [93, 95]
Compatibility	"The degree of correspondence between an innovation and existing values, past experiences and needs of potential adopters." [93, 95]

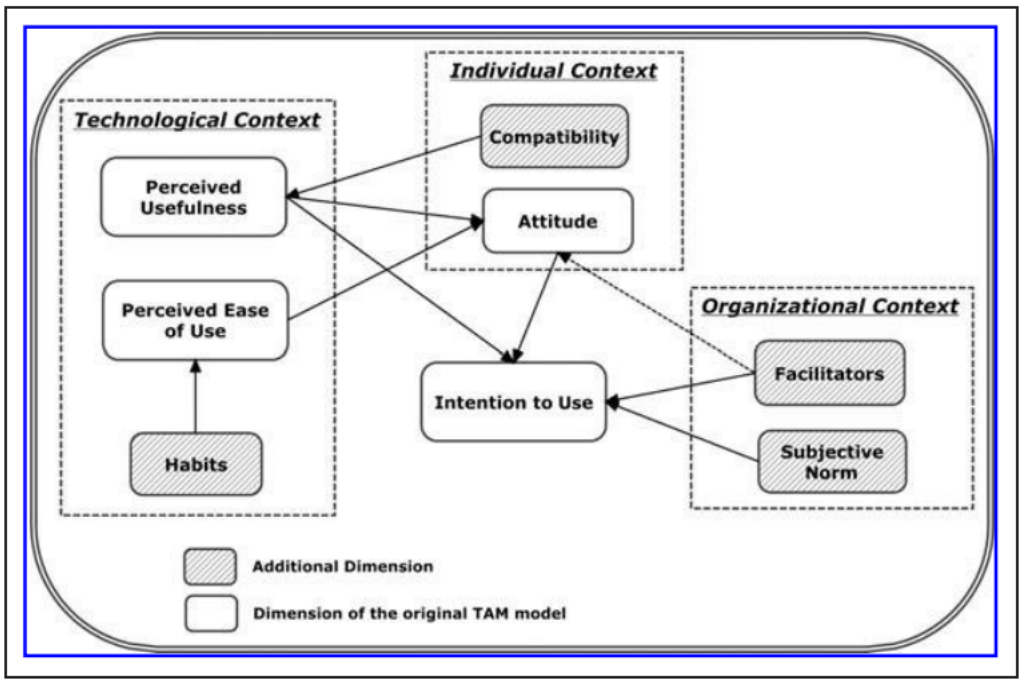


FIGURE 9. MODIFIED TECHNOLOGY ACCEPTANCE MODEL [95]

Framework for non-adoption, abandonment, scale-up, spread and sustainability

There can occur some challenges when it comes to actual implementation of an intervention. This can lead to non-adoption or abandonment of the intervention by individuals or unsuccessful attempts to scale up, spread or maintain an intervention at system or organization level for a long period of time [96]. Greenhalgh et al. [96] constructed an evidence-based, theory-informed but pragmatic framework for the evaluation of successfulness of an innovation used in healthcare. This resulted in the framework for non-adoption, abandonment, scale-up, spread and sustainability (NASSS). This framework consists of thirteen questions within six different domains. These six domains are the condition, the technology, the value proposition, the adopter system (patient or caregiver), the health or care organization and the wider context [96]. The framework can be used prospectively to examine the challenges that may occur when implementing an intervention. The framework can also be used retrospectively to study the elements that worked and did not work when implementing the intervention [96]. The different constructs and overview of the NASSS framework can be found in table 13 and figure 10 below.

Table 13. The NASSS framework

Construct	Definition
Condition	"The extent to which the nature and progression of the condition has been assessed and the extent to which the condition is 'suitable' for the technology (i.e., well-characterized, predictable, well-understood, fits in current care)" [96].
Technology	"The extent to which key features (I.e., physical and symbolic features) of the technology, the data generated by the technology, support and knowledge needed to use the technology and sustainability of the technology has been assessed" [96].
Value proposition	"The extent to which a new technology is worth developing in the first place and for whom it creates value" [96].
Adopters	"The extent to which a new technology will be adopted (used and accepted) by staff, patients and caregivers of patients" [96].
Organization	"The degree of resources and infrastructure (capacity, funding, size of organization) available in the organization in order to implement the technology and necessary changes (readiness, routines, implementation tasks) to implement the technology" [96].
Wider system	"The degree of political, economic, regulatory, professional and sociocultural shifting towards implementing the new technology" [96].
Embedding and adaption over time	"The extent to which the technology can adapt and can adjust to unforeseen circumstances over time" [96].

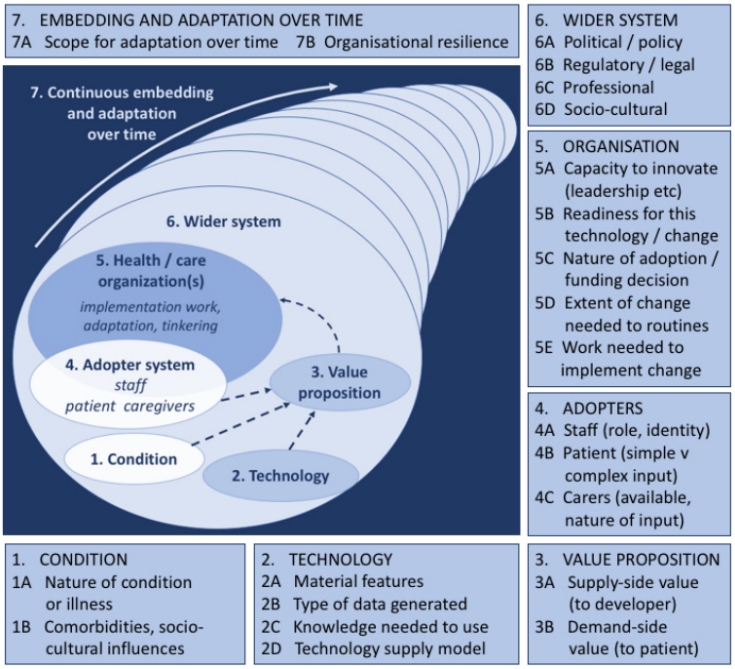


FIGURE 10. THE NASSS FRAMEWORK[96]

Appendix 3 - Interview scheme Patient

Introductie

Goedendag,

Mijn naam is Carine Gotink en ik ben op dit moment bezig met mijn afstudeeropdracht voor de master gezondheidswetenschappen aan de Universiteit Twente. Op dit moment gebruikt u de Diameter app om uw leefstijl te monitoren en doet u mee aan de gecombineerde leefstijlinterventie CooL.

De Diameter app bestaat uit een aantal onderdelen die uw leefstijl meten: het monitoren van uw beweging met de Fitbit, het bijhouden van uw voedselinname met het voedingsdagboek, het bijhouden van uw glucosewaarden met de Freestyle Libre. Daarnaast krijgt u ook digitale coachingsberichten (tips, e-mails, doelen opstellen) via de Diameter. Met dit interview willen wij meer inzicht krijgen in uw ervaringen met de Diameter en hoe u het vindt om de leefstijlmetingen en de digitale coaching te gebruiken in combinatie met CooL.

Ik verwacht dat het interview ongeveer een half uur zal gaan duren, maar dit kan variëren naar aanleiding van uw antwoorden.

Als u het goed vindt neem ik dit interview op met een geluidsopname. Hiermee kan ik na het interview nogmaals uw antwoorden terugluisteren en uitschrijven. Deze geluidsopnamen zullen alleen worden gebruikt voor dit onderzoek en blijven volledig anoniem. Gaat u akkoord met deelname aan dit interview? En gaat u akkoord met het opnemen van dit interview? Ik zou u willen vragen het volgende formulier te lezen en als u het eens bent het formulier te ondertekenen.

Heeft u nog vragen die u wilt stellen voordat we aan het interview beginnen? Als u geen vragen heeft, start ik de opname en kunnen we beginnen.

START AUDIO OPNAME

Het doel van dit onderzoek is om meer inzicht te krijgen in de ervaringen van mensen met diabetes type 2 die deelnemen aan het CooL programma en daarbij de Diameter gebruiken als technologische ondersteuning. Dit zijn twee interventies die in de toekomst, samen of apart van elkaar, kunnen worden ingezet voor de behandeling van diabetes type 2.

De volgende vragen gaan over uw ervaringen met het CooL programma ondersteunt door de Diameter. In dit interview gaat het over uw mening, dus er zijn geen goede of foute antwoorden.

- ❒ De afgelopen weken heeft u tijdens uw deelname aan het CooL programma de Diameter app gebruikt. Hoe vond u het om het CooL programma te combineren met de Diameter app?

- ❒ Hoe vond u het om uw leefstijl te meten met de technologische ondersteuning(en) *(Fitbit, Freestyle Libre, voedingsdagboek)*?
    - Hoe vond u het om deze leefstijl metingen te combineren met het CooL programma?
    - Wat vond u prettig/minder prettig aan het gebruiken van de leefstijl metingen als (technologische) ondersteuning bij het CooL programma?

- In hoeverre vond u het gemakkelijk om de leefstijlmetingen behorend bij de Diameter te combineren met uw deelname aan het CooL programma?
    - Wat vond u makkelijk?
    - Wat vond u moeilijk?

❒ Hoe vond u het om digitaal gecoacht (*tips, e-mails, doelen stellen*) te worden in de Diameter naast de persoonlijke coaching tijdens het CooL programma
- Hoe vond u het om de digitale coaching te combineren met het CooL programma?
- Wat vond u prettig/niet prettig aan het gebruiken van de coaching via de Diameter als ondersteuning bij het CooL programma?
- In hoeverre vond u het gemakkelijk om de digitale coaching van de Diameter te combineren met uw deelname aan het CooL programma?
    - Wat vond u makkelijk?
    - Wat vond u moeilijk?

❒ In hoeverre vond u het van toegevoegde waarde om het CooL programma te combineren met de Diameter ten opzichte van een CooL programma zonder Diameter?
- Wat maakte het wel/niet van toegevoegde waarde om CooL en de leefstijlmetingen met elkaar te combineren?
- Wat maakt het wel/niet van toegevoegde waarde om de coachingsberichten uit de Diameter te combineren met de CooL sessies?

❒ Wat vindt u van de activiteiten die horen bij het CooL programma *(bijvoorbeeld naar de bijeenkomsten gaan, opdrachten uitvoeren, doelen opstellen)*?
- Lukt het u om alle activiteiten die bij CooL horen uit te voeren?
    - Welke activiteiten lukken u wel/niet om uit te voeren? Wat maakt dat dit wel/niet lukt?

❒ Wat vindt u van de activiteiten die horen bij de Diameter *(bijvoorbeeld voedingsdagboek bijhouden, fitbit omdoen, weekdoel instellen, doelen behalen, coach berichten bekijken)?*
- Lukt het u om alle activiteiten die horen bij de Diameter uit te voeren?
    - Welke activiteiten lukken u wel/niet om uit te voeren? Wat maakt dat dit wel/niet lukt?

❒ In hoeverre vindt u dat de informatie uit de Diameter bijdraagt aan de bijeenkomsten en activiteiten die horen bij het CooL programma?
- In hoeverre vindt u dat de informatie uit de leefstijlmeting aansluit bij CooL?
    - Wat maakt dat dit wel/niet goed aansluit
- In hoeverre vindt u dat de informatie uit de digitale coaching aansluit bij CooL?
    - Wat maakt dat dit wel/niet goed aansluit?
- Op welke manier kan de Diameter (en alle onderdelen die erbij horen) beter bijdragen aan de bijeenkomsten en activiteiten van het CooL programma?

❒ In hoeverre denkt u dat u door het meten van uw leefstijl als ondersteuning bij het CooL programma beter in staat bent om uw leefstijldoelen te behalen?

- Wat maakt dat u door het meten van uw leefstijl als ondersteuning bij CooL beter/niet beter in staat bent om uw leefstijldoelen te behalen?

❒ In hoeverre denkt u dat u door de digitale coach berichten als ondersteuning bij het CooL programma beter in staat bent om uw leefstijldoelen te behalen?
- Wat maakt dat u door de digital coach berichten als ondersteuning bij CooL beter/niet beter in staat bent om uw leefstijldoelen te behalen?

❒ In hoeverre vindt u dat het CooL programma in combinatie met ondersteuning door leefstijlmetingen en digitale coaching een toevoeging is aan de zorg in het ziekenhuis?
- Wat maakt dat u de combinatie wel/geen toevoeging vindt?

❒ In hoeverre vindt u het belangrijk dat uw zorgverlener u aanmoedigt om gebruik te maken van een technologische ondersteuning, zoals de Diameter, tijdens uw deelname aan een leefstijlinterventie?
- Wat maakt dat u aanmoediging van uw zorgverlener wel/niet belangrijk vindt?
- In welke mate heeft u ondersteuning nodig van uw zorgverlener bij het gebruiken van een technologische ondersteuning, zoals de Diameter bij het CooL programma?
  - Wat voor een ondersteuning heeft u nodig van uw zorgverlener?

❒ In welke mate vond u het u het leuk om de leefstijlmetingen en digitale coaching tegelijkertijd met het CooL programma te gebruiken?
- Wat maakte het leuk/niet leuk om de leefstijlmetingen in combinatie met CooL te gebruiken?

❒ In hoeverre bent u eraan gewend geraakt om uw activiteiten voor het CooL-programma te combineren met het meten van uw leefstijl in het dagelijks leven?
- Zou u, na afloop van dit onderzoek, uw leefstijl willen blijven meten als ondersteuning bij CooL?
  - Wat maakt dat u uw leefstijl wel/niet zou willen blijven meten als ondersteuning bij CooL programma?

❒ Wat vindt u van de tijd die het kost om de Diameter (metingen en coaching) naast het CooL programma te gebruiken?
- Hoeveel tijd denkt u dat eraan kwijt bent? (*per week*)

❒ Wat vindt u van de kennis en vaardigheden (*hoeveelheid instructie die nodig is om de Diameter te kunnen gebruiken, digitale vaardigheden, het goed kunnen interpreteren van de gegevens in de Diameter*) die u nodig heeft om uw leefstijl te meten om dit als ondersteuning bij CooL te gebruiken?

❒ Wat zijn voor u redenen om technologie die leefstijl meten en u coachen, zoals de Diameter, te gebruiken als aanvulling op het CooL programma?

- ❒ Hoe tevreden bent u over het gebruik van de Diameter als ondersteuning bij uw deelname aan het CooL programma?
    - Welk cijfer, op een schaal van 1 – 10, zou u het combineren van het CooL programma en de leefstijlmetingen geven?
    - Welk cijfer, op een schaal van 1 – 10, zou u het combineren van het CooL programma met de digitale coaching geven?

Dit waren alle vragen die ik voor u had.

Heeft u nog aanvullende opmerkingen over uw ervaringen met het CooL programma ondersteund door het meten van uw leefstijl?

Heeft u nog andere vragen?

Afsluiting

Dan zijn we nu aan het einde gekomen van het interview. Ik wil u hartelijk bedanken voor uw deelname aan dit interview en het delen van uw ervaringen. Met uw antwoorden gaan we onderzoeken of het haalbaar is om de Diameter app en een leefstijlinterventie met elkaar te combineren voor de behandeling van diabetes type 2. Hartelijk bedankt voor uw tijd.

EINDE AUDIO OPNAME

Appendix 4 – Informed consent Patient

TOESTEMMINGSVERKLARING

Voor deelname aan het wetenschappelijk onderzoek:

"Het gebruik van de Diameter als onderdeel van het CooL programma"

Evaluatie van het gebruik van de Diameter app als onderdeel van het CooL programma voor het stimuleren en behouden van een gezonde leefstijl bij type 2 diabetes mellitus patiënten.

- Ik ben op de hoogte van het doel van het onderzoek. Ik heb vragen kunnen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik weet dat de gegevens die zijn verzameld gebruikt zullen worden voor het verdere onderzoek als ik besluit vroegtijdig te stoppen met het onderzoek. Op aanvraag kunnen mijn onderzoeksgegevens verwijderd worden.
- Ik weet dat voor de controle van het onderzoek sommige mensen toegang tot al mijn gegevens kunnen krijgen. Die mensen staan vermeld in de informatiebrief. Ik geef toestemming voor die inzage door deze personen.
- Ik weet dat er geluidopnames van het interview worden gemaakt en dat de geluidsopnames uitsluitend voor onderzoeksdoeleinden worden gebruikt.
- Ik geef toestemming om mijn gegevens te gebruiken, voor de doelen die in de informatiebrief staan.
- Ik geef toestemming om gegevens nog maximaal 15 jaar na afloop van dit onderzoek te bewaren.
- Ik geef □ **wel**

  □ **geen**

  toestemming om mijn persoonsgegevens langer te bewaren en te gebruiken voor toekomstig onderzoek op het gebied van mijn aandoening en/of de onderzochte behandelwijze.
- Ik geef □ **wel**

  □ **geen**

  toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.
- Ik wil meedoen aan dit onderzoek.

Naam proefpersoon:

Handtekening:

Datum: __ / __ / __

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening:

Datum: __ / __ / __

Appendix 5 - Interview scheme Healthcare professional

Introductie

Goedendag,

Mijn naam is Carine Gotink en ik ben op dit moment bezig met mijn afstudeeropdracht voor de master gezondheidswetenschappen aan de Universiteit Twente. De universiteit Twente, ZGT en Roessingh Research and Development hebben samen een app ontwikkeld voor het meten en coachen van leefstijl bij mensen met diabetes type 2, met de naam Diameter.

In ZGT zijn sinds januari 2022 een aantal patiënten gestart met een gecombineerde leefstijlinterventie (GLI), namelijk de Coaching op Leefstijl (CooL) interventie. Tegelijkertijd gebruiken deze patiënten de Diameter app voor dagelijkse leefstijlmetingen en digitale coaching.

De Diameter app bestaat uit een aantal onderdelen die leefstijl meten: het monitoren van beweging met de Fitbit, het bijhouden van voedselinname met het voedingsdagboek en het bijhouden van glucosewaarden met de Freestyle Libre. Daarnaast krijgen gebruikers ook digitale coachingsberichten (tips, e-mails, doelen opstellen) via de Diameter.

eHealth toepassingen, zoals de Diameter, kunnen als zelfstandige interventie worden ingezet, maar kunnen mogelijk ook worden ingezet samen met andere interventies zoals een GLI. Op deze manier kan er een vorm van *blended lifestyle coaching* worden gecreëerd. Dit betekent dat face-to-face leefstijlcoaching wordt ondersteund met een app voor het dagelijks monitoren en coachen van leefstijl. In dit onderzoek wordt het CooL programma ondersteund door de Diameter.

Met dit interview wil ik meer inzicht krijgen in uw mening en ervaringen met leefstijlprogramma's en eHealth toepassingen gericht op leefstijl. Ook bespreek ik graag ik met u of en hoe leefstijlinterventies, zoals de Diameter en CooL, met elkaar kunnen worden geïntegreerd en kunnen worden ingezet in de tweedelijnszorg voor diabetes type 2 patiënten.

Ik verwacht dat het interview ongeveer 30-60 minuten zal gaan duren, maar dit kan variëren naar aanleiding van uw antwoorden.

Met uw goedkeuring zou ik graag dit interview op willen nemen met een geluidsopname. Hiermee kan ik na het interview nogmaals uw antwoorden terugluisteren en uitschrijven. Deze geluidsopnamen zullen alleen worden gebruikt voor dit onderzoek en blijven volledig anoniem. Gaat u akkoord met het opnemen van dit interview? Ik zou u willen vragen het volgende formulier te lezen en als u het eens bent het formulier te ondertekenen.

Heeft u nog vragen die u wilt stellen voordat we aan het interview beginnen? Als u geen vragen heeft, start ik de opname en kunnen we beginnen.

START AUDIO OPNAME

Het doel van dit interview is om uw mening en ervaringen met eHealth toepassingen gericht op leefstijl en leefstijlprogramma's voor de zorg van diabetes type 2 patiënten te bespreken. Daarnaast bespreek ik graag met u of en hoe de Diameter gecombineerd kan worden met een persoonlijk leefstijlprogramma zoals CooL in de tweede lijn. In dit interview gaat het over uw mening. Er zijn dus geen goede of foute antwoorden.

Eerst zal ik mijzelf nog even voorstellen. **Korte introductie**

Algemeen

- ❒ Zou u uzelf kort willen voorstellen? Wie bent u en wat voor werk doet u?

- ❒ Wat is uw rol binnen het zorgpad voor diabetes type 2 patiënten?

Deel 1: persoonlijke leefstijlcoaching

- ❒ In hoeverre bent u bekend met persoonlijke (face-to-face) leefstijlcoaching, zoals de gecombineerde leefstijlinterventie CooL?

  Indien niet mee bekend: het CooL programma is een gecombineerde leefstijlinterventie waarbij een deelnemer met obesitas of overgewicht begeleiding en advies krijgt over voeding, beweging en gedrag om een gezondere leefstijl te ontwikkelen. Tijdens het tweejarige programma heeft de deelnemer regie over zijn/haar eigen traject en vervult de leefstijlcoach een ondersteunende rol tijdens groepssessies en individuele sessies met de deelnemers.

- ❒ Wat vindt u van persoonlijke leefstijlcoaching bij de behandeling van patiënten met diabetes type 2?

- ❒ In hoeverre denkt u dat persoonlijke leefstijlcoaching van toegevoegde waarde is bij de behandeling van patiënten met diabetes type 2 in de tweede lijn?

Deel 2: digitale leefstijltoepassingen

- ❒ In hoeverre bent u bekend met eHealth toepassingen gericht op leefstijlverandering?
  - In welke mate gebruikt u al eHealth toepassingen om leefstijl van patiënten te monitoren?

- ❒ Wat vindt u van digitale leefstijlcoaching en monitoring bij de behandeling van patiënten met diabetes type 2?

De Diameter is een app die diabetes type 2 patiënten digitaal kan coachen en leefstijl kan monitoren door middel van het bijhouden van glucosewaarden, beweging en voedselinname. De volgende vragen gaan over de Diameter.

- ❒ In hoeverre denkt u dat het gebruik van digitale leefstijlcoaching en leefstijlmonitoring, zoals met de Diameter, van toegevoegde waarde is bij de behandeling van patiënten met diabetes type 2? *(bijvoorbeeld: sneller monitoren van patiënten, verbeteren van monitoring, efficiënter monitoren, vergroten van werkprestaties)*
  - Wat zou u moeten of willen kunnen met de Diameter om bij te kunnen dragen aan de zorg die u levert aan T2DM patiënten?
  - Welke voor- en nadelen ziet u bij het gebruiken van de Diameter bij de behandeling van diabetes type 2 patiënten?

- ❒ In hoeverre denkt u dat u de data (*glucosewaarden, voedingsinname, beweging*) die verzameld wordt met de Diameter zou kunnen gebruiken bij de behandeling van uw patiënten?
  - In welke mate denkt u dat de data die verzameld wordt door de Diameter makkelijk kunt gebruiken in uw consulten?

❒ In hoeverre denkt u dat patiënten bereid zijn om hun leefstijl te monitoren en zich digitaal te laten coachen met de Diameter app?

- Wat zouden voor patiënten redenen kunnen zijn voor het wel of niet gebruiken van de Diameter app?
- In welke mate denkt u dat patiënten de uitkomsten van de data die verzameld wordt met de Diameter makkelijk kunnen gebruiken bij het veranderen van hun leefstijl?

❒ Zou u de Diameter adviseren aan mensen met diabetes type 2 voor het veranderen van hun leefstijl?

- Wat maakt dat u de Diameter wel/niet zou adviseren?

Deel 3: Blended lifestylecoaching: combineren van digitale leefstijlcoaching en monitoring en persoonlijke leefstijlcoaching

Blended lifestylecoaching is een benaming die kan worden gebruikt voor het combineren van face-to-face leefstijlcoaching met een leefstijltechnologie. In dit onderzoek wordt het CooL programma gecombineerd met de Diameter. De volgende vragen gaan over deze mogelijke combinatie.

❒ Wat vindt u van het combineren van de Diameter en het CooL programma, waarbij de Diameter dient als dagelijkse digitale leefstijlcoach tussen de persoonlijke coaching sessies van CooL door?

❒ In hoeverre denkt u dat het monitoren van leefstijl en het ontvangen van digitale coaching met de Diameter toegevoegde waarde heeft voor een leefstijlprogramma zoals CooL?

- In welke mate denkt u dat patiënten door het gebruik van de Diameter tijdens het leefstijlprogramma beter in staat zijn hun leefstijldoelen te behalen?
- In hoeverre denkt u dat het inzetten van de gecombineerde leefstijlcoaching bijdraagt aan het *managen* van hun diabetes *(symptomen, behandeling, emoties, leefstijlverandering*)?

Leefstijlinterventies, zoals de Diameter en CooL, voor diabetes type 2 patiënten (met comorbiditeiten, complicaties of moeilijk reguleerbare glucosewaarden) worden nog in beperkte mate ingezet in de tweede lijn. Leefstijlbegeleiding wordt gedaan door leefstijlcoaches, fysiotherapeuten en diëtisten. Verwijzingen voor GLI's lopen via de eerste lijn.

❒ In hoeverre denkt u dat het van toegevoegde waarde is om deze gecombineerde interventie aan te bieden binnen de tweede lijn voor diabetes type 2 patiënten?

- Welke voor- en nadelen ziet u bij het inzetten van deze gecombineerde leefstijlcoaching bij de behandeling van diabetes type 2 patiënten?

Deel 4: Implementatie van *blended lifestyle coaching* in de tweede lijn

❒ In hoeverre ziet u mogelijkheden om deze vorm van *blended lifestylecoaching* (CooL aanvullen met de Diameter) in te zetten binnen uw huidige praktijk/uw huidige behandelplan van patiënten met diabetes type 2? (*bijvoorbeeld naar doorverwijzen*)

- Wat zijn volgens u randvoorwaarden om *blended lifestyle coaching* succesvol in te zetten in de praktijk?
- Wat zijn mogelijke belemmeringen voor het inzetten van *blended lifestylecoaching* in de praktijk?

- ❒ In hoeverre denkt u dat deze vorm van *blended lifestyle coaching* (combineren van de Diameter en CooL) geschikt is voor deze doelgroep en ziekte: diabetes type 2 patiënten in de tweede lijn?
    - Wat zouden redenen kunnen zijn voor het wel of niet inzetten van deze gecombineerde interventie bij diabetes type 2 patiënten in de tweede lijn?
      (Bijvoorbeeld: meerdere zorgpaden, co-morbiditeit, communicatieproblemen, sociaaleconomische belemmeringen)

- ❒ In welke mate zullen er door het inzetten van gecombineerde leefstijlcoaching veranderingen in het werkproces/behandelplan nodig zijn?
    - Indien er veranderingen nodig zijn: In welke mate weegt het werk dat nodig is om deze veranderingen in het behandelplan door te voeren op tegen eventuele voordelen die de gecombineerde interventie met zich meebrengt?

- ❒ In hoeverre denkt u dat zorgverleners met wie u samenwerkt positief staan tegenover het inzetten van *blended lifestylecoaching* als onderdeel van de behandeling van diabetes type 2?
    - Wat zouden voor zorgverleners redenen kunnen zijn voor het wel of niet inzetten van *blended lifestyle coaching*?

- ❒ In hoeverre heeft u vertrouwen in deze gecombineerde vorm van leefstijl coaching? *(zoals bijvoorbeeld de betrouwbaarheid van de data en privacy en beveiligingsoverwegingen)*

- ❒ In welke mate vindt u dat er vanuit de organisatie [ziekenhuis] voldoende ondersteuning is om deze vorm van *blended lifestyle coaching* in te zetten bij de behandeling van diabetes type 2? (*Bijvoorbeeld: voldoende infrastructuur, training, technische ondersteuning*)

Dit waren alle vragen die ik voor u had.

Heeft u nog vragen of opmerkingen?

Afsluiting

Dan zijn we nu aan het einde gekomen van het interview. Ik wil u hartelijk bedanken voor uw tijd en deelname aan dit interview.

EINDE AUDIO OPNAME

Appendix 6 – Interview Lifestyle coach

Introductie

Goedendag,

Mijn naam is Carine Gotink en ik ben op dit moment bezig met mijn afstudeeropdracht voor de master gezondheidswetenschappen aan de Universiteit Twente. De universiteit Twente, ZGT en Roessingh Research and Development hebben samen een app ontwikkeld voor het meten en coachen van leefstijl bij mensen met diabetes type 2, met de naam Diameter.

In ZGT zijn sinds januari 2022 een aantal patiënten gestart met een gecombineerde leefstijlinterventie (GLI), namelijk de Coaching op Leefstijl (CooL) interventie. Tegelijkertijd gebruiken deze patiënten de Diameter app voor dagelijkse leefstijlmetingen en digitale coaching.

De Diameter app bestaat uit een aantal onderdelen die leefstijl meten: het monitoren van beweging met de Fitbit, het bijhouden van voedselinname met het voedingsdagboek en het bijhouden van glucosewaarden met de Freestyle Libre. Daarnaast krijgen gebruikers ook digitale coachingsberichten (tips, e-mails, doelen opstellen) via de Diameter.

eHealth toepassingen, zoals de Diameter, kunnen als zelfstandige interventie worden ingezet, maar kunnen mogelijk ook worden ingezet samen met andere interventies zoals een GLI. Op deze manier kan er een vorm van *blended lifestyle coaching* worden gecreëerd. Dit betekent dat face-to-face leefstijlcoaching wordt ondersteund met een app voor het dagelijks monitoren en coachen van leefstijl. In dit onderzoek wordt het CooL programma ondersteund door de Diameter.

Met dit interview wil ik meer inzicht krijgen in uw mening en ervaringen met leefstijlprogramma's en eHealth toepassingen gericht op leefstijl. Ook bespreek ik graag ik met u of en hoe leefstijlinterventies, zoals de Diameter en CooL, met elkaar kunnen worden geïntegreerd en kunnen worden ingezet in de tweedelijnszorg voor diabetes type 2 patiënten.

Ik verwacht dat het interview ongeveer 30-60 minuten zal gaan duren, maar dit kan variëren naar aanleiding van uw antwoorden.

Met uw goedkeuring zou ik graag dit interview op willen nemen met een geluidsopname. Hiermee kan ik na het interview nogmaals uw antwoorden terugluisteren en uitschrijven. Deze geluidsopnamen zullen alleen worden gebruikt voor dit onderzoek en blijven volledig anoniem. Gaat u akkoord met het opnemen van dit interview? Ik zou u willen vragen het volgende formulier te lezen en als u het eens bent het formulier te ondertekenen.

Heeft u nog vragen die u wilt stellen voordat we aan het interview beginnen? Als u geen vragen heeft, start ik de opname en kunnen we beginnen.

START AUDIO OPNAME

Het doel van dit interview is om uw mening en ervaringen met eHealth toepassingen gericht op leefstijl en leefstijlprogramma's voor de zorg van diabetes type 2 patiënten te bespreken. Daarnaast bespreek ik graag met u of en hoe de Diameter gecombineerd kan worden met een persoonlijk leefstijlprogramma zoals CooL in de tweede lijn. In dit interview gaat het over uw mening. Er zijn dus geen goede of foute antwoorden.

Eerst zal ik mijzelf nog even voorstellen. **Korte introductie**

Algemeen

- ❒ Zou u uzelf kort willen voorstellen? Wie bent u en wat voor werk doet u?

- ❒ Wat is uw rol binnen het zorgpad voor diabetes type 2 patiënten?

- ❒ Kunt u iets vertellen over uw CooL sessies?

Deel 1: digitale leefstijltoepassingen

- ❒ In hoeverre bent u bekend met eHealth toepassingen gericht op leefstijlveranderingen?
  - In welke mate gebruikt u al eHealth toepassingen om leefstijl van uw deelnemers te monitoren?

In dit onderzoek is de Diameter app ingezet bij diabetes type 2 patiënten in de tweede lijn. De Diameter is een app die diabetes type 2 patiënten digitaal kan coachen en leefstijl kan monitoren door middel van het bijhouden van glucosewaarden, beweging en voedselinname.

- ❒ Wat vindt u van digitale leefstijlcoaching en monitoring bij de behandeling van patiënten met diabetes type 2? (toegevoegde waarde)

Deel 2: Blended lifestylecoaching: combineren van digitale leefstijlcoaching en monitoring en persoonlijke leefstijlcoaching

Blended lifestylecoaching is een benaming die kan worden gebruikt voor het combineren van face-to-face leefstijlcoaching met een leefstijltechnologie. In dit onderzoek wordt het CooL programma gecombineerd met de Diameter. De volgende vragen gaan over deze mogelijke combinatie.

- ❑ Wat vindt u van het combineren van de Diameter met het CooL programma, waarbij de Diameter dient als dagelijkse digitale leefstijlcoach tussen de persoonlijke coaching sessies van CooL door?

- ❑ In hoeverre denkt u dat het gebruik van digitale leefstijlcoaching en leefstijlmetingen, zoals de Diameter, van toegevoegde waarde is bij het CooL programma ten opzichte van een CooL programma zonder digitale ondersteuning?
  - In hoeverre denkt u dat een technologische ondersteuning, zoals de Diameter, past binnen het CooL programma?
  - *In hoeverre denkt u dat deze twee interventies gemakkelijk met elkaar te integreren (onderdelen van CooL + Diameter combineren) zijn?*
  - Welke voor- en nadelen ziet u bij het gebruiken van de Diameter in het CooL programma

- ❒ In hoeverre denkt u dat u de data (*glucosewaarden, voedingsinname, beweging*) die verzameld wordt met de Diameter zou kunnen gebruiken binnen het CooL programma?
  - In welke mate denkt u dat de data die verzameld wordt door de Diameter makkelijk kunt gebruiken in uw CooL sessies?

❒ In hoeverre denkt u dat deelnemers van het CooL programma bereid zijn om hun leefstijl te monitoren en zich digitaal te laten coachen met de Diameter app?

- Wat zouden redenen kunnen zijn voor het wel of niet gebruiken van de Diameter binnen het CooL programma?
- In welke mate denkt u dat deelnemers de uitkomsten van de data die verzameld wordt met de Diameter makkelijk kunnen gebruiken bij het veranderen van hun leefstijl?

❒ In welke mate denkt u dat deelnemers door het gebruik van de Diameter in combinatie met de CooL sessies beter in staat zijn hun doelstellingen (opgesteld in CooL programma) te behalen?

❒ Zou u de Diameter adviseren aan diabetes type 2 deelnemers van het CooL programma?

- Wat maakt dat u de Diameter wel/niet zou adviseren?

Leefstijlinterventies, zoals de Diameter en CooL, voor diabetes type 2 patiënten (met comorbiditeiten, complicaties of moeilijk reguleerbare glucosewaarden) worden nog in beperkte mate ingezet in de tweede lijn. Leefstijlbegeleiding wordt gedaan door leefstijlcoaches, fysiotherapeuten en diëtisten. Verwijzingen voor GLI's lopen via de eerste lijn.

❒ In hoeverre denkt u dat het van toegevoegde waarde is om deze gecombineerde interventie aan te bieden binnen de tweede lijn voor diabetes type 2 patiënten?

- Welke voor- en nadelen ziet u bij het inzetten van deze gecombineerde interventie bij de behandeling van diabetes type 2 patiënten?

Deel 3: Implementatie van *blended lifestyle coaching*

❑ In hoeverre ziet u mogelijkheden om deze vorm van blended lifestylecoaching (CooL + Diameter) in te zetten binnen de uw huidige praktijk?

- Wat zijn volgens u randvoorwaarden om blended lifestyle coaching succesvol in te zetten in de praktijk?
  Wat zijn mogelijke belemmeringen voor het inzetten van blended lifestylecoaching in de praktijk?

❒ In hoeverre denkt u dat deze vorm van *blended lifestyle coaching* (combineren van CooL met de Diameter) geschikt is voor deze doelgroep en ziekte: diabetes type 2 patiënten?

- Wat zouden redenen kunnen zijn voor het wel of niet inzetten van deze gecombineerde interventie bij diabetes type 2 patiënten (Bijvoorbeeld: meerdere zorgpaden, co-morbiditeit, communicatieproblemen, sociaaleconomische belemmeringen)

❒ In welke mate zullen er door het gebruik van de Diameter in het CooL programma veranderingen in uw werkproces nodig zijn?

- Indien er veranderingen nodig zijn: In welke mate weegt het werk dat nodig is om deze veranderingen in het CooL programma door te voeren op tegen eventuele voordelen die de Diameter met zich meebrengt?

❒ In hoeverre denkt u dat zorgverleners met wie u samenwerkt positief staan tegenover het gebruik van blended lifestyle coaching als onderdeel van de behandeling van diabetes type 2?

- Wat zouden voor zorgverleners redenen kunnen zijn voor het wel of niet van de inzetten van blended lifestyle coaching?

❒ In hoeverre heeft u vertrouwen in deze gecombineerde vorm van leefstijlcoaching? *(zoals bijvoorbeeld de betrouwbaarheid van de data en privacy en beveiligingsoverwegingen)*

❒ In welke mate heeft u ondersteuning nodig om digitale leefstijltoepassingen zoals de Diameter als ondersteuning bij het CooL programma in te zetten voor het bevorderen van een gezonde leefstijl van diabetes type 2 patiënten? (Bijvoorbeeld: voldoende infrastructuur, training, technische ondersteuning)

❒ In hoeverre vindt u het belangrijk dat u de Diameter naar eigen inzicht kunt inzetten binnen het CooL programma?

Dit waren alle vragen die ik voor u had.

Heeft u nog vragen of opmerkingen?

Afsluiting

Dan zijn we nu aan het einde gekomen van het interview. Ik wil u hartelijk bedanken voor uw tijd en deelname aan dit interview.

EINDE AUDIO OPNAME

Appendix 7 – Informed consent Healthcare professionals

Informatieblad voor onderzoek 'gecombineerde leefstijlcoaching'

Doel van het onderzoek

Dit onderzoek wordt uitgevoerd door Carine Gotink (masterstudent Health Sciences)

De universiteit Twente, Ziekenhuisgroep Twente (ZGT) en Roessingh Research and Development hebben samen een app ontwikkeld voor het meten en coachen van leefstijl bij mensen met diabetes type 2, met de naam Diameter. De Diameter app bestaat uit een aantal onderdelen die leefstijl meten: het monitoren van beweging met de Fitbit, het bijhouden van voedselinname met het voedingsdagboek en het meten van glucosewaarden met de Freestyle Libre. Daarnaast krijgen gebruikers ook digitale coachingsberichten (tips, e-mails, doelen opstellen) via de Diameter. In ZGT zijn sinds januari 2022 een aantal patiënten gestart met een gecombineerde leefstijlinterventie (GLI), namelijk de Coaching op Leefstijl (CooL) interventie. Tegelijkertijd gebruiken deze patiënten de Diameter app voor dagelijkse leefstijlmetingen en digitale coaching. eHealth toepassingen, zoals de Diameter, kunnen als zelfstandige interventie worden ingezet, maar kunnen mogelijk ook worden ingezet samen met andere leefstijlcoaching interventies zoals een GLI. Op deze manier kan er een vorm van *blended lifestyle coaching* worden gecreëerd. Om te achterhalen of het mogelijk om deze twee interventies met elkaar te combineren wordt er een haalbaarheidsstudie uitgevoerd waarbij zowel het perspectief van de patiënt als het perspectief van de zorgprofessional wordt onderzocht. De onderzoeksdata zullen worden gebruikt in het afstudeeronderzoek van de onderzoeker.

Hoe gaan we te werk?

U neemt deel aan een onderzoek waarbij we informatie zullen vergaren door:

- U te interviewen en uw antwoorden te noteren/op te nemen via een audio-opname/video-opname. Er zal ook een transcript worden uitgewerkt van het interview.

Potentiële risico's en ongemakken

- Er zijn geen fysieke, juridische of economische risico's verbonden aan uw deelname aan deze studie. U hoeft geen vragen te beantwoorden die u niet wilt beantwoorden. Uw deelname is vrijwillig en u kunt uw deelname op elk gewenst moment stoppen.

Vergoeding

U ontvangt voor deelname aan dit onderzoek geen vergoeding.

Vertrouwelijkheid van gegevens

Wij doen er alles aan uw privacy zo goed mogelijk te beschermen. Er wordt op geen enkele wijze vertrouwelijke informatie of persoonsgegevens van of over u naar buiten gebracht, waardoor iemand u zal kunnen herkennen. Voordat onze onderzoeksgegevens naar buiten gebracht worden, worden uw gegevens geanonimiseerd. In een publicatie zullen anonieme gegevens of pseudoniemen worden gebruikt. De audio-opnamen, formulieren en andere documenten die in het kader van deze studie worden gemaakt of verzameld, worden opgeslagen op een beveiligde locatie bij de Universiteit Twente en op de beveiligde (versleutelde) gegevensdragers van de onderzoekers. De onderzoeksgegevens

worden bewaard voor een periode van 15 jaar. Uiterlijk na het verstrijken van deze termijn zullen de gegevens worden verwijderd of worden geanonimiseerd zodat ze niet meer te herleiden zijn tot een persoon. De onderzoeksgegevens worden indien nodig (bijvoorbeeld voor een controle op wetenschappelijke integriteit) en alleen in anonieme vorm ter beschikking gesteld aan personen buiten de onderzoeksgroep.

Tot slot is dit onderzoek beoordeeld en goedgekeurd door de ethische commissie van de faculteit BMS(domain Humanities & Social Sciences)

Vrijwilligheid

Deelname aan dit onderzoek is geheel vrijwillig. U kunt als deelnemer uw medewerking aan het onderzoek te allen tijde stoppen, of weigeren dat uw gegevens voor het onderzoek mogen worden gebruikt, zonder opgaaf van redenen. Het stopzetten van deelname heeft geen nadelige gevolgen voor u of de eventueel reeds ontvangen vergoeding.

Als u tijdens het onderzoek besluit om uw medewerking te staken, zullen de gegevens die u reeds hebt verstrekt tot het moment van intrekking van de toestemming in het onderzoek gebruikt worden.

Wilt u stoppen met het onderzoek, of heeft u vragen en/of klachten? Neem dan contact op met de onderzoeker.

Carine Gotink
Masterstudent Health Sciences
Universiteit Twente

Voor bezwaren met betrekking tot de opzet en of uitvoering van het onderzoek kunt u zich ook wenden tot de Secretaris van de Ethische Commissie / domein Humanities & Social Sciences van de faculteit Behavioural, Management and Social Sciences op de Universiteit Twente via ethicscommitee-hss@utwente.nl. Dit onderzoek wordt uitgevoerd vanuit de Universiteit Twente, faculteit Behavioural, Management and Social Sciences. Indien u specifieke vragen hebt over de omgang met persoonsgegevens kun u deze ook richten aan de Functionaris Gegevensbescherming van de UT door een mail te sturen naar dpo@utwente.nl

Tot slot heeft u het recht een verzoek tot inzage, wijziging, verwijdering of aanpassing van uw gegevens te doen bij de Onderzoeksleider.

Door dit toestemmingsformulier te ondertekenen erken ik het volgende:

1. Ik ben voldoende geïnformeerd over het onderzoek door middel van een separaat informatieblad. Ik heb het informatieblad gelezen en heb daarna de mogelijkheid gehad vragen te kunnen stellen. Deze vragen zijn voldoende beantwoord.

2. Ik neem vrijwillig deel aan dit onderzoek. Er is geen expliciete of impliciete dwang voor mij om aan dit onderzoek deel te nemen. Het is mij duidelijk dat ik deelname aan het onderzoek op elk moment, zonder opgaaf van reden, kan beëindigen. Ik hoef een vraag niet te beantwoorden als ik dat niet wil.

Naast het bovenstaande is het hieronder mogelijk voor verschillende onderdelen van

het onderzoek specifiek toestemming te geven. U kunt er per onderdeel voor kiezen wel of geen toestemming te geven. Indien u voor alles toestemming wil geven, is dat mogelijk via de aanvinkbox onderaan de stellingen.

3. Ik geef toestemming om de gegevens die gedurende het onderzoek bij mij worden verzameld te verwerken zoals is opgenomen in het bijgevoegde informatieblad.	JA □	NEE □
4. Ik geef toestemming om tijdens het interview opnames (geluid / beeld) te maken en mijn antwoorden uit te werken in een transcript.	□	□
5. Ik geef toestemming om mijn antwoorden te gebruiken voor quotes in de onderzoekspublicaties.	□	□
6. Ik geef toestemming om de bij mij verzamelde onderzoeksdata te bewaren en te gebruiken voor toekomstig onderzoek en voor onderwijsdoeleinden.	□	□
Ik geef toestemming voor alles dat hierboven beschreven staat.	□	

Naam Deelnemer: Naam Onderzoeker:

Handtekening: Handtekening:

Datum: Datum:

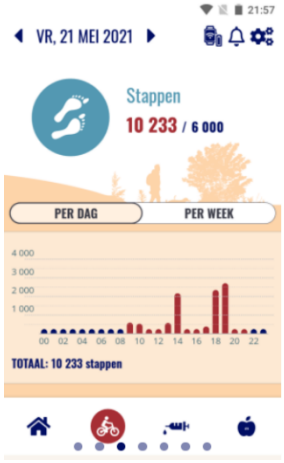
Appendix 8 – Information overview

Informatie 'gecombineerde leefstijlcoaching: Diameter + CooL'

De Diameter

De Diameter is een app die de leefstijl van mensen met diabetes type 2 meet en mensen met diabetes type 2 digitaal coacht. De Diameter bestaat uit de volgende elementen:

- Leefstijldoelen opstellen (op het gebied van voeding en beweging)
- Het bijhouden van glucosewaarden (handmatig of met de Freestyle Libre sensor)
- Het bijhouden van beweging (handmatig of met de Fitbit app)
- Het bijhouden van voeding (met een voedingsdagboek; inzicht in voedingswaarden)
- Dagelijkse informatieve of motiverende berichten (over gezond leven)
- Wekelijkse oefeningen (ten behoeve van het opgestelde leefstijldoel)
- Wekelijkse e-mail (informatie en tips over het veranderen van leefstijl)



Het CooL programma

Het Coaching op Leefstijl (CooL) programma is een gecombineerde leefstijlinterventie (GLI) waarbij een deelnemer met obesitas of overgewicht begeleiding en advies krijgt van een leefstijlcoach over voeding, beweging en gedrag om een gezondere leefstijl te ontwikkelen. Tijdens het tweejarige programma heeft de deelnemer regie over zijn/haar eigen traject en doelstellingen en vervult de leefstijlcoach een ondersteunende rol tijdens groepssessies en individuele sessies met de deelnemers. Het programma bestaat uit een behandelfase en onderhoudsfase waarbij stapsgewijs het leefpatroon verbeterd wordt om zo een duurzame verandering van leefstijl te realiseren. Het uiteindelijke doel is: gewichtsverlies, verbeteren van lichamelijke fitheid, gezondheidswinst en een betere kwaliteit van leven voor de deelnemers.

Blended lifestyle coaching: het combineren van CooL en de Diameter (in de tweede lijn)

De Diameter, kan als zelfstandige interventie worden ingezet, maar kan mogelijk ook worden ingezet samen met het CooL programma. Op deze manier kan er een vorm van *blended lifestyle coaching* worden gecreëerd. *Blended lifestyle coaching* is een benaming die kan worden gebruikt voor het combineren van face-to-face leefstijlcoaching met een app. De Diameter dient dan als dagelijkse digitale leefstijlondersteuning tussen de persoonlijke coachingssessies van CooL door. In Ziekenhuisgroep Twente (ZGT) zijn sinds januari 2022 een aantal patiënten gestart met het CooL-programma. Tegelijkertijd gebruiken deze patiënten de Diameter app voor dagelijkse leefstijlmetingen en digitale coaching.